



Llywodraeth Cynulliad Cymru  
Welsh Assembly Government

# The Future Delivery of Pathology Services in Wales

---

*August 2008*



NHS  
WALES  
GIG  
CYMRU



## **Foreword by the Assembly Minister for Health and Social Services**

A world class NHS in Wales demands a world class Pathology service. The NHS in Wales will continue to change and develop in response to the recent consultation document, "Proposals to change the structure of the NHS in Wales". Pathology will be a key service within these new arrangements, not least because modern medicine is heavily dependent on Pathology testing for the diagnosis and monitoring of most diseases. Nowadays it would be unthinkable to try to manage cancer without histological examination of the tumour or to manage diabetes without measuring the blood sugar. Technological advances have revolutionised the types of test possible and the way these tests can be provided. The application of knowledge of the structure of DNA to medicine has been profound, and has taken place within a generation.

Pathology teams have been heavily involved in making these scientific advances available in healthcare and in developing sophisticated systems of quality control to ensure that test results are both reliable and meaningful. These tests have proved so useful that demand for them has spiralled and Pathology teams everywhere are now faced with that familiar problem in healthcare; of shepherding their resources to provide the best service possible, now and in the future. Pathology services are complex and the availability of accurate information is essential.

The proposals contained within The Future Delivery of Pathology Services in Wales outline our approach at national, regional and local levels. These will need to dovetail with the planning and delivery arrangements that we develop for the NHS in Wales. The proposals build on the collaborations underway in modernising Pathology services in Wales and on the service engagement that has occurred as part of the Welsh Assembly Government's Pathology Modernisation Project. This model of future service delivery for Pathology will enable informed decisions about Pathology service provision across Wales to be made.

I will look to our professionals in Pathology to lead the creation of our first class Pathology service for the 21<sup>st</sup> century.



**Edwina Hart AM MBE**  
**Minister for Health and Social Services**



<b>Contents</b>		<b>Page</b>
	<b>Executive Summary and Recommendations</b>	<b>5</b>
<b>1</b>	<b>Background</b>	<b>9</b>
	1.1 Origins and current practice of Pathology	9
	1.2 Pathology disciplines	10
	1.3 Recent developments in Pathology service provision	10
	1.4 Benchmarking	11
<b>2</b>	<b>Strategic context</b>	<b>12</b>
	2.1 Demographics	12
	2.2 Designed for Life	13
	2.3 Diagnostic Services Strategy	16
	2.4 Pathology Modernisation Project	17
	2.5 Other UK Pathology reviews	18
<b>3</b>	<b>Current provision of Pathology services in Wales</b>	<b>19</b>
	3.1 Pathology service activity	20
	3.2 Information Management & Technology	23
	3.3 Workforce	24
	3.4 National Pathology services	25
	3.5 Current inter-Trust initiatives	28
<b>4</b>	<b>Current pressures on Pathology services in Wales</b>	<b>31</b>
	4.1 Quality standards	31
	4.2 Workforce requirements	34
	4.3 Growth in Demand	35
<b>5</b>	<b>Future delivery of Pathology services in Wales</b>	<b>36</b>
	5.1 Quality	36
	5.2 Efficiency	37
	5.3 Effectiveness	39
	5.4 Service reorganisation	42
	5.5 Planning and Delivery	44

## **Appendices**

A	Wales Pathology Modernisation Project	46
B	Modernisation of Pathology services in South Wales	49
C	Options appraisal workshop	50
D	Networks seminar	52
E	Networked services	53
F	Criteria for inspection as a network by CPA	58
G	Point of Care Testing Governance Policy – Pathology Testing. Why, When and How? A User Guide	60

<b>References</b>	<b>67</b>
-------------------	-----------

<b>Bibliography</b>	<b>68</b>
---------------------	-----------

## Executive Summary and Recommendations

Pathology services in Wales provide essential diagnostic information to enable the care of patients in and out of hospital. They have historically delivered increasing work volume with relatively small increases in funding largely as a result of increased automation and efficient practice, and there are many fine examples of development and reform in the service today. But there are also challenges: not all Pathology services in Wales are currently fully accredited, and current structures for service delivery are unlikely to be sustainable within future revenue streams, given the demands placed upon the service. There are great opportunities for the service to embrace new technology to improve the patient pathway and to develop working relationships with clinical teams to improve the quality and efficiency of the health service in Wales as a whole. Future models for service delivery need to optimise the ability to do this.

Archie Cochrane's themes of *effectiveness* and *efficiency* have gained currency in the dialogue on the modernisation of Pathology services across the UK. <sup>(1)</sup> In this context efficiency refers to the optimal use of resources mainly within the pathology laboratory, and effectiveness refers to the ability of pathology services to improve the provision of healthcare by generating an accurate and timely diagnosis, and monitoring disease progress and treatment.

In future Pathology services must operate to quality standards across Wales, and these standards are described more fully in the National Service Framework for Pathology in Wales, which is the companion document to the Future Delivery document.

- **Pathology services should be developed so they comply with all relevant standards, including CPA accreditation**

There is room to improve the efficiency of pathology services in a number of ways. One key to this is to create critical mass in test numbers where possible, so that equipment is fully utilised and that appropriate roles are created to ensure that the workforce is developed. It is important that service configuration supports this, while allowing Pathology teams to work alongside clinical teams to maximise effectiveness. It is important to remember that the workforce accounts for the majority of costs in pathology laboratories, so strategies to improve staffing efficiency can pay dividends:

- **Services should be located to maximise critical mass, provided this does not compromise local service delivery**
- **The use of automation in Pathology laboratories should be maximised**
- **Point of Care Testing (POCT) should be deployed where these tests are clinically effective, cost effective and of appropriate quality**
- **The use of Lean, Six Sigma and other process engineering tools should be maximised**
- **The use of current generation Information Technology should be maximised**
- **The Pathology workforce needs to be further developed to support flexible working and improve and extend their roles through better training and support**
- **Pathology should be developed as an 'end to end' service**
- **Laboratory premises should be constructed to optimise workflow**

There are also a number of measures that can be taken to ensure that the effectiveness of Pathology services in supporting clinical teams is optimised:

- **As far as is possible, Pathology tests and the mechanisms for requesting and reporting them should be standardised across Wales**
- **A philosophy of 'Do Once and Share' should be promoted across Pathology services in Wales**
- **The place and the resource required for Pathology tests in the patient care pathway should be established at an early stage in care planning**
- **Decision support for Pathology testing should be developed**
- **Feedback processes to clinicians on their testing practice should be developed**
- **The clinical leadership of Pathology services should be fostered**

Building on the collaborations that already exist in Wales, Pathology services in Wales should be developed to replace the existing hospital-based laboratory departments with Pathology services that serve hospital networks. There is also a need to co-ordinate the Pathology service across the three Welsh Healthcare regions, and to take a National view of Pathology services:

- **Six Pathology Services should be developed from the existing hospital-based Pathology laboratory services in Wales and the process of moving to three regionally managed services should be explored \***
- **Existing National networks will continue and be appropriately enhanced and developed**
- **Laboratories providing tertiary services should be integrated**
- **The three existing Regional Pathology Networks/Forum should be further developed**
- **A regional approach should be taken to develop comprehensive plans that enable patients to have appropriate access to Pathology testing services outside the hospital setting**
- **A National Pathology Forum for Wales should be established**

\* At the time that proposals for Pathology services were being developed, the merger of Pontypridd & Rhondda and North Glamorgan NHS Trusts was under consideration and no announcements had been made concerning other potential Trust mergers. At the point at which the proposals were finalised, the merger of Pontypridd & Rhondda and North Glamorgan NHS Trusts to form the Cwm Taf NHS Trust had been announced. Following a further announcement, consideration was being given to the merger of Swansea and Bro Morgannwg NHS Trusts and Ceredigion & Mid Wales, Pembrokeshire & Derwen and Carmarthenshire NHS Trusts.

As of 1st April 2008 Ceredigion, Pembrokeshire & Derwen and Carmarthenshire NHS Trusts merged to form the Hywel Dda NHS Trust, Pontypridd & Rhondda and North Glamorgan NHS Trusts merged to form the Cwm Taf NHS Trust and Swansea and Bro Morgannwg NHS Trusts merged to form the Abertawe Bro Morgannwg University NHS Trust. These Trust mergers will facilitate implementation of the proposals for Pathology services. In North Wales plans are being developed to create a managed Pathology service to encompass the services currently delivered by the laboratories at Ysbyty Gwynedd, Bangor; Ysbyty Glan Clwyd, Rhyl and Ysbyty Maelor, Wrexham.

Steps should be taken to optimise the planning of Pathology services in future, and to create a consistent overview of costs in the service across Wales to allow rational decisions to be taken on future service provision:

- **Opportunities arising from the likely formation of a National NHS Board should be exploited**
- **All Pathology services in Wales should participate in an approved benchmarking scheme**
- **Clear links between service revenue and activity should be established**
- **Pathology budgets should be apportioned to the business areas of blood sciences, microbiology, cellular pathology and tertiary services**
- **Pathology budgets must be constructed consistently to allow proper cost comparisons**

Together, these recommendations constitute a set of measures that allow immediate action to be taken to continue with the development of Pathology services in Wales, and provide a firm footing for future service developments based on an informed view of the service as a whole.

# 1. Background

## 1.1 Origins and current practice of Pathology

The origins of modern Pathology can be traced from the anatomists of the Italian renaissance, through the development of microscopy, to the incorporation of contemporary molecular techniques to diagnose disease. 70% of medical diagnoses in current practice are dependant on Pathology tests, and clinically led Pathology services are a critical and integral part of modern healthcare. By providing diagnostic information at critical points in the patient journey, Pathology services free up healthcare resources by rationalising the need for intervention, targeting it where it will do the most good.

Pathology services have shown impressive advances in efficiency by coping with rapidly increasing workload with limited resources. Although many pathology diagnostic processes are now automated, the Pathology workforce remains both the most important, and the most valuable asset in the service, accounting for around two-thirds of the annual budget in most laboratories. The Pathology workforce includes *Medical Consultants* - many of whom directly deliver clinical services; *Clinical Scientists*; *Biomedical Scientists*; *Medical Laboratory Assistants and other support staff*. Pathology teams work together to deliver services which are technically sophisticated, increasingly automated and dependant on Information Technology (IT). Processes for quality control are highly developed within Pathology teams, who also typically have budgetary responsibility for the service they provide.

The Pathology service encompasses all the steps from the request of a diagnostic test to the use of the result by a clinician or patient to directly inform patient care. The steps from the test request to the arrival of the specimen in the laboratory are usually referred to as *Pre-analytical*, processes within the laboratory are referred to as *Analytical* and the steps from the production of the result in the lab to its use in clinical care as *Post-analytical*.

The monitoring of analytical processes and initial storage of results is facilitated by a Laboratory Information Management IT System or LIMS. In many hospitals the LIMS interfaces to an electronic patient care record to allow hospital-based clinicians to see test results as soon as they become available and most LIMS are interfaced with GP computer systems to deliver results to primary care. In Wales a Welsh Clinical Portal is being developed which will enable electronic requesting of pathology tests (Test Requesting and Result Reporting, or TRRR) in both primary and secondary care.

## 1.2 Pathology disciplines

Pathology services are divided into a number of disciplines:

**Clinical Haematology and Blood Transfusion** is responsible for the analysis of blood and related cells, and the safe provision of blood components for transfusion. Clinical haematologists are heavily involved in the direct clinical care of patients with diagnoses such as leukaemia, lymphoma and haemophilia.

**Clinical Biochemistry** is responsible for the analysis of the chemistry of blood and other samples. Clinical biochemists manage patients with diabetes, lipid disorders and other metabolic problems. This discipline has seen rapid growth in the number of tests requested by clinicians particularly as GPs have developed monitoring services for patients with chronic disease.

**Histopathology and Cytopathology** is responsible for the diagnosis of cancer and non-malignant conditions by the microscopy and analysis of tissue samples from patients, and histopathologists are responsible for ascertaining the cause of death through post mortem studies.

**Medical Microbiology** is the study of the causes and management of infectious diseases. These can be caused by viruses, bacteria, microfungi, protozoa and parasites. Medical microbiologists also have a key role in the prevention, management and control of infection in both hospitals and the community.

**Immunology** is responsible for the identification of different types of immune reaction and for the management of patients affected by diseases of the immune system

**Laboratory Genetics** comprising **Cytogenetics** (the analysis of chromosomes) and **Molecular Genetics** (the analysis of DNA at sequence level) is responsible for the analysis of genes in samples from patients suspected of having genetic diseases or predisposition to common conditions. As such it has a major role to play in the prediction of future illnesses, including chronic conditions, not just in an individual but also their relatives, in contrast to most Pathology tests that only diagnose current disease in individuals. Aside from the determination of inherited (germline) mutations, Laboratory Genetics also finds acquired (somatic) mutations in various forms of cancer and leukaemia.

## 1.3 Recent developments in Pathology service provision

Existing pathology services have grown up alongside the hospital infrastructure. Every District General and Teaching Hospital in Wales has an attached laboratory. This has the advantage of promoting integration between the Pathology service and clinical teams, but in the 21<sup>st</sup> century may not always be the most efficient way to deliver services, when the optimal

critical mass for some services may exist above the level of the individual hospital laboratory. For the most part these laboratories operate autonomously, however specialist work is transferred to referral laboratories working as co-operative networks.

Demand from the clinical service has shown a steep rate of growth in recent years; over the past three years, and in common with other parts of the UK, growth in demand across Pathology services in Wales has averaged 10% per annum. The growth in demand has been particularly steep in clinical biochemistry due to an increased number of requests from general practitioners partially due to the introduction of the Quality and Outcomes Framework.

The management and budgetary arrangements for Pathology services in Wales are varied, as they have been historically in other parts of the UK, but what they have in common is a need to address increased demand with constrained resources, so that Pathology services have typically shown impressive rises in productivity. This has been achieved by adapting working practice, and in particular through the introduction of automation. Pathology services are also experienced in working collaboratively with the independent sector, particularly in the areas of equipment and reagent leasing and IM&T. In recent years managed service contracts have gained currency as a cost-effective working relationship.

## 1.4 Benchmarking

Two schemes operate in the UK to allow the objective comparison of Pathology services:

The **National Pathology Alliance Benchmarking Service** run from **Keele University** covers the disciplines of clinical biochemistry, haematology and blood transfusion, histopathology and cytology, microbiology, virology, and immunology. The Clinical Management Unit of Keele University has developed the benchmarking scheme in association with representation from a wide range of participating laboratories. The scheme allows participants to compare their performance with other laboratories within the UK with participating Trusts grouped to reflect the scale of their laboratory provision.

The measurements used in this benchmarking exercise have been refined over a number of years through discipline specific committees. This approach ensures that the information produced remains relevant to the participants.

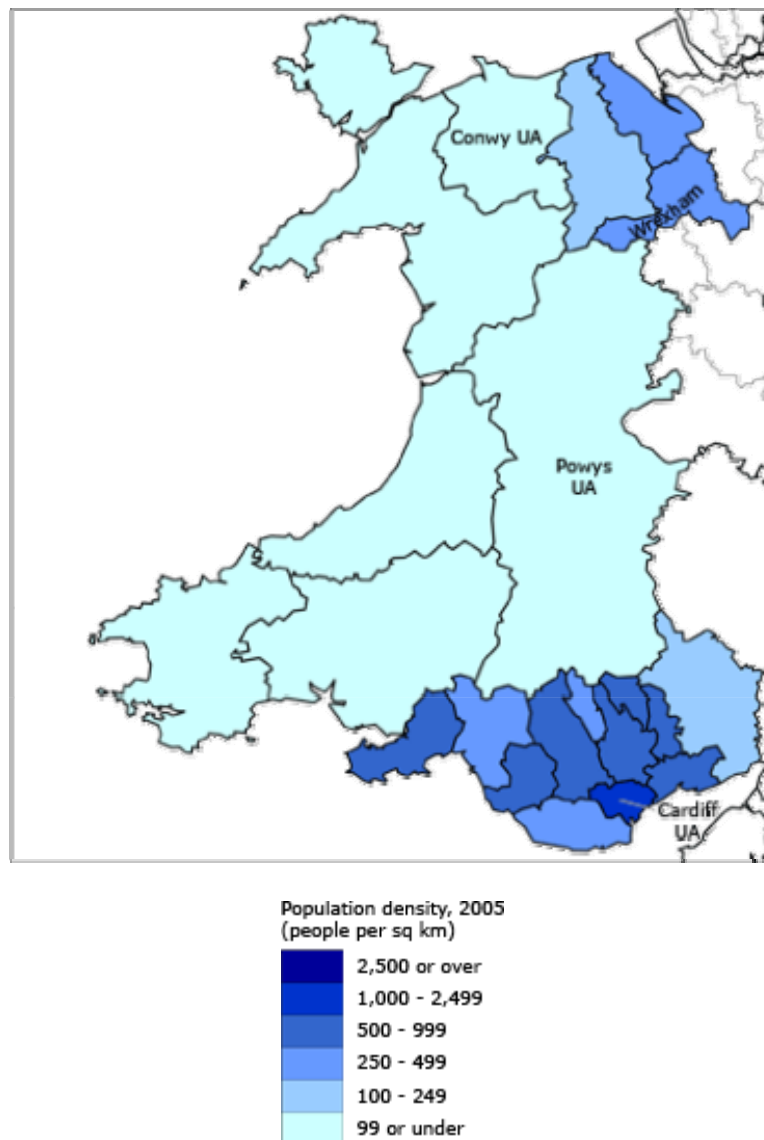
The **Acute Hospitals Portfolio – Pathology Module** provides an evidence base for decisions, by assessing performance across a range of pathology-related areas, backed up by interpretation by independent local auditors. The exercise is repeated every four years.

## 2. Strategic Context

### 2.1 Demographics

In 2005 the population of Wales was 2,958,590, giving an average population density of 142.4 per square kilometre (361 per square mile). Approximately three quarters of the population live in the south of the country, with population density ranging from over 2,500 per square kilometre in Cardiff to 25 per square kilometre in Powys. The population of Wales is projected to increase to 3,037,000 by 2011 and to 3,165,000 by 2021.

The map below shows population density in Wales by unitary authority, 2005



Sources: Statistics for Wales and Government Actuary's Department

## 2.2 Designed for Life

*Designed for Life: Creating World Class Health and Social Care for Wales in the 21<sup>st</sup> Century* (May 2005) provides a vision which will be delivered through a series of three-year Strategic Frameworks. In conjunction with this vision, the Welsh Assembly Government is developing and implementing plans for Pathology Modernisation in Wales to ensure that the Designed for Life and Diagnostic Services Strategy requirements are met.

Designed for Life identifies the need to provide appropriate evidence based, quality assured clinical treatment and care. This will require the development of a more corporate approach in NHS Wales with organisations working together rather than separately.

Designed for Life is being delivered through a series of strategic frameworks, each covering three years:

*Phase 1, Redesigning Care 2005-08*, places emphasis on service redesign and reconfiguration via clinical networks and performance management as key enablers for improving health and social care in Wales. *Phase 2, Delivering Higher Standards*, focuses on the delivery of higher standards of clinical service and quality, followed by *Phase 3, Ensuring Full Engagement*, which aims to deliver full engagement by 2015, characterised by improving standards of health, and a responsive service providing high quality care and efficient and effective use of resources.

Pathology services are a pivotal element in the delivery of other clinical services and in meeting key performance targets for the NHS. Over 70% of all patients accessing care in either primary or secondary care settings require a pathology investigation for diagnosis or treatment monitoring purposes. The ability of the NHS in Wales to meet national targets, particularly with regard to bed utilisation, waiting times and disease management for example, will depend to a significant degree on the effectiveness and efficiency with which pathology services are provided.

Implementation of the secondary care reconfiguration framework will see significant changes with services being provided at four levels:

- Level 1: Primary Care Networks
- Level 2: Local Acute Services
- Level 3: Specialist and Critical Centres
- Level 4: Tertiary and Highly Specialist Centres

The modernisation of Pathology services will be crucial to the successful implementation of future plans at all four levels to ensure that:

- Services are accessed whenever they are required
- Services are designed so that patients'/clients problems are resolved as early in the pathway as possible.

- The use of technology and tele-health reduce the need for hospital visits and home testing kits are used more.
- Assessments and investigations can be conducted locally and results stored electronically so that they do not need to be repeated.
- Using the latest technology, diagnostic services will move test requests and results, images, and information from patient to service centres to specialists, so that equipment is used to full capacity and results are available on demand.
- Hospitals can develop specialist units for people who have specific long-term conditions, staffed by well trained professionals and backed by high quality diagnostics.
- Waiting times continue to fall with a wait of no more than 26 weeks from GP or dental referral to treatment (including diagnostic and therapy treatment).

As part of the process undertaken to develop the future vision, Pathology Services have been mapped against the four levels in "*Designed for Life*" as illustrated in the following table:

Designed for Life Care Level	Pathology service issues
<b>Level 1 - Primary and community based care</b>	<ul style="list-style-type: none"> <li>• Service currently provided by laboratories – balance between laboratories and Point of Care Testing (POCT)</li> <li>• Current and future need for POCT should be established</li> <li>• Clinical effectiveness of POCT systems to be determined vs. improved transport systems/IT provision</li> <li>• POCT data must be captured and transferred to the electronic clinical record</li> <li>• Need for more coordinated approach to POCT involving LHBs and laboratories</li> <li>• Geography will influence requirements in any locality</li> </ul>
<b>Level 2. Local acute medical and surgical services</b>	<ul style="list-style-type: none"> <li>• Small, providing a rapid response service for haematology and chemistry</li> <li>• Multidisciplinary with Associate Practitioner roles being developed</li> <li>• Co-dependency with the local Level 3 facility using common standards, unified data management and staff rotation</li> <li>• Provision of phlebotomy/POCT</li> </ul>
<b>Level 3 – Major centres dealing with complex cases</b>	<ul style="list-style-type: none"> <li>• Microbiology, histology (including post-mortem) and 'cold' blood sciences services</li> <li>• Dynamic relationship between level 2, 3 &amp; 4 facilities and across organisations</li> <li>• Transport times between Level 1 &amp; 2 and Level 3 would need to be considered at an early stage</li> <li>• Focus on the 'clinical services' to ensure best fit</li> <li>• Need for appropriate commissioning process</li> <li>• Need for workforce development</li> </ul>
<b>Level 4 - Tertiary care</b> <b>Highly Specialist Centres</b>	<ul style="list-style-type: none"> <li>• Specialist national services</li> <li>• Improved access to training and development</li> <li>• Wider access to R&amp;D</li> <li>• Develop planning and collaboration for R&amp;D</li> </ul>

Source: Workshop session during First Pathology Modernisation Conference, May 2006

## 2.3 Diagnostic Services Strategy

The Diagnostic Services Strategy presented a 10 year vision for the future and looked to a more strategically managed service, to ensure consistent, high quality services in all parts of Wales supporting a modernised health service configuration and providing good value for money in both investment and everyday operation.

The Strategy was developed in close consultation with professionals and managers in Wales. It reflects a desire from those involved in the provision of diagnostic services to see changes in the way in which they are delivered and run, and in the way they are viewed by others.

The Diagnostic Services Strategy for Wales is built on the following strategic principles:

- Clear organisational infrastructure arrangements should be developed to support the delivery of modern diagnostic services. The range, infrastructure and role of services must be planned strategically to make optimum use of resources whilst ensuring the provision of services meets the needs of people in all parts of Wales.
- Demand must be managed effectively to ensure that services are used and delivered in the most efficient and cost effective manner.
- All Diagnostic Services should participate in accreditation schemes.
- The workforce must be structured around the known and projected needs of Diagnostic Services to enable them to maximise skills utilisation and to deliver effective and high quality services.
- The workforce must be valued, supported and their skills used effectively.
- Training and development should be considered and integrated across disciplines and geographical regions.
- The deployment of facilities should be planned strategically to ensure an appropriate match of demand and capacity, taking account of both access and quality requirements.
- The deployment of equipment should be planned strategically to ensure an appropriate match of demand and capacity, taking account of both access and quality requirements.
- The development of new technologies should be planned strategically to ensure an appropriate match of demand and capacity.
- An integrated information management and technology infrastructure is crucial to the delivery of modern diagnostic services.
- An integrated transport system should be developed to support the delivery of modern diagnostic services.

In response to the comments received following publication of the draft Diagnostic Services Strategy for Wales, *Getting Results*, which was published for consultation in 2004, WHC (2004) 061 was issued which set out the results of the consultation and established the basis for the future development of diagnostic services in Wales. The Welsh Assembly Government welcomed the support for a more strategic approach to

investment and stated its intention to take forward the recommendations which included strong leadership, improved planning and service rationalisation, to match and support broader service reconfiguration unconstrained by existing organisational and Trust boundaries.

## **2.4 Pathology Modernisation Project**

The Pathology Modernisation Project forms part of the Diagnostic Services Strategy Programme and was established to ensure that the recommendations in the Diagnostic Services Strategy are implemented. The implementation phase of the project was initiated in 2005 with the aim of improving patient care through improved quality, equity, sustainability and efficiency of pathology services. The project objectives include the need to:

- establish a baseline of information against which future pathology service provision could be evaluated
- establish a National Framework for the modernisation of pathology services in Wales
- establish a mechanism for providing firm central direction for pathology modernisation
- deliver a series of workpackages that address the key issues and challenges highlighted
- identify, promulgate and ensure the adoption of best practice across Wales and beyond
- facilitate, develop and/or implement radical solutions to identified problems

The project scope embraces all of the pathology disciplines provided by the NHS in Wales: Blood Transfusion, Clinical Biochemistry, Cytology, Genetics, Clinical Haematology, Histopathology, Immunology, Microbiology, Tissue Typing and Toxicology.

The project structure, workstreams and membership are shown in Appendix A.

## 2.5 Other UK Pathology reviews

August 2006 saw the publication of the Report of the Review of NHS Pathology Services in England by Lord Carter of Coles.<sup>(2)</sup> This document made a number of recommendations, including the production of a national specification for the delivery of Pathology services, the creation of clear performance standards for the service and the creation of managed service networks as freestanding providers of Pathology services. The issues of IT connectivity, tariff/reimbursement, integrated service improvement, workforce change and clinical leadership/change management were all identified as critical elements for the improvement of the service. Following publication of the report pilot projects were established in England, with the development of an accurate costing model as a key strategic aim. The output from these pilots should be available as a follow-up report later this year.

In November 2006 The Future of Pathology Services in Northern Ireland was produced.<sup>(3)</sup> This review, chaired by Dame Ingrid Allen, recommended the formation of a single managed network to provide Pathology services in Northern Ireland, with rationalisation of services in the province.

In Scotland a Scottish Pathology Network (SPAN) has been established to 'improve pathology services by creating and developing a Scotland wide Managed Diagnostic Network which will steer modernisation, including service change and redesign, to ensure provision of an effective pathology service which anticipates and responds to user needs, future requirements, national guidelines and meets Clinical Pathology Accreditation Standards'.<sup>(4)</sup>

### 3. Current provision of Pathology services in Wales

At present most Pathology services are managed and delivered locally by thirteen NHS Trusts across Wales from eighteen hospital laboratories, although there is increasing collaboration between pathology services. The National Screening Services, the National Public Health Service laboratories and the Welsh Blood Service are hosted by Velindre NHS Trust.

#### Hospital Laboratories in Wales in 2007

Table 1 below lists current hospital laboratory locations:

Hospital Laboratory	Trust	Location
<b>North Wales</b>		
Ysbyty Maelor	North East Wales NHS Trust ****	Wrexham
Ysbyty Glan Clwyd	Conwy & Denbighshire NHS Trust ****	Rhyl
Ysbyty Gwynedd	North West Wales NHS Trust	Bangor
<b>Mid and West Wales</b>		
Bronglais	Ceredigion & Mid Wales NHS Trust *	Aberystwyth
Withybush	Pembrokeshire and Derwen NHS Trust *	Haverfordwest
West Wales	Carmarthenshire NHS Trust *	Carmarthen
Prince Phillip	Carmarthenshire NHS Trust *	Llanelli
Singleton	Swansea NHS Trust **	Swansea
Morrison	Swansea NHS Trust **	Swansea
Princess of Wales	Bro Morgannwg NHS Trust **	Bridgend
Neath	Bro Morgannwg (lab run via Swansea) **	Port Talbot
<b>South East Wales</b>		
Royal Glamorgan	Pontypridd & Rhondda NHS Trust ***	Llantrisant
Prince Charles	North Glamorgan NHS Trust ***	Merthyr Tydfil
University Hospital Wales	Cardiff and Vale NHS Trust	Cardiff
Llandough	Cardiff and Vale NHS Trust	Cardiff
Royal Gwent	Gwent Healthcare NHS Trust	Newport
Nevill Hall	Gwent Healthcare NHS Trust	Abergavenny
Caerphilly District Miners	Gwent Healthcare NHS Trust	Caerphilly

Note – The following Trust mergers have taken place with effect from 1<sup>st</sup> April 2008:

- \* Ceredigion & Mid Wales NHS Trust, Pembrokeshire & Derwen NHS Trust and Carmarthenshire NHS Trust to form Hywel Dda NHS Trust
- \*\* Swansea NHS Trust and Bro Morgannwg NHS Trust to form Abertawe Bro Morgannwg University NHS Trust
- \*\*\* Pontypridd & Rhondda NHS Trust and North Glamorgan NHS Trust to form Cwm Taf NHS Trust
- \*\*\*\* North East Wales NHS Trust and Conwy & Denbighshire NHS Trust are currently consulting on proposals to merge.

### **3.1 Pathology service activity**

The following tables show the number of tests performed (Table 2) and the staff and non-staff budgets (Table 3) for the year April 2005 to March 2006 in Pathology laboratories across Wales.

These data should be interpreted with a number of qualifications, and the future collection of Pathology service data will need to be developed so that more direct comparisons can be made across the service. The issue of comparable data collection in the Pathology service is not confined to Wales. It delayed publication of the 2005 Acute Hospital Portfolio (AHP) report <sup>(5)</sup>, which provided national (UK wide) data for Pathology services, and has been recognised as a major issue by the Carter review in England.

Counting the number of tests performed by the Pathology service is not as straightforward as it might at first appear. Many of these tests are grouped together in test sets. The number of individual tests per set can vary between labs, and care must be taken not to count individual tests in one lab and test sets in another. This issue is compounded due to the way laboratory information systems have been configured in different laboratories. The information in Table 2 was gathered through a manual data collection process with each individual Trust working to an agreed dataset and provides a current 'high level' view of activity.

Budgetary information for the service is shown in Table 3, but again must be interpreted with caution. Some medical staff also work in the clinical service, and their costs may or may not appear in the Pathology budget. The 'overheads' attributed to the Pathology budget by the host organisation are highly variable, as is the attribution of income streams generated by the service e.g. work for other NHS, or private, organisations.

**Table 2 Pathology Activity by Discipline April 2005 to March 2006**

WORKLOAD 2005/06 Totals are x 1000 (except PMs)		Haematology (sets)	Transfusion	Clinical Chemistry (sets)	Immunology	Virology (tests)	Microbiology (sets)	Histopathology (slides)	Genetics	Gynae Cytology (samples)	Non-Gynae Cytology	Post Mortems
North East Wales		308	55	711			149	68		15	2	645
Conwy and Denbighshire		332	44	772	10	NPHS	NPHS	80		15	2	688
North West Wales		421	24	982		NPHS	NPHS	63		16	7	626
Ceredigion	Hywel Dda NHS Trust	111	13	283	4	NPHS	NPHS	10			1	211
Pembrokeshire and Derwen		220	10	397			63	40		9	1	198
Carmarthenshire		343	15	842	30	NPHS	NPHS	37		19	2	386
Swansea	Abertawe Bro Morgannwg University NHS Trust	671	65	1269	26	NPHS	NPHS	141		29	4	962
Bro Morgannwg		270	19	570			93	38		11	1	377
Pontypridd and Rhondda	Cwm Taf NHS Trust	288	13	734	2	26	127	38		21	2	359
North Glamorgan		198	21	558	5	8	88	18		9	2	385
Cardiff and Vale		907	147	2161	183	NPHS	NPHS	269	8*	35	11	1104
Gwent		892	109	2643	65		519	107		38	4	861
NPHS						240	1100					
<b>Discipline Total</b>		4961	535	11922	325	274	2139	909	8	217	39	6802
<b>TOTAL (x 1000) excluding post mortems</b>		<b>21329</b>										

*Notes:*

*The NPHS provides Microbiology to six Trusts*

*\* The All-Wales Laboratory Genetics Service provides services to all Trusts in Wales*

*During this period, the Welsh Blood Service processed the following samples:*

<i>108,834</i>	<i>routine donation and microbiology testing</i>
<i>1,693</i>	<i>reference serology including compatibility testing</i>
<i>31,749</i>	<i>routine antenatal screening</i>
<i>3,979</i>	<i>histocompatibility and immunogenetics</i>
<i>5,253</i>	<i>samples from potential volunteer stem cell donors</i>

Source: Manual data collection exercise undertaken by Trust Pathology Departments,  
February 2007

**Table 3 Laboratory Out-turn Costs April 2005 to March 2006**

PATHOLOGY COSTS £000 2005 / 06		Staff	Non-Staff	Total
North East Wales		4,073	2,830	6,903
Conwy and Denbighshire		2,921	1,534	4,455
North West Wales		2,682	1,531	4,213
Ceredigion	Hywel Dda NHS Trust	1,529	617	2,146
Pembrokeshire and Derwen		2,707	1,054	3,761
Carmarthenshire		4,391	2,133	6,524
Swansea	Abertawe Bro Morgannwg University NHS Trust	6,872	4,230	11,102
Bro Morgannwg		4,312	3,008	7,320
Pontypridd and Rhondda	Cwm Taf NHS Trust	4,028	2,161	6,189
North Glamorgan		3,710	1,158	4,868
Cardiff and Vale		17,283	10,680	27,963
Gwent		11,290	5,889	17,179
NPHS		9,000	4,100	13,100
<b>TOTAL</b>		<b>74,798</b>	<b>40,925</b>	<b>115,723</b>

Notes:

- 1) Conwy and Denbighshire excludes NPHS contract, blood components, Consultant Haematologists, Infection Control, phlebotomy and transport
- 2) North West Wales excludes NPHS contract, blood and plasma products, 7 WTE Consultants, 0.52 WTE staff grade Haematologist
- 3) Ceredigion excludes Consultant Haematologist and non-Consultant medical staff
- 4) Swansea excludes Consultant Haematologist

Source: Trust annual accounts 2005 / 2006

### 3.2 Information Management & Technology

There are currently 13 Pathology Laboratory Information Management Systems (LIMS) in use across Wales provided by two suppliers. Table 4 shows the distribution of LIMS across Wales. These systems are locally configured, are not integrated and do not operate to common definitions and coding standards, while the All Wales Laboratory Genetics Service does not currently have a LIMS. This results in significant difficulties in collecting consistent data for strategic planning and benchmarking, and does not facilitate networking between Trusts.

Both systems are 'green screen', developed around 20 years ago, and neither is currently marketed by the company which owns it as a first-choice system. The degree to which the results held in the LIMS are viewable by clinicians through an Electronic Patient Record is currently variable across Wales. The use of data held in the LIMS to performance manage the service and to directly populate disease databases is also very variable, and represents an underexploited resource.

**Table 4 Laboratory Information Management Systems across Wales**

<b>Laboratories using iSOFT Laboratory Information Management Systems (LIMS)</b>			
Ysbyty Maelor	North East Wales NHS Trust		Wrexham
Ysbyty Glan Clwyd	Conwy & Denbighshire NHS Trust		Rhyl
Ysbyty Gwynedd	North West Wales NHS Trust		Bangor
Bronglais	Ceredigion & Mid Wales NHS Trust	Hywel Dda NHS Trust	Aberystwyth
Withybush	Pembrokeshire and Derwen NHS Trust		Haverfordwest
West Wales	Carmarthenshire NHS Trust		Carmarthen
Prince Phillip	Carmarthenshire NHS Trust		Llanelli
Princess of Wales	Bro Morgannwg NHS Trust	Abertawe Bro Morgannwg University NHS Trust	Bridgend
Royal Glamorgan	Pontypridd & Rhondda NHS Trust	Cwm Taf NHS Trust	Llantrisant
Prince Charles	North Glamorgan NHS Trust		Merthyr Tydfil
University Hospital Wales	Cardiff and Vale NHS Trust		Cardiff
Llandough	Cardiff and Vale NHS Trust		Cardiff
Royal Gwent	Gwent Healthcare NHS Trust		Newport
Caerphilly District Miners	Gwent Healthcare NHS Trust		Caerphilly
<b>Laboratories using Clinysis LIMS</b>			
Neath	Bro Morgannwg (lab run via Swansea)	Abertawe Bro Morgannwg University NHS Trust	Port Talbot
Morrison	Swansea NHS Trust		Swansea
Singleton	Swansea NHS Trust		Swansea
Nevill Hall	Gwent Healthcare NHS Trust		Abergavenny

### 3.3 Workforce

Workforce data for Pathology workforce has been collected manually. This was necessary because of variations in the application of Electronic Staff Record (ESR) codes, inconsistent attribution of staff to Pathology budgets and the transfer of staff between organisations for training. In addition this exercise coincided with the Agenda for Change re-banding of the non-medical workforce, although this, together with ESR and the New Consultant Contract, should offer ways to improve workforce data comparability in future.

**Table 5 Staff establishment by Trust as per budget 2006/07 (includes BMS trainees in established posts)**

Staff Establishment as per budget 2006 / 07		Medical Staff (Consultant)	Medical Staff (Non Consultant)	Clinical Scientists	Biomedical Scientists	All other staff
North East Wales		9.0 <i>0.5 WTE Consultant ex-budget</i>	1	2	57.82	49.34
Conwy and Denbighshire		6.4	1.8	2.0	45.1	43.07
North West Wales		7.1 <i>7.1 WTE Consultants ex-budget</i>	0.52 <i>Non Consultant Haematology staff ex-budget</i>	1.5	44.39	42.02
Ceredigion	Hywel Dda NHS Trust	4.69 <i>1 Consultant Haematologist ex-budget</i>	<i>Non Consultant Haematology staff ex-budget</i>	1.0	40.84 <i>8 Haematology BMS staff ex-budget</i>	10.01 <i>6 Haematology MLA staff ex-budget</i>
Pembrokeshire and Derwen		6.0	1.2	1.0	29.0	22.21
Carmarthenshire		7.5	0.0	0.0	52.0	53.98
Swansea	Swansea Bro Morgannwg University NHS Trust	12.12 <i>1 Consultant Haematologist ex-budget</i>	2.0	3.0	100.77	87.66
Bro Morgannwg	University NHS Trust	8.7	1.0	0.0	50.91	37.93
Pontypridd and Rhondda	Cwm Taf NHS Trust	7.6	2.0	2.0	61.7	49.2
North Glamorgan		8.0	1.6	2.0	48.18	21.93
Cardiff and Vale		20.85	16.3	51.2	158.36	78.06
Gwent		21.2	0.0	7.4	160.24	110.55
NPHS		17.0	9.0	10.0	118.0	72.0
Welsh Blood Service		3.7	1.27	22.3	29.5	7.08

*Note - Cardiff and Vale data excludes staff on All-Wales training schemes  
WBS data include ante-natal testing, blood donor testing and patient antibody quantitation but exclude WTAIL and QA staff*

### **3.4 National Pathology services**

A number of Pathology services operate successfully across Wales. These include services hosted by Velindre NHS Trust and less formal service collaborations.

#### **National Public Health Service (NPHS) <sup>(6)</sup>**

The NPHS Microbiology Services are provided from laboratories in Aberystwyth, Bangor, Cardiff (University Hospital of Wales and Llandough sites), Carmarthenshire (Carmarthen and Llanelli sites), Rhyl and Swansea. They provide laboratory, clinical and scientific support that underpins communicable disease diagnosis and management.

This includes:

- laboratory diagnostic services to hospitals and general practitioners
- infection management services to hospitals and general practitioners
- a key role in hospital infection control programmes
- involvement in regional and national surveillance programmes
- assistance to Health Protection Teams in relation to outbreaks and community infection control

In addition to these general functions NPHS Microbiology laboratories provide all-Wales and UK specialist and reference facilities and a source of medical and scientific advice and support for colleagues in NHS laboratories.

#### **Screening Services <sup>(7)</sup>**

Screening Services currently require pathology support for the all Wales breast, cervical and antenatal screening programmes. Additional pathology services will also be required to support the bowel screening programme. Services delivered include cellular pathology and blood sciences.

#### **Breast Screening**

The delivery of pathology services in Breast Screening is well established and focussed on specialist centres. It is not anticipated that modernisation will require major changes.

#### **Antenatal Screening**

Antenatal screening comprises various tests, currently commissioned by LHBs. Antenatal Screening Wales has limited ability therefore to influence service provision and future delivery of services may be influenced by arrangements agreed between Trusts.

## **Bowel Screening**

It is anticipated that the primary screening test (for faecal occult blood) will be delivered through one all-Wales screening centre. The delivery of histopathology generated by colonoscopy is subject to discussion and agreement by the Steering Board.

## **Cervical Screening**

In 2006 Cervical Screening Wales (CSW) initiated a process of consultation with Trusts and Directorates on future developments, highlighting a range of issues that the service faces. As a result, networking arrangements are currently developing in line with possible Trust reconfiguration and include the following:

- West Wales 'three counties' discussion: Agreement in principle that networking will follow establishment of any new Trust structure - formal links have not been established
- Abertawe Bro Morgannwg Pathology Service: CSW has been consulted on proposals for future delivery of the service
- Cwm Taf: interim ad-hoc reporting support arrangements are in place between the laboratories
- Cardiff and the Vale: Cytology is already centralised; no proposals have been made for histopathology
- Gwent – has already consolidated or agreed delivery of their services on a single site.
- North Wales – agreement reached on cytology network implementation with two Trusts.

## **Newborn Screening Programme <sup>(8)</sup>**

The All Wales newborn screening programme is hosted by Cardiff and Vale NHS Trust. The screening programme, based on heel prick testing for thyroid disease, phenyl ketonuria, cystic fibrosis and duchenne muscular dystrophy is regarded as one of the most effective and efficient programmes in the UK. New conditions are likely to be screened for in the foreseeable future including sickle cell anaemia and other inborn errors of metabolism (MCAD). This will require modernisation of equipment and IT systems given the high clinical risk involved in making or missing a diagnosis.

## **Welsh Blood Service <sup>(9)</sup>**

The Welsh Blood Service (WBS) is a Division of the Velindre NHS Trust. It serves the area of South, Mid and West Wales.

Mobile blood collection sessions are held daily. A fleet of 20 vehicles serves the blood collection/delivery operation. Blood is returned to the headquarters for laboratory immunohaematological and microbiological testing and for the production of various blood components.

The WBS provides a 24-hour immunohaematology laboratory reference and medical support service. It is entirely responsible for all the solid organ and bone marrow transplant tissue typing for its region of supply, and runs the Welsh Bone Marrow Registry, which manages the HLA testing and provision of stem cell donations for transplantation to patients in the UK and overseas. The WBS also hosts two national, CPA-accredited EQA schemes: the UK National External Quality Assessment Scheme for Histocompatibility and Immunogenetics; and the WASPS serological proficiency scheme.

The WBS also undertakes routine antenatal screening.

### **Wales External Quality Assessment Scheme (WEQAS)** <sup>(10)</sup>

WEQAS is hosted by Cardiff and Vale NHS Trust but is managed independently of the clinical pathology service. It is one of the largest External Quality Assessment (EQA) providers for Clinical Biochemistry in the UK. EQA is an essential part of providing quality laboratory diagnostic services, and participation in EQA is required for laboratory accreditation by Clinical Pathology Accreditation (UK) Ltd.

EQA schemes provide an external audit, performance analysis and educational advisory service, including preparation and provision of specimens for participating laboratories. They provide advice and assistance to laboratories including a performance surveillance role, alerting the National Quality Assurance Advisory Panel (NQAP) and Trust Chief Executives of poor performance.

### **Laboratory Genetics Services and Networks** (hosted by Cardiff & Vale NHS Trust) <sup>(11)</sup>

NHS laboratory genetics services in the UK are provided on a regional basis, which in Wales means the All-Wales Laboratory Genetics Service based in Cardiff. The genetics White Paper in 2003 recognised the large proportion of molecular tests that must be outsourced (ca. 20%) and set up the NHS UK Genetic Testing Network (UKGTN; <http://www.ukgt.nhs.uk/gtn/index.html>), both to approve tests performed in accredited laboratories as clinically valid and technically accurate, and provide a direct link to the Genetics Commissioning Advisory Group (GenCAG).

The White Paper also gave test turnaround time targets (TaTs), funds (in England) for investment in new staff and equipment to automate, and encouraged regional genetics laboratories to form into consortia, modelled on those consortia already extant in Scotland (four laboratories) and London (five laboratories) to help meet these TaTs and obtain economies of scale. A number of consortia have been set up, and the service in Wales is now part of the largest consortium, a federated network of six regional laboratories: Salisbury, Cambridge, Oxford, Bristol, Exeter, and Cardiff (SCOBEC), which covers 26% of the UK population. Medium-throughput tests have been rationalised such that tests previously performed in perhaps four or five centres are now provided in just two.

UKGTN tests provided by individual centres are also part of the equation. Such networking works well in molecular genetics because all centres acknowledge they cannot individually provide sufficient local breadth of services and thus they must work together. This is helped by an agreed set of tests, to agreed standards, linked to commissioning of services. TaTs are being achieved, and the total number of gene tests available via UKGTN has increased from 275 in 2003 to over 340 in 2007. It is also evident that "molecular genetic" testing is becoming a core part of many aspects of diagnostic pathology in all disciplines, with translation of research into clinical tests in many areas of pathology.

### **Immunology** <sup>(12)</sup>

To make and implement cooperative decisions, information needs to be exchanged freely to an agreed common format. Since 1999 senior laboratory staff in Newport, Cardiff, Swansea, Merthyr, Llanelli and the Consultant Clinical Immunologist(s) have met 3-monthly in Welsh Immunology Laboratory (WIL) meetings, and have:

- Harmonised analytical methods, assay platforms, reagents and results reporting
- Disseminated Standard Operating Procedures from Cardiff and customised them where relevant to local needs
- Discussed all labs' meeting minutes at Welsh Immunology Laboratories (WIL) meetings to draw together common issues
- Initiated and performed audit projects within WIL
- Gathered workload & analogous data (e.g. turnaround time) assay-by-assay in the Keele format

Future plans will depend on laboratory reconfiguration.

### **3.4 Current Inter-Trust initiatives**

Considerable progress has been made within Pathology to modernise services and this work is being further developed through a wide range of inter-Trust initiatives, both between individual Trusts or within Regions.

#### **North Wales** <sup>(13)</sup>

The three NHS Trusts in North Wales, North West Wales NHS Trust, Conwy & Denbighshire NHS Trust and North East Wales NHS Trust, serve a population of approximately 750,000. Within each Trust there is an acute hospital with an on-site pathology laboratory.

Following the North Wales Secondary Care Review it was recommended that Pathology services move towards the establishment of a Managed Service Network. At the North Wales Planning Forum held in June 2007 the Chief Executives agreed for a Network to be established. It was initially tasked with the following:

- Repatriation of work to North Wales
- Consider the strengths of each Department to see where they could take a North Wales lead
- Workforce planning

### **South East Wales** <sup>(14)</sup>

From April 2008 there will be three acute Trusts in South East Wales:

The Cardiff and Vale NHS Trust serves a local population of around 450,000, currently hosts laboratories on two hospital sites, (the laboratories on the University Hospital of Wales are distributed across the site), and also provides many of the specialist tertiary services for Wales. It also hosts the antenatal and newborn screening services for Wales.

The Gwent Healthcare NHS Trust serves a population of around 550,000, and hosts three hospital laboratories. Pathology modernisation is aligned to the Clinical Futures strategy, which will see level 3 clinical services delivered by a single Specialist and Critical Care Centre (SCCC) operating in a hospital network with six Local Hospitals, three of which will have Medical Assessment Units (extended Local Hospitals or eLHs). In future pathology services will be focussed on the SCCC, with Rapid Reporting Blood Sciences labs at the three eLHs. Recent work has included the amalgamation of the senior biomedical staffing structure across haematology and biochemistry to a single blood sciences structure, installation of high throughput robotic automation for blood sciences at the Newport site, localisation of the microbiology laboratory service and blood transfusion serology from Caerphilly to Newport, and centralisation of all histology processing on the Newport site.

In the North Glamorgan and Pontypridd NHS Trusts a review process for Pathology Services was established in 2007 to support the merger of the Trusts into a single NHS Trust (Cwm Taf NHS Trust) from April 2008. The new Trust covers a population of 380,000 and hosts two hospital laboratories.

In September 2007 a South East Wales Pathology Forum, accountable to the South East Wales Chief Executives group, was formed to co-ordinate Pathology provision across South East Wales.

### **Mid and West Wales** <sup>(15)</sup>

Pathology network meetings have been held regionally in Mid and West Wales since mid-2004. To the east of the region a partnership was established during 2007 between the Bro Morgannwg and Swansea NHS Trusts to create the Morgannwyg Pathology Service, which would provide a single management model for Pathology services to a population of 540,000 from four hospital laboratories. The service was initially hosted by the Swansea NHS Trust. Workstreams were established for the disciplines of cellular pathology, clinical chemistry, haematology and microbiology, and a number of subgroups were created to develop the service infrastructure. Swansea and

Bro Morgannwg NHS Trusts merged to form Abertawe Bro Morgannwg NHS Trust with effect from 1<sup>st</sup> April 2008.

The future organisation of Pathology services in the west of the region are being considered as part of the Trust merger between Carmarthen, Ceredigion and Pembrokeshire & Derwen NHS Trusts which merged to form Hywel Dda NHS Trust from 1<sup>st</sup> April 2008.

Future network arrangements are to be the subject of consultation between the member organisations.

## 4. Current pressures on Pathology services in Wales

Pathology teams have to provide a diagnostic service of increasing detail and volume with resources which are also subject to pressure, especially in the area of workforce.

### 4.1 Quality standards

Pathology services have always had a keen understanding of quality issues as they apply to the reliability of test results, and sophisticated quality control processes are in place inside laboratories. However, in recent years, and in common with other parts of the health service, external quality standards for the service have increased in number and detail.

UK Pathology services are accredited by **Clinical Pathology Accreditation (UK) Ltd (CPA)**. CPA aim to work in partnership with provider organisations to maintain the standards necessary for accreditation. The scheme involves an external audit of the ability to provide a service to quality standards. Inspection teams visit in a four yearly cycle and comprise a professional regional assessor and two peer assessors, usually one scientist and one clinician, both of whom are working pathologists. The inspection includes assessment of the Quality Management system, laboratory infrastructure, test accuracy and timeliness, staff performance, and user satisfaction. It seeks evidence of quality from CPA accredited External Quality Assurance (EQA) Schemes which include the UK National External Quality Assessment Scheme (UKNEQAS) and Wales External Quality Assessment Scheme (WEQAS). CPA has formed a partnership with the United Kingdom Accreditation Service (UKAS). UKAS is a national accreditation body recognised by government to assess against internationally agreed standards, laboratories, sample testing, and inspection and calibration services. Its remit covers industry and many other public sector organisations.

One of the recommendations in the Diagnostic Services Strategy was that diagnostic service providers must enrol in accreditation schemes where they exist or as they are developed. The Welsh Assembly Government accepted this recommendation and looked to all pathology services providers to seek accreditation and put in place a plan to meet accreditation requirements (WHC 2004 (061)). At present not all pathology services in Wales are CPA accredited. Improving on this position is an important objective for the modernisation of the Pathology service in Wales. Table 6 gives an overview of accreditation status at March 2008.

CPA has generated a list of criteria to describe features of a networked laboratory service which enable them to inspect it as a single service. These criteria are included for reference as Appendix F.

**Table 6 Laboratory CPA Accreditation Status in Wales March 2008**

Trust		Clinical Biochemistry	Haematology	Histopathology / Cytology	Microbiology
North East Wales		AA	AA	AA	AA
Conwy and Denbighshire		CA	FA	CA	CA*
North West Wales		FA	FA	AA	CA*
Ceredigion	Hywel Dda NHS Trust	FA	CA	AA	CA*
Pembrokeshire and Derwen		FA	AA	NA	AA
Carmarthenshire		CA	AA	NA	CA*
Swansea	Abertawe Bro Morgannwg University NHS Trust	CA	NA	CA	CA*
Bro Morgannwg		FA	CA	CA	CA
Pontypridd and Rhondda	Cwm Taf NHS Trust	FA	CA	FA	CA
North Glamorgan		CA	CA	AA	AA
Cardiff and Vale		CA	CA	CA	CA*
Gwent (North)		FA	FA	CA	FA
Gwent (South)		CA	FA	CA	FA

\* NPHS Network

Key:

FA = Fully accredited

NA = Not currently accredited

CA = Conditional approval

AA = Enrolled with CPA, awaiting accreditation

Note: The Welsh Blood Service holds full CPA accreditation for its Immunohaematology, Histocompatibility, Immunogenetics and EQA services

The **Medicines and Healthcare products Regulatory Agency** (MHRA) is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. The supply of blood from donor to recipient is now governed by EU statute. Statutory Instrument 2005 No. 50 and its Amendment (SI 2005/2898) about blood safety and quality became effective from 8 November 2005. The Regulations set the standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. The Principal Regulations require services (primarily the national blood services of England, Wales, Scotland and Northern Ireland - the "UK Blood Service") to be authorised and inspected, a process very similar to the existing arrangements operated by the MHRA for the manufacture of medicines.

The statute requires hospital blood banks to establish systems for quality management and haemovigilance<sup>1</sup> and the MHRA to have powers to monitor compliance. A hospital blood bank is defined in the Regulations as any unit within a hospital which stores and distributes and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities. Inspections of blood banks where problems are identified may be carried out by the MHRA. Blood banks or blood establishments that are operating as blood banks are required to submit an annual return to the department setting out how they comply with the requirements of the Regulations. Blood establishments and hospital blood banks are required to report any serious adverse events or serious adverse reactions related to blood and blood components to the MHRA.

Following public concern about the use of human tissues for research and teaching without fully informed consent, the government established the **Human Tissue Authority (HTA)**. This body is the regulator under the Human Tissue Act which applies to England, Wales and Northern Ireland (Scotland has separate legislation). The Human Tissue Authority is also one of the Competent Authorities in the UK under the EU Tissue and Cells Directive. The Human Tissue Authority has produced codes of practice on consent, donations of organs, tissues and cells for transplantation, post-mortem and anatomical examination, and removal, storage and disposal of human organs and tissue. Since September 2006, institutions are required to be licensed to remove and store human tissue. The establishment of the Human Tissue Authority has had significant implications for all branches of pathology, but particularly for histopathology.

An additional consideration for Laboratory facilities is the need to make them secure against terrorist threat. Counter-terrorist Officers are currently visiting NHS laboratory premises to make recommendations on improved security. These include modification to the fabric of the laboratory and tighter access controls in some cases as part of heightened security measures.

**Healthcare Standards for Wales: Making the Connections, Designed for Life** <sup>(16)</sup> set out the Welsh Assembly Government's common framework of healthcare standards to support the NHS and partner organisations in providing effective, timely and quality services across all healthcare settings. It confirmed that the healthcare standards would be used by **Healthcare Inspectorate Wales (HIW)** as part of their processes for assessing achievement against the quality domains in healthcare providers and commissioners across Wales. From April 2007, healthcare organisations in Wales were required to undertake self-assessments against the healthcare standards and make an annual public declaration of how they have performed.

## 4.2 Workforce requirements

It is widely recognised that workforce development will be an important issue for Pathology over the coming years. The Diagnostic Services Strategy in Wales and numerous Royal College of Pathologists and Professional Association documents all point to the challenges on the horizon as current staff approach and reach retirement age over the next 5 to 10 years. In order to ensure that the right numbers of people are recruited in the right place at the right time it is necessary to not only understand demand, but also to understand the profile of the current workforce and to be able to predict accurately what will be needed, when and where. This in turn will inform training and education plans and will allow a coordinated and comprehensive approach to workforce planning to take place.

It is recognised that staffing data currently available contains inconsistencies. However, once the Electronic Staff Record and Agenda for Change are fully implemented, reliable staffing information should be more readily available.

The introduction of the new consultant contract in Wales provides an opportunity to make explicit the amount of time required for the medical provision of Pathology services, and offers a convenient mechanism to develop medical workforce plans. However, the contract is time limited and properly requires the incorporation of time for supporting professional activities into the consultant job plan.

The **EU Working Time directive** (93/104/EC) has had a significant impact on the management of pathology services, particularly with regard to delivery of services outside normal working hours. This will be a key objective within the work being undertaken relating to workforce.

**Agenda for Change** is in the process of being implemented across pathology services in Wales and should provide opportunities for staff development, career progression, and the development of new roles necessary for a modernised pathology service.

Having identified the need for the workforce in Pathology to be re-profiled, with a focus on the appropriate use of skills and competences to deliver redesigned services, flexible approaches to staffing and entry routes, and the requirement for staff to work in new ways, the **Career Framework for Healthcare Scientists in the NHS**<sup>(17)</sup> has been adopted UK wide to:

- Introduce an integrated career framework encompassing all disciplines and employment groups within the workforce based on roles and functions and linked to transferable skills and competences
- Clearly identify pathways for progression and transfer, supported by learning and development providing enhanced opportunities
- Provide national consistency and maximum flexibility to support local service delivery, the expansion and extension of current roles and the emergence of new roles

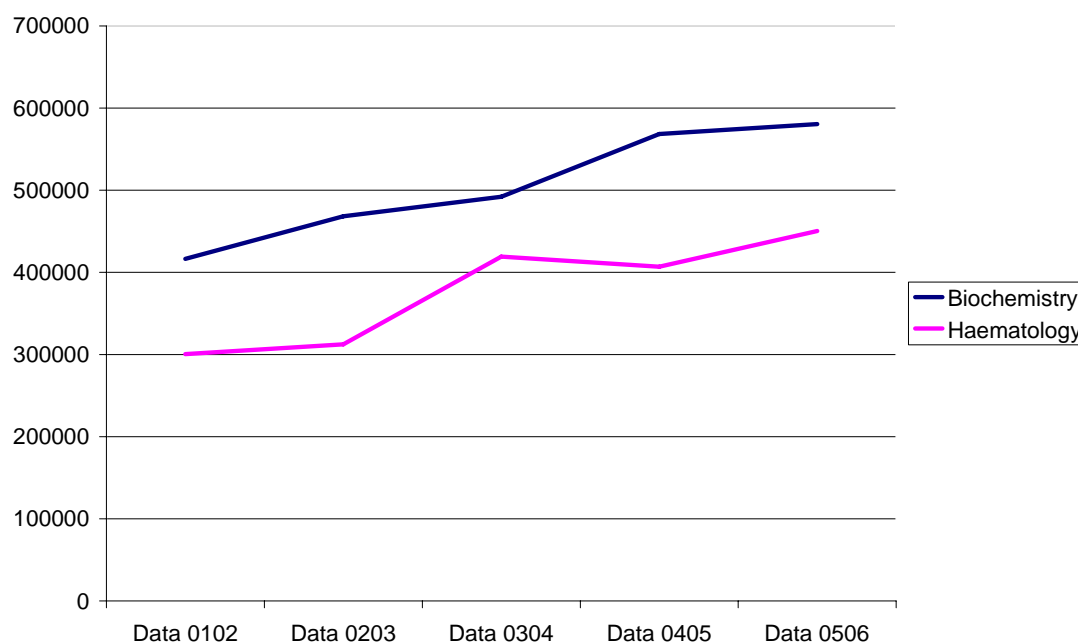
### 4.3 Growth in demand

Activity in most areas of Pathology has increased significantly over recent years. Reasons for this include:

- The GMS Contract
- National Service Frameworks
- NICE Guidelines
- Increases in screening
- Development of new diagnostic tests
- Cancer targets
- Increasing age of population
- Increases in disease prevalence
- Increased availability of new therapies/interventions
- Wider availability of tests

It is anticipated that increases will continue due to initiatives such as the Quality and Outcomes Framework, future screening initiatives and the need to meet and sustain waiting times targets.

The graph below shows changes in mean annual workload (requests) in Biochemistry and Haematology 2001/02 to 2005/06 for laboratories participating in National Pathology Alliance Benchmarking in the UK.



% change	2001/02 to 2002/03	2002/03 to 2003/04	2003/04 to 2004/05	2004/05 to 2005/06
<b>Biochemistry</b>	<b>+12.48</b>	<b>+5.05</b>	<b>+15.53</b>	<b>+2.13</b>
<b>Haematology</b>	<b>+3.98</b>	<b>+34.17</b>	<b>-2.98</b>	<b>+10.70</b>

Source: National Pathology Alliance Benchmarking Service

## 5. Future delivery of Pathology Services in Wales

There has been significant involvement from those providing Pathology services in shaping the vision for the future delivery of pathology services in Wales. In addition to a review commissioned by the Welsh Assembly Government to identify and evaluate alternative models of pathology service delivery for South Wales, information gathering interviews have been held with individuals and a series of events such as workshops and seminars have been held, a sample of which are included in Appendices B, C and D.

The following proposals for the organisation of Pathology services in Wales build on progress that has already been made across the Principality. They have been framed for implementation within a short timeframe, and to lay the ground for future harmonisation of the service. The sections on **Quality, Efficiency and Effectiveness** describe working practice that should be achievable across the service. The section on **Service reorganisation** describes an incremental approach to the development of Pathology networking which is synchronised with clinical service reorganisation in Wales. The section on **planning and delivery** describes a way to develop an accurate view of Pathology service activity across Wales which will allow an informed view of the service to be taken, on which further service developments can be based and which will provide a transparent understanding of costs across the service.

The diagnostic information provided from Pathology plays a critical role in most patient pathways and any team developing care pathways should take this into account. Technological change has had a major impact on Pathology services, and this will continue to be the case. The future Pathology service must be flexible enough to support new models of clinical care and to exploit technological advances as they arrive.

### 5.1 Quality

Patients and clinicians have a right to expect that diagnostic tests and the mechanism for providing them will be delivered to consistently high quality standards across Wales. The diagnostic service needs to be designed around the patient, and should be responsive to the needs of the clinicians who directly provide clinical services.

The **National Pathology Framework (NPF) for Wales** is the companion document to the Future Delivery document and sets out standards for Pathology services in Wales. The NPF:

- identifies the aspects of broader healthcare standards that impact on Pathology
- clarifies the quality standards to which Pathology services will be expected to perform
- provides the context within which changes in laboratory organisation can be evaluated

- provides a framework against which bids for capital expenditure can be evaluated
- provides guidance for Trusts and LHBs and a performance management tool for Regional Offices to measure the performance of Pathology services
- informs the planning and delivery of Pathology services at local, regional and national level

Evidence of compliance with these standards will enable organisations to meet the Healthcare Standards for Wales.

WHC (2004)061 recommends that all Pathology service providers should enrol in accreditation schemes where they exist and put in place a plan to meet the accreditation requirements. It is therefore recommended that **Pathology services should be developed so they comply with all relevant standards, including CPA accreditation.**

In order to promote effective delivery of clinical services as close to the patient as possible **Point of Care testing should be deployed where these tests are clinically effective, cost effective and of appropriate quality.** Robust economic evaluation should be developed where this does not exist, and Point of Care Pathology tests should only be used when they can demonstrate that quality assurance standards are being met, and that the benefits and risks have been fully considered. Pathology services must be configured to allow the appropriate governance and management of any Point of Care tests (Appendix G).

## 5.2 Efficiency

Any proposals for the future delivery of pathology services must secure increased efficiency of services and should take account of the following:

**Services should be located to create economies of scale, provided this does not compromise local service delivery.** For routine (non-urgent) testing the options to create critical mass by rationalising services should be actively explored. For test results required to support clinical decision making within 4 hours of request e.g. haematology and chemistry testing to support A&E departments, the service will need to be provided on site, by either a full laboratory service, a limited 'essential services lab' service or Point of Care testing.

**The use of appropriate automation in Pathology laboratories should be maximised.** Increased automation has been a mainstay of previous efforts to cope with an increasing workload within a constrained budget, and has the additional advantage of reducing the potential for human error. There is some potential for further automation, and this should be actively explored, although it may require service rationalisation to achieve the necessary economies of scale.

**The use of Lean, Six Sigma and other process engineering tools should be maximised.** There is increasing evidence of the benefit of these strategies in maximising workforce efficiency and empowerment, and improved quality, particularly for processes which remain largely manual. Some Lean concepts seem particularly useful in Pathology laboratories. Examples of the impact of lean process mapping in Pathology laboratories include dramatic increases in the efficiency of specimen reception areas, and improvements in the length and variability of specimen turn-around times.

Table 7 below shows a range of useful LEAN concepts for Pathology services.

<b>Useful Lean Concepts for Pathology services</b>
<ul style="list-style-type: none"><li>• Identification of value and waste in processes</li><li>• Creation of continuous process flow</li><li>• Use of 'pull' systems to avoid overproduction</li><li>• Reduction in quality checks by getting quality right 'first time'</li><li>• Use of standardised tasks</li><li>• Visual controls to improve awareness of processes</li></ul>

**Laboratories should be made efficient through the redesign of laboratory premises.** There should be active consideration of laboratory reprovision or remodelling where current premises do not support an efficient delivery of service.

**The use of up-to-date Information Technology should be maximised.** Laboratory reception areas are typically busy and heavily workforce dependent. Electronic order communications software has undoubted potential to both improve efficiency, and to improve the appropriate use of laboratory tests by allowing 'just in time' decision support for clinicians. Equally Laboratory Information Management Systems represent an underexploited data source both to enable improved clinical care and to optimise the performance of pathology services. It is critically important that the IT infrastructure for the service reflects and fully enables the business model for service delivery, so that service reorganisation is not constrained by location and host organisation.

The Pathology Modernisation Project in collaboration with Informing Healthcare is currently developing plans to replace the current disparate Laboratory Information Management Systems (LIMS) with an integrated All Wales system that will deliver consistent, accessible and comparable data between all the Welsh pathology laboratories.

Order communications functionality (TRRR) is being developed as a core functionality of the Wales Clinical Portal, and roll out of this across Wales should begin during 2008.

**The Pathology workforce needs to be developed to support flexible working by improving and extending their roles with appropriate training and support, which in turn will enhance service quality and efficiency and improve staff retention.** By ensuring that work is assigned to the most appropriate trained member of staff they will have opportunities to utilise and further develop their skills. This will also enable senior staff to have the necessary time to develop service effectiveness. Opportunities for working across traditional laboratory disciplines should be explored where this will make more efficient use of the workforce.

**Pathology should be developed as an 'end to end' service.** Transport and phlebotomy services are critical determinants of service efficiency and offer opportunities to regulate the flow of work into laboratories. It is often these aspects of the service where the greatest improvements in service efficiency are to be gained. Where the Pathology service does not provide these services they should be specified through a well constructed service level agreement.

### **5.3 Effectiveness**

Optimising the working relationship between the Pathology team and clinical teams is the key to improving the effectiveness of Pathology. There are many examples of the contribution Pathology tests make to clinical care including:

#### **Blood tests for Cardiac "Troponin" transform the diagnosis and management of patients with heart attacks**

The development and introduction of blood tests for cardiac troponin in biochemistry laboratories has radically changed the clinical management of cardiac patients. These tests are very sensitive to minor degrees of heart muscle damage and highly specific as cardiac troponin is only found in the heart and not other tissues. This has led to the re-definition of "myocardial infarction" and has driven many of the changes in the diagnosis and management of patients with "acute coronary syndromes".

#### **D-dimer testing reduces the need for leg vein imaging**

Deep vein thrombosis is a common diagnostic problem in acute care. Provided the patient has a low clinical score for the diagnosis then a blood test for d-dimer levels can establish whether it is safe to discharge the patient without the need for imaging of the leg veins. In the past, patients were treated with heparin while waiting for imaging, many as hospital inpatients.

**Tests for monitoring diabetes are key to improvements in clinical care in general practice and hospitals.**

Increasing numbers of patients with diabetes need to be managed in primary and secondary care. Laboratory monitoring of patients is key to achieving best diabetic control to help prevent or delay the onset of complications such as heart disease, eye problems or kidney failure.

Blood and urine tests are vital to assess long term sugar control (HbA1c test) early warning for kidney problems (urine microalbumin and creatinine), and lowering the risk of coronary heart disease (cholesterol and other blood lipids)

These tests are now an integral part of the general medical services contract for all general practitioners.

**Point of Care Testing improves care of patients on warfarin**

Careful monitoring of the INR (which monitors the drug effect) is necessary for patients taking warfarin, because of the risk of bleeding when taking this drug. Point of care devices of appropriate quality and cost are now available for this test allowing patients to get a result, and warfarin dose, immediately, and removing the need to transport specimens to a lab.

**Pathology selects breast cancer patients who benefit from Herceptin**

Herceptin is an expensive but effective new drug for early and late stage metastatic breast cancer. Research has shown that only patients with tumours that over-express the target receptor (HER-2) will benefit from this treatment. Pathological testing of tumours for over-expression of HER-2 identifies those who will benefit from this treatment and avoids ineffective and expensive treatment in others who can then be offered alternatives.

**Pathology panel improves treatment for lymphoma victims in Wales**

Accurate classification of the tumour is a prerequisite for appropriate treatment of lymphoma - a malignant tumour of cells of the immune system. Such classification is often difficult and requires examination of the tumour tissue by several different branches of pathology. The All Wales Lymphoma Panel is a formal collaboration (network) of specialists in histopathology, haematology, immunology, cytogenetics and molecular pathology from across Wales that facilitates and co-ordinates the accurate classification of these tumours. This allows oncologists to provide appropriate treatment to patients; the work of the panel has significantly improved the treatment of lymphoma patients in Wales

### Laboratory tests reduce need for endoscopy & duodenal biopsy

Coeliac disease is caused by an immunological reaction to proteins in wheat resulting in autoimmune pathology in the gut that can cause malabsorption. It is common, affecting more than 1 in 100 of the population. Until recently this has required endoscopy and duodenal biopsy of many suspected individuals to diagnose those who do have it. The availability of laboratory immunology tests for antibodies against Tissue Transglutaminase (TTG) has enabled suspected patients with suspicious symptoms to have this blood test, thus reducing the number of endoscopy and biopsy procedures when this test is negative. Debate now centres around whether endoscopy and biopsy needs to be performed at all in such TTG+ patients.

It is important to encourage appropriate requesting of Pathology tests by clinical teams. Inappropriate testing is costly, wasteful of time, and may result in unnecessary inconvenience or harm to the patient when extra tests are generated unnecessarily. A number of measures can be shown to improve clinical governance in this area. **As far as possible, Pathology tests and the mechanisms for requesting and reporting should be standardised across Wales.** This streamlines training of staff, and reduces the need for retraining as staff move around the service.

The proper management of demand requires a detailed understanding of the way clinicians work and generate requests. In order to reduce the amount of work required to achieve this across the service **a philosophy of 'Do Once and Share' should be promoted across Pathology services in Wales, and in future the place of Pathology tests in the patient care pathway should be established at an early stage in care planning** so that proper service engagement and planning can take place.

Pathologists are concerned at the time training clinicians have to develop a detailed understanding of Pathology tests and their limitations. However information technology can provide a solution by allowing access to guidance on test requesting; and **decision support for Pathology testing should be developed**, using the TRRR functionality being developed for the Wales Clinical Portal. As part of the audit process, **feedback to clinicians on their testing practice should be provided.**

Good clinical leadership is essential to focus and develop Pathology services, and to ensure that they are effectively interfaced with clinical services, so **the clinical leadership of Pathology services should be fostered.**

## 5.4 Service reorganisation

Pathology services in Wales should follow a path of increasing integration and harmonisation that builds upon the progress that has already been made by the service. Laboratory facilities should be located appropriately within the hospital network to enable proper economies of scale by rationalising services where necessary. At the same time, provision of tests to inform critical decision points in the patient pathway should be as local as the technology and test price allows.

At the time that proposals for Pathology services were being developed, the merger of Pontypridd & Rhondda and North Glamorgan NHS Trusts was under consideration and no announcements had been made concerning other potential Trust mergers. At the point at which the proposals were finalised, the merger of Pontypridd & Rhondda and North Glamorgan NHS Trusts to form the Cwm Taf NHS Trust had been announced. Following a further announcement, consideration was being given to the merger of Swansea and Bro Morgannwg NHS Trusts and Ceredigion & Mid Wales, Pembrokeshire & Derwen and Carmarthenshire NHS Trusts.

As of 1st April 2008 Ceredigion, Pembrokeshire & Derwen and Carmarthenshire NHS Trusts merged to form the Hywel Dda NHS Trust, Pontypridd & Rhondda and North Glamorgan NHS Trusts merged to form the Cwm Taf NHS Trust and Swansea and Bro Morgannwg NHS Trusts merged to form the Abertawe Bro Morgannwg University NHS Trust. These Trust mergers will facilitate implementation of the proposals for Pathology services.

North East Wales and Conwy & Denbighshire NHS Trusts are currently consulting on proposals to merge.

In future Pathology services should be delivered by networks of laboratories rather than by standalone laboratories based in District General Hospitals. These networks should reflect local clinical service provision, and Pathology Services within the network should be appropriately co-located with clinical services. Integration between locally networked services and existing national service networks should be developed and optimised.

In addition to the current national networks and based on the current direction of travel, **Six Pathology Services should be developed from the existing Trust-based Pathology laboratory services in Wales and the process of moving to three regionally managed services should be explored.**

### North Wales:

1. In North Wales plans are being developed to create a managed Pathology service to encompass the services currently delivered by the laboratories at Ysbyty Gwynedd, Bangor; Ysbyty Glan Cwyd, Rhyl and Ysbyty Maelor, Wrexham. This network will serve a population of approx 720,000.

## **Mid and West Wales:**

2. In the West of Mid and West Wales a Pathology service will be created as a result of Trust reconfiguration to encompass the services currently delivered by the laboratories at Prince Phillip Hospital, Llanelli; West Wales Hospital, Carmarthen; Withybush Hospital, Haverfordwest and Bronglais Hospital, Aberystwyth. This will serve a population of approx 360,000.

3. In the East of Mid and West Wales plans were in the process of being implemented to create the Morgannwg Pathology Service encompassing the services currently delivered by the laboratories at Neath Hospital, Port Talbot; Morriston Hospital, Swansea; Singleton Hospital, Swansea and the Princess of Wales Hospital, Bridgend. However, from 1<sup>st</sup> April 2008, as a result of the formation of the Abertawe Bro Morgannwg University NHS Trust, a Pathology service will be created to encompass the services currently being delivered by the above laboratories. This will serve a population of approx 500,000.

## **South East Wales**

4. In the East of South-East Wales the Pathology service encompassing the services delivered by the laboratories at Nevill Hall Hospital, Abergavenny; the Royal Gwent Hospital, Newport and the Caerphilly District Miners Hospital, Caerphilly should be developed further. This serves a population of approx 550,000.

5. In the West of South-East Wales a Pathology service will be created as a result of Trust reconfiguration to encompass the services currently delivered by the laboratories at the Royal Glamorgan Hospital, Llantrisant and Prince Charles Hospital, Merthyr Tydfil. This will serve a population of approx 310,000.

6. In the South of South-East Wales the Pathology service encompassing the laboratories at the University Hospital of Wales, Cardiff and Llandough Hospital, Penarth should be developed further. This serves a local population of approx 450,000, and also supports tertiary services provided across Wales. At present the labs providing tertiary services are fragmented geographically. It is recommended that laboratories providing tertiary services should be integrated.

At regional level there is a need to co-ordinate Pathology service provision between neighbouring Pathology services to avoid unnecessary service duplication, ensure accreditation and to allow service rationalisation to create critical mass where appropriate. The Pathology service needs to be interfaced with clinical services, such as cancer services and cardiac services, which are organised regionally, and with the nationally provided Pathology services

Because of this, **the three existing Regional Pathology Networks/Forum should be further developed** to facilitate service engagement with cancer, cardiac and other regional clinical services, and to co-ordinate service provision between the Pathology services in the South-

East and Mid and West Wales regions (Appendix E). In North Wales the intention is that pathology services will be managed as a single network and the regional networks/forums in the Mid and West and South East should be tasked with considering **the benefits of moving to regionally managed services**.

In addition, **a regional approach should be taken to develop comprehensive plans that enable patients to have appropriate access to Pathology testing services outside the hospital setting**, particularly where this has been shown to improve patient experience in the management of chronic diseases.

There is also a need to take a national view of Pathology services across Wales in order to:

- promote integration between local and national Pathology services
- facilitate a practice of 'do once and share' between Pathology services across Wales
- co-ordinate work which cannot be done below national level, e.g. the specification of an All-Wales LIMS
- oversee benchmarking of Pathology services and develop appropriate measures of performance
- review and develop the Pathology National Framework on a regular basis
- promote the development of clinical leadership of Pathology services in Wales
- undertake Workforce planning

The current Pathology Modernisation Project has made good progress promoting these aims, but has a finite lifespan. By the time it draws to a close **a National Pathology Forum for Wales should be established** to promote integration of Pathology services across Wales and to be responsible for supporting service delivery to consistently high standards against the National Pathology Framework.

## **5.5 Planning and Delivery**

The planning and delivery of Pathology services can provide challenges. The current commissioning environment is fragmented, with discussions taking place between LHBs (and Health Commission Wales for specialist and tertiary services) and the existing hospital-based laboratories. Amalgamation of service providers to six local Pathology services should help with this, and **opportunities arising from the likely formation of a National NHS Board should be exploited**.

The true costs of Pathology services are difficult to establish at present. Future decisions on the delivery of Pathology need to be supported by a more informed view of the resource used to generate test results in the service. In future **all Pathology services in Wales should participate in an approved benchmarking scheme**, and the detail of this will form an

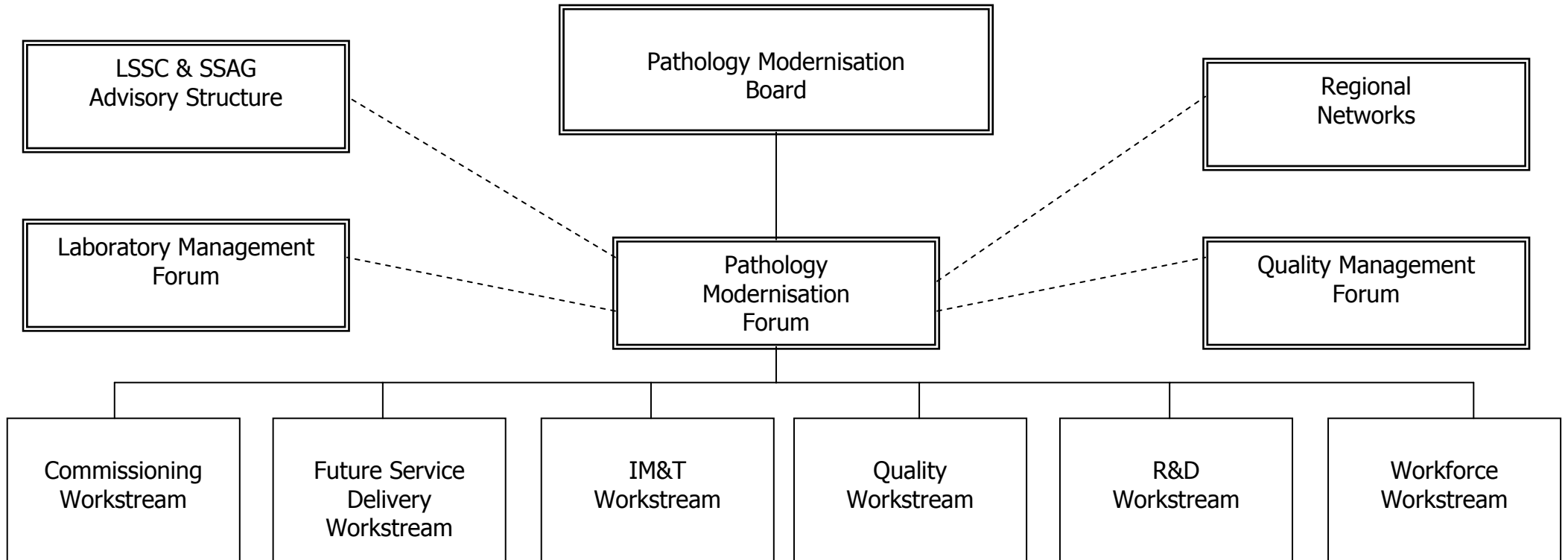
important part of the work of the Pathology Modernisation Project, so that in future all Pathology providers in Wales describe their activity in the same way.

Pathology services need to be able to plan against predictable revenue streams, and to facilitate this there **should be a clear link between service activity and revenue** through a mechanism agreed as part of the planning process.

To enable proper cost comparisons to be made between Pathology providers, **Pathology budgets should be apportioned to the business areas of blood sciences, microbiology, cellular pathology and tertiary services.** There is currently variability in the way Trusts attribute overheads, clinical consultant sessions and income to Pathology departments, and in future **Pathology budgets must be constructed consistently to allow proper cost comparisons.**

# Appendix A Wales Pathology Modernisation Project Structure and Membership

## PROJECT STRUCTURE



### KEY:

- LSSC - Laboratory Services Sub Committee
- SSAG - Scientific Services Advisory Groups
- IM&T - Information Management & Technology
- R&D - Research & Development

## PROJECT BOARD

Representing	Member	Role & Organisation
WAG	Christine Miles	Director of the South East Wales Region
IHC	Gwyn Thomas	Director, IHC
PMF	Paul Miller	Chief Executive, Velindre NHS Trust
LHB Chief Executives	Alan Brace	Chief Executive, Carmarthenshire LHB
Trust Chief Executives	Gren Kershaw	Chief Executive, Conwy & Denbighshire NHS Trust
Royal College of Pathologists (Wales)	Geraint Williams	Consultant Histopathologist, Cardiff and Vale NHS Trust
Clinical Pathology Services	Grant Robinson	Chief of Staff, Gwent Healthcare NHS Trust
LSSC	Keith Griffiths	Chair Laboratory Services Sub-Committee, Consultant Biochemist, North West Wales NHS Trust
Partnership Forum	Steve Sloan	Lead Officer for Health, Amicus
CMO's Office, WAG	Jenny Frost	Deputy Chief Scientific Advisor, WAG
NLIAH	Andrew Lewis	NLIAH
WAG	Ian Stead	Director of Human Resources, NHS Wales
Diagnostic Services Programme	Lindsey Davies	Programme Director, Programme Management Unit
Pathology Modernisation Project	Margie Fielden	Project Manager, Programme Management Unit

## PATHOLOGY MODERNISATION FORUM

Representing	Member	Organisation
Chief Executives	Paul Miller (Chair)	Velindre NHS Trust
Programme Director	Lindsey Davies	Programme Management Unit
Deputy Chief Scientific Advisor	Jenny Frost	Welsh Assembly Government
SSAG Chairs	Ian McDowell (Clinical Chemistry) (David Hullin with effect from November 2007 )	Cardiff & Vale NHS Trust Pontypridd and Rhondda NHS Trust
	Andrew Goringe (Haematology)	Cardiff & Vale NHS Trust
	Mark Hastings (Microbiology) (Ann Lewis with effect from October 2007)	NPHS
	David Griffiths (Histology)	Cardiff & Vale NHS Trust
Immunology	Paul Williams	Cardiff & Vale NHS Trust
Genetics	Ian Frayling	All Wales Laboratory Genetics Service
NPHS	Mike Simmons	NPHS
Partnership Forum	Doug Proctor	North Glamorgan NHS Trust
HCW	Ash Paul (to October 2007)	Health Commission Wales
GPC Wales	David Bailey	GPC Wales
Laboratory Management Forum	Andrew Crowder	Cardiff & Vale NHS Trust
Quality Management Forum	Tim von Pokorny	Gwent Healthcare NHS Trust
Regional Networks	SE – Andrew Crowder	Cardiff & Vale NHS Trust
	M&W – Ray Rooke	Swansea NHS Trust
	N – Adrian Thomas	Conwy & Denbighshire NHS Trust
Commissioning Workstream	Alan Brace	Carmarthenshire LHB
Project Manager	Margie Fielden	Programme Management Unit
Audit Office	Mandy Townsend	Wales Audit Office
IHC	Simon Gillings	Informing Healthcare
NLIAH	Claire Lloyd	National Leadership and Innovation Agency for Healthcare
R&D Workstream	Ed Guy	National Public Health Service
WDU	Will Oliver	Workforce Development and Education Contracting Unit
POCT Group	Annette Thomas	Welsh External Quality Assessment Scheme
IM&T Workstream	Keith Griffiths	North West Wales NHS Trust

## **Appendix B**

### **Modernisation of Pathology services in South Wales**

Between January and August 2006, a review commissioned by the Welsh Assembly Government was undertaken to identify and evaluate alternative models of pathology service delivery for South Wales (comprising the Mid and West and South East regions).

The review made a number of recommendations:

- Pathology services should be developed using a network approach to service delivery.
- Pathology services should be aligned to reflect the clinical models being developed under Designed for Life and the potential for centralisation of activity on Level 3 hospital sites should be explored.
- That flexibility to meet differing local circumstances should be set within the context of agreed principles regarding the future shape of pathology services
- As part of the ongoing Pathology modernisation agenda, the modelling framework developed within the review should be applied as a tool to develop future laboratory plans and assess the impact of local initiatives.

## Appendix C Options appraisal workshop

An Options Appraisal workshop facilitated by Professor Chris Price from the Carter Review Team took place on 23<sup>rd</sup> March 2007. The group discussed the benefit criteria and the options and then scored the options. Following the workshop, stakeholders were given the opportunity to rescore a reduced number of options. No major changes emerged.

### Option Appraisal Benefit Criteria

#### 1. Quality

The option has the ability to:

- provide services across Wales to CPA standards
- standardise protocols
- manage demand
- manage POCT
- Support the delivery of best practice

#### 2. Efficiency

The option has the ability to:

- maximise productivity
- provide specialised tests cost-effectively in Wales or through networking outside Wales where appropriate
- evaluate and procure equipment
- secure efficient specimen collection and transport

#### 3. Workforce

The option has the ability to:

- develop workforce plans (including skill mix and cross-discipline working)
- recruit and retain
- train and develop

#### 4. Clinical Integration

The option has the ability to:

- facilitate communication with clinicians and patients
- integrate with national/regional healthcare strategy

#### 5. Research & Development

The option has the ability to:

- create scientific critical mass
- develop and respond to new tests & technology

#### 6. Commissioning

The option has the ability to:

- control costs
- link finance to activity

#### 7. Change management

The option has the ability to:

- be implemented, either immediately or through a phased approach, without compromising service delivery
- support future service flexibility

# OPTIONS SCORECARD

BENEFIT CRITERION	WEIGHT %	Option 1 Do nothing		Option 2 Maintain current direction		Option 3 Three federated networks		Option 4 Three managed networks		Option 5a Nationally managed service with 3 regional management		Option 5b Nationally managed service with 3 regional management groups – direct employment of all staff		Option 6 Single organisation		Option 7 Discipline based networks – may combine federated and networks	
		Score	Weight x Score	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score	Score	Weight x Score
Quality	30	0	0	3	90	1	30	4	120	4	120	4.5	135	4	120	4	120
Efficiency	20	0	0	3	60	1	20	4	80	3.5	70	4.5	90	4	80	1	20
Workforce	12	0	0	2	24	1	12	3	36	4	48	5	60	5	60	2	24
Clinical Integration	12	3	36	3	36	2.5	30	3	36	3	36	3	36	3	36	2	24
Research and Development	12	1	12	3	36	3	36	4	48	5	60	5	60	5	60	3	36
Commissioning	4	1	4	1	4	1	4	4	16	4	16	4	16	4	16	2	8
Change Management	10	5	50	5	50	4	40	3	30	3	30	3	30	2	20	2	20
<b>TOTAL</b>	<b>100</b>	<b>102</b>		<b>300</b>		<b>172</b>		<b>366</b>		<b>380</b>		<b>427</b>		<b>392</b>		<b>252</b>	

## **Appendix D      Networks seminar**

In response to the need to more clearly understand the various network models that emerged from the options appraisal exercise, a Network Seminar was held in Builth Wells, on the 4<sup>th</sup> July 2007, at which the following presentations were made:

***“Experiences of Forming a Pathology Network in Cumbria & Lancashire”***

Presented by – Les Martin, Network Manager, Cumbria & Lancashire Pathology Network.

***“An Evolving Network”***

Presented by – Peter Huntley, Director, Kent & Medway Pathology Network.

***“NPHS Microbiology Network”***

Presented by – Dr Mark Hastings, Microbiology Lead, National Public Health Service.

***“Networking in Screening”***

Presented by – Bryan Rose, Head of Business & Service Development.

***“Welsh Blood Service – An Overview”***

Presented by – Dr R M Jones, Medical Director (& Acting Director) Welsh Blood Service.

***“Laboratory Genetics Networks – UKGTN & SCOBEC”***

Presented by – Dr Ian Frayling, Director All Wales Laboratory Genetics Service.

***“South West Wales Cancer Network, Telemedicine Project”***

Presented by – Delyth Lewis, Pathology Telemedicine Project, South West Wales Cancer Network.

***“North Wales”***

Presented by – Dr Keith Griffiths, Consultant Biochemist North West Wales NHS Trust.

***“Morgannwg Pathology Service”***

Presented by – Andrew Evans, Director of Pathology Bro Morgannwg NHS Trust & Dr Wynne Williams, Director of Pathology Swansea Hospitals NHS Trust & Interim Clinical Director.

## Appendix E Networked services

### Welsh Health Circular (2005) 076 - Clinical Networks

#### Summary

Developing Clinical Networks to become “engines of improvement” in delivery of specialist health services will be an important objective over the next few years as acute service reconfiguration matures across Wales as part of the Wanless reform agenda. This circular establishes a framework allowing a consistent approach without losing the benefit of diversity. Further discussion on future commissioning arrangements will take place during 2005/06 and this guidance may then need to be amended.

#### Action

From 01.12.05 all Networks should:

- be founded on a written establishment agreement
- be registered with the Health and Social Care Department’s Regional Offices
- be clinically driven
- be engaged by Trusts whenever they find difficulties in managing alone issues that the Network could help resolve
- have considered preparation of a work plan, and where appropriate have a development plan in place

In addition,

- Commissioners will be expected to draw on Networks’ expertise when preparing needs assessments and in developing local strategies and commissioning plans
- all Assembly policy leads should by then have come to a view on the role of existing and potential Networks and agree with them both their current and future role.

#### Background

1. Amongst its objectives *Improving Health in Wales* the Plan included the establishment of Clinical Networks, initially, for cancer and CHD. *The Review of Health and Social Care in Wales* advised by Sir Derek Wanless suggested that new mechanisms need to be created to ensure that the Assembly has the leverage to ensure effective and coordinated services are delivered by networks of partners.
2. Two major objectives of the Assembly Government are to reconfigure services and to ensure that services meet quality standards. Networks can potentially act as powerful change agents in achieving these, allowing rapid uptake of evidence for what should be done and how, without reference to the artificial constraints of organisational boundaries.

A vital driver for change is well-informed commissioning. Networks can help provide and implement evidence, and used well can make a crucial contribution to commissioning decisions and to supporting practice change.

#### A. Types of network

3. A definition of a network might be *Linked groups of health professionals and organisations from primary, secondary and/or tertiary care, working in a co-ordinated manner, unconstrained by existing organisational boundaries, to ensure equitable provision of high quality clinically effective services.* They might also in certain cases include local authority representation.
4. In practice, networks will differ, depending on their purpose, and they will change their form as they gather confidence and gain or lose responsibilities. Some are very tightly managed to ensure a consistent service through all providers – as for example with Cervical Screening Wales, which includes every Trust in Wales.
5. Commissioners will often need to work together to secure consistent access to high quality services

and to drive service change. This is especially so if an individual commissioner is hard pressed to devote sufficient resources to elements of a large agenda or if several commissioners receive major elements of a complex service from one provider. Providers will often need to work together to ensure that service changes are well managed, that service components mesh together safely and effectively, and that they back each other up when pressure rise. In some cases, for instance where services contain several levels of service and face the need for rapid and significant change, networks might need to include both commissioners and providers.

6. Local Health Boards (LHBs) are the principal commissioners of secondary care services and are accountable for assessing the needs of their local population and securing suitable services to address them, in partnership with other agencies. Local commissioning derives its strength and its legitimacy from its local roots in the Local Health Board and Local Authority, and from those bodies acting in concert. Therefore any **commissioning network** must offer each LHB the potential over the longer term of securing better services and outcomes for its local population than it could achieve working alone.
7. Where appropriate, commissioner networks will include HCW - Health Commission Wales (Specialist Services) and local authorities. Networks will be expected to help resolve commissioning issues at the interface between secondary and tertiary care.
8. Commissioning networks will differ according to the service to be commissioned, and can change over time. Table 1 shows some of the potential variables; the status of any Network at any point in time might combine elements from different columns:

	Early stage	Developing stage	Advanced stage
Funding	The network operates by negotiating with the partners	The network controls elements of the commissioning budget e.g. an agreed quota from each partner or new investment funds	The network has full control over the budget
Leadership	There is a rotating lead	One LHB takes the lead	A single senior management lead is in place
Staffing	Existing LHB staff are used	The lead LHB provides the staff	There are separately funded staff
Strategic grip	Changes are tactical, responding ad hoc to issues	Audit against standards provides hard evidence for change	Changes deliver an agreed long-term plan
Authority	Advisory, with issues raised with relevant commissioners	Commissioning strongly influenced by Network advice	The Network can radically change services
Scope	Only elements of a service are affected		The Network applies to a whole service
Management control	All changes require unanimity	Changes are according to a voting system	Networks take collective responsibility both for managing the network and for implementing decisions taken
Quality control	Identifying some standards		Accreditation of providers

9. **Provider networks** operate beyond the boundaries of individual Trusts (often at an All Wales level). Provider networks draw their authority from the combined expertise that they wield and their ability to improve services on the ground. The management element of the network may lie with the providers themselves, or be provided by the commissioner, as is the case with the Paediatric

Intensive Care Network. Because provider networks will acquire a greater understanding of the needs and circumstances of the service they provide, Commissioners will be expected to draw on their expertise when preparing needs assessments and developing local strategies and commissioning plans. At present provider Networks include those for Genetic Services, Breast and Cervical Cytology Services, Paediatric Intensive Care and Renal Services in South Wales.

10. Provider networks will differ according to the service, and can change over time.

Table 2 shows some of the potential variables; the status of any Network at any point in time might combine elements from different columns:

	Early stage	Developing stage	Advanced stage
Funding	The network operates by negotiating with partners	The network manages elements of the budget e.g. an agreed quota from each partner	The network has full control over the budget
Leadership	There is a rotating lead	One provider takes the lead	A single senior management lead is in place
Staffing	Existing staff are used	The lead provides the staff	There are separately funded staff
Operational mode	There is ad hoc management of issues		There are agreed protocols for managing issues
Strategic grip	Changes are tactical		Changes deliver an agreed long-term plan
Scope	Only elements of a service are affected		The Network applies to a whole service
Management control	All changes require unanimity		Changes are according to a voting system

11. **Combined commissioning and provider networks** can bring together both the power of commissioning and the opportunities providers have to remould service from the base. They need to pay heed to the issues raised in paragraphs 3-10 above; their evolution will combine elements from tables 1 and 2. There are combined commissioner and provider networks for Cancer and Cardiac Services.

## B. Network Essentials

12. Networks need a clear objective, should wherever possible help tackle priority issues and must have clear accountability arrangements. Therefore, their purpose and operating rules and the responsibilities of those composing the Network, of whatever type it is, must be written down and agreed to ensure that it is properly managed.
13. Networks might be created in response to a decision by the Assembly, or might emerge from decisions at local level. All Networks create mutual responsibilities. The partners agree to work together and cede some level of independent working, to ensure the population they serve receives the greatest benefit from available resources. In addition, Networks operate across and outside the normal managerial relationships, which are there to ensure coherence and accountability. To avoid confusion, free-riding and loss of control, there must be clarity and certainty in the way that Networks operate, especially in the following areas:

### *a. clarity about aims and objectives*

14. Networks should aim to co-ordinate the use of available resources to ensure equitable access to and the delivery of good quality and effective care; their function is to support the clinical process to achieve the best outcomes for patients. In doing so they should consider:

a. *The service to the user* - looking at care from the patient's view; analysing the care pathway, and intervening as early and as effectively as possible; reducing health inequalities and maximising equity of access; applying relevant standards of care; defining the contribution to be made by each of the Network's members – clearly the most direct way of securing the views of patients and carers is to ask them and from an early stage their contribution of to the development the Network should be considered, and this should be reviewed as appropriate

b. *Resource use* - using all resources effectively, and searching out options for improvement in their use; setting priorities for change and development; using opportunities to influence decisions and processes for resource allocation minimising bureaucracy, simplifying decision-making and ensuring timely action.

c. *The results* - maximising the impact of every intervention opportunity; measuring clinical outcomes and the extent to which health care and support needs of patients and their families/cares are met; auditing across the network compliance with standards and care pathways

d. *Network development* - fostering a culture of collaboration, partnership, teamwork and learning.

### ***b. clarity about accountability and performance management***

15. Network governance arrangements must be clear. There may need to be a Network Board, with sufficiently senior representation (clinical or other) from each LHB and/or Trust to support decisions and follow-through. The role, responsibility, time commitment, accountability and subsequent communication requirements for each network participant must be determined at the outset and described in the establishment agreement. Any support staff for each network should be formally employed by a host LHB or Trust, which will be financially accountable for the resources levied from each stakeholder organisation to fund the support costs. There may be grounds for a national board to provide an overview, as for example where there are separate Networks in each Region, as with cancer, or where a number of Networks have a shared interest, as with Children and Young People's Specialised Services.
16. Each Network should institute its own formal performance management process, and the Regional Office should oversee this.

### ***c. clarity about clinical accountability and clinical governance***

17. Chief Executives of LHBs and NHS Trusts cannot pass their legal responsibility for clinical governance to the Clinical Network. However, Networks will need to develop a framework for dealing with clinical governance issues, including clear protocols for reporting clinical governance issues to the relevant Chief Executive (or nominated clinical governance lead). Individual health care professionals have the responsibility of conforming to the guidance of their individual registration authorities in the way that they conduct network business.
18. Networks will likely develop over time. Some have now reached the point where they can accredit providers and effectively mould services. Where Networks wish to secure additional responsibilities, they should in the first instance raise the matter with the relevant Assembly policy lead.

## **C. Formal Requirements**

19. If designed and run well, Networks can strengthen the roles of commissioners and providers, and of both. They also offer an opportunity for stronger clinical leadership of service change. While differences are natural and welcome, all Networks must contribute strongly to service objectives. Therefore the Assembly expects Networks to be much more assertive in improving standards and driving service change, and in particular will require that from 01.12.05:
  - a. All Networks will have a formal establishment agreement clarifying their purpose, objectives, membership (with their accountability), support requirements and performance management

arrangements. The Annex to this paper contains a checklist of issues to be covered by such an agreement.

b. All Networks will be registered with the Health and Social Care Department's Regional Offices, which will monitor the operation and development of Networks to ensure that they function effectively and are adequately involved in the planning and commissioning processes within their regions. Network Chairs should be appointed after agreement with the relevant Regional Director.

c. Networks will be clinically driven.

d. Commissioners will be expected to draw on Networks' expertise when preparing needs assessments and in developing local strategies and commissioning plans.

e. Trusts will involve relevant Networks whenever they find difficulties in managing issues alone.

f. All Networks will have formally considered preparation of a work plan with clear criteria by which to measure progress and achievements against objectives. Where appropriate they should have or be preparing a development plan covering a number of years as agreed centrally. This plan must reflect existing resources, including workforce, and changes needed within the network in order to achieve the requirements set at a national and local level in terms of service standards, care quality and other appropriate criteria.

g. Drawing on this paper, all Assembly policy leads, working as appropriate with Health Professionals from the Office of the Chief Medical Officer, nominated Service Directors, and Regional Directors, should consider the role of existing and potential Networks in relation to planning, commissioning and performance improvement and agree with them both their current status and their possible future development role.

### **The Network Establishment Agreement**

As set out in paragraph 19a, each Network should have a formal agreement governing its working. This should cover most or all of the following:

- Service area covered
- Participating organisations
- Purpose of the network
- Principles on which the network is based
- Date by which a work plan is expected
- Clarity about the role of constituent bodies
- Name of the Chair and time commitment expected
- Those who need to be on the Network Board in order to achieve these, clearly specifying their role, responsibility, time commitment, constituency and authority to commit their organisation
- The role of the Network in the context of overall service commissioning e.g. what part of service commissioning the Network will aim to influence and how this might link to primary care contracting
- Role and responsibilities of the various network members - how are they expected to discharge their role, e.g. to whom do they need to communicate what
- How other bodies who have an interest in the network will be involved/communicated with
- How the participation of service users and carers is to be achieved
- How the network is to be managed e.g., frequency of meetings, quoracy
- What support does the network require (costed)
- The "host" of the network (if required)
- Clearly expressed expectations/requirements such as:
  - shared and understood "terms of engagement"
  - a communication strategy
  - a work plan to monitor its own internal performance and that of its members
  - protocols for service delivery
  - standards – are they mandatory or advisory
- In-year objectives
- Relationship with other bodies – for example the National Public Health Service, which can be a source of evidence and advice on both service issues and network management.

## **Appendix F. Criteria for inspection as a network by CPA**

### **CPA Guidance on the Accreditation of Managed Pathology Networks**

1. The Department of Health has published Draft Guidance on Modernising Pathology Services.
2. The guidance advocates the establishment of managed pathology networks, while recognizing issues of accountability and the need for an incremental approach to network development.
3. CPA will be asked increasingly to accredit a variety of managed networks as these evolve to meet local needs and circumstances.
4. CPA needs to formulate clear guidance on what is and is not a managed pathology network capable of accreditation.

The crucial test of a managed pathology network is that its Quality Management System can be assessed through a single horizontal audit at any one of its component units.

#### **What is an accreditable Managed Pathology Network? CPA`s View**

5. Every unit in the network will comply with all CPA standards but those key standards, mainly `A` standards, defining a true managed network are as follows:

- > **The network, or the parent organisation of which it is a part, shall be an entity that can be held legally responsible (A1.1)**
- > **It shall have a single Quality Management System (A1.2)**
- > **It shall be defined in a single organisational chart (A1.4)**
- > **It shall have a single Quality Policy (A3)**
- > **There shall be a single Quality Manual (A6) which may contain separate sections for its component units**
- > **There may be more than one Quality Manager (A7) but they shall operate to the same policies and procedures**
- > **There shall be a single Annual Management Review (A11)**
- > **There shall be regular meetings between management and the staff involved in all branches of the network (B8)**
- > **Users shall be assured of equity of access to pathology data ( D2) and interpretive advice (G2,G5)**
- > **There shall be a single User Manual (E1) which may contain separate sections for its constituent units**
- > **There shall be a common format for requesting investigations (E2) and reporting results (G2)**
- > **There shall be a common format for written procedures ( SOP`s) across the network (A8,A9,A10,B3,C6,D1,D2,D3,H1,E3,E4,E5,E6,F2,F3,G1,G3,G4)**

**6.** A managed network will therefore :

- > Operate under a single CPA reference number
- > Submit one application form with one Quality Manual
- > Be subject to a single assessment for which there will be a single report
- > Have a single CPA status for all its constituent units

**7.** If a network feels it does not meet these standards during its formative period of incremental development, it is advised to apply as separate departments retaining their own registration numbers and separate CPA status.

**8.** In CPA`s view, a managed pathology network must be distinguished from for example:

- > A Trust merger at management level where pathology departments retain separate identities
- > networks of cooperating professionals without identified management arrangements.

**Policies & Procedures**

**Jan 2003**

**PAC input Feb 5**

**Appendix G            POINT OF CARE TESTING GOVERNANCE POLICY – PATHOLOGY TESTING.  
WHY, WHEN AND HOW? A USER GUIDE**

**WHY?**

The Welsh Scientific Advisory Committee produced guidance for “The use of Diagnostic Equipment and Procedures outside the Diagnostic Laboratory” in 1984, and this was updated in 2004. The second document was circulated under cover of a Welsh Health Circular (WHC (2005) 005).

This document updates earlier guidance for users of point of care testing (POCT) devices and addresses the governance issues surrounding POCT. It reiterates the earlier advice that there should be close liaison between users at the POCT site and an accredited laboratory. The document also provides guidance on how to implement and manage a POCT service.

***For the purpose of this document POCT is defined as any diagnostic test done by non-laboratory staff outside a recognised diagnostic laboratory whether in primary or secondary care or other community sites.***

*Examples of POCT devices include:*

*Blood glucose meters, Urinalysis test strips, Pregnancy test kits, Coagulometers, HbA<sub>1c</sub>, analysers, Rapid test kits for infectious disease markers, Bilirubinometers, blood gas analysers, electrolyte analysers, lipid analysers and cardiac marker test kits.*

The vision for health and social care services in Wales described in ‘**Designed for Life: Creating World-Class Health and Social Care for Wales in the 21<sup>st</sup> Century**’, published in May 2005 aims to improve health and reduce, and where possible eliminate, inequalities. The integration of all elements of health and social care so that the citizen will be seen and treated by high quality staff at home or locally with the provision of quality assured and evidence based clinical treatment and care appropriate to need, is likely to increase the demand for, and use of POCT devices.

**Clinical Governance is an essential part of any POCT service.**

Healthcare organisations have an obligation to ensure that care is delivered by healthcare professionals based on evidence based practice (Healthcare Standards for Wales, Standard 11), and that patients and service users are provided with effective treatment and care based on nationally agreed best practise and guidelines (Standard 12).

Users of POCT must be able to demonstrate that quality assurance standards are being met, the benefits have been fully considered and all risks associated with the acquisition and use of the devices are minimised (Standard 19).

Furthermore, users should be aware that liability under the Consumer Protection Act (1987) will only remain with the manufacturer or supplier of a device if the user can demonstrate that POCT equipment has been used in strict accordance with the manufacturer's instructions.

Use of POCT as an alternative to laboratory testing must be supported by an accredited diagnostic laboratory, and prior agreement for this support formalised.

## WHEN?

Before deciding whether to implement POCT it is essential for potential users to establish a clinical need, including an examination as to whether reconfiguration of a central laboratory service would be a viable option. The clinical need should be evidence based clearly identifying the risks and benefits of introducing a POCT service.

Benefits	Risks
Faster decision making for patient management	Mis-diagnosis
Patient compliance with treatment	Inadequate training and competence
Treatment optimisation	Inappropriate use of resources
Reduction in hospital visits / more convenient for patient	Limitations of equipment and methodology
	Inadequate or incorrect results

**Any existing POCT service must be reviewed in light of this guidance.**

## HOW?

### 1. CONTACT LABORATORY

The accredited laboratory will take responsibility for providing advice on the purchase of devices, training, maintaining and monitoring the quality of these services. A resource will need to be identified for this support. There should be close liaison between users and the accredited laboratory on all issues relating to POCT as verified in the Checklist see Appendix 1

### 2. PREPARING THE BUSINESS CASE

A business case demonstrating the clinical and economic benefits must be submitted in conjunction with the accredited laboratory to the appropriate governing body (normally a POCT Committee or Group) . For an example of a Business case refer to Appendix 2.

Business cases for widely used POCT may be prepared by commissioners of services for example, LHB and Trusts.

### **3. CHOOSING THE APPROPRIATE DEVICE**

Once a need has been established, the next step is to identify the appropriate device. Before acquisition consideration needs to be given to accuracy and imprecision of results, compatibility with the local laboratory (including calibration, standardisation and units), robustness of the device, traceability of results and service contingency in the event of equipment failure. With regard to the latter it is essential that any POCT service should replicate a centrally provided service, and not seek to introduce or extend test repertoire. The accredited laboratory will advise on the suitability of devices in line with the All Wales POCT Procurement Strategy.

### **4. AGREE SLA WITH LABORATORY**

An agreed "Operational Policy" satisfying the site requirement and defining the accredited laboratory obligations is **mandatory**. This should be incorporated into a Service Level Agreement (SLA) as outlined in the Appendix. (3). Roles and responsibilities of personnel must be clearly identified.

### **5. OPERATING PROCEDURES AND TRAINING**

There must be documented procedures to cover all aspects of the operation of the device including interpretation and limitations of procedure. The Laboratory will be able to provide assistance in developing these procedures.

**Operators must not carry out procedures in which they have not been adequately trained.**

The local laboratory has a responsibility to provide appropriate training and employers have a duty to ensure access to that training. The POCT supplier may also have educators who will provide assistance in training. However, third party training may not cover all aspects. All Wales POCT Steering Committee approved training and competency documents for the most common POCT devices are available to download at <http://howis.wales.nhs.uk/sites3/page.cfm?orgid=460&pid=15109>, Point of Care Resources, Pathology Modernisation, Diagnostic Services Strategy Programme, Programme Management Unit website.

**Operators' competence shall be objectively and independently assessed**

### **6. RECORD KEEPING / CONNECTIVITY**

The results of all patient and quality assurance samples, time, date, and operator details must be recorded. It is essential that procedures are in place to ensure that results are both returned to the clinician and placed in the patient's records with their POCT source identified. Where possible, systems that allow the connectivity of POCT devices to external data systems, including the electronic patient record, must be used.

## 7. MONITORING PERFORMANCE

Users of POCT should also have a sound understanding of the principles of Quality Assurance such as internal quality control (IQC), External quality assessment (EQA) and audit. Examples of an annual review are available on the Point of Care resource page <http://howis.wales.nhs.uk/sites3/page.cfm?orgid=460&pid=15109>. Participation in IQC and EQA is mandatory, and resources to achieve this must be born by the user unless they are included within the SLA.

IQC tests must be performed **by the user on site** at agreed intervals. These are tests done on samples with known values. Control samples, however, only indicate instrument performance; they **do not** help in assessing that the **sample collection** has been done in a correct manner.

EQA: This is when samples with unknown values are tested for peer group assessment, i.e. comparison of a set of results obtained for a given sample at a number of sites. The accredited laboratory can either organise a local Scheme or recommend appropriate accredited External Quality Assessment schemes.

Audit: Documentation must be available to allow full audit trails

## 8. MAINTENANCE

It is essential that the routine maintenance and calibration of equipment is carried out according to the manufacturer's instructions. Failure to properly maintain equipment may give misleading or dangerous results. The accredited laboratory can advise in setting up maintenance schedules and establish Operating Procedures; however, resources for equipment maintenance are bourn by the user unless they are included within the SLA.

## 9. SAFETY

Operators shall be trained in safety procedures as detailed in the training documents. . Laboratories should take an advisory role on health and safety matters. The requirements of *Health and Safety at Work Act 1974*, the *COSHH regulations 1988* and the *Safe Working and Prevention of Infection in Clinical Laboratories Code 1991*, will apply to POCT sites as detailed in the training documents.

## REFERENCES

1. WSAC/D/1/84, "The use of Diagnostic Equipment and procedures outside the diagnostic Laboratory"
2. WHC (2005)005
3. Designed for Life: Creating World-Class Health and Social Care for Wales in the 21<sup>st</sup> Century. Welsh Assembly Government, May 2007
4. MDA Device Bulletin. DB2002 (03): Management and Use of IVD Point of Care Test Devices 2002.
5. Department of Health. Clinical Governance: in the new NHS. London: Department of Health, 1999. (Health Service Circular: HSC (99) 065).
6. Healthcare Standards for Wales, Making the Connections - Designed for Life. Welsh Assembly Government, May 2007

## Appendix (1) CHECK LIST

Question	Yes/No	Action/Date
Have you identified a clinical need?		
Have you looked at all your options?		
Have you contacted an appropriate accredited Laboratory for advice and consultation?		
Is there an approved business case in place? An example can be found in Appendix 2		
Have you secured a supply of reagents and consumables?		
Is there a Service Level Agreement between you and the Laboratory?		
Do you have written operating and training procedures in place?		
Have you arranged for all users to receive appropriate training and competency assessment?		
Have you addressed all Health and Safety requirements?		
Are you able to interface with existing IT?		
Have you arranged to monitor performance?		

## Appendix (2) PREPARATION OF A BUSINESS CASE FOR POCT

1. **Please give a brief overview of the proposed POCT scheme.** Include information on which group of staff will be performing the testing, where the testing will be performed and which sites / Directorates will be using the POCT under your responsibility as POCT lead.
2. **Identify the need for this POCT by answering the following questions:**
  - a) What clinical benefits will this POCT Scheme Provide? For example Convenience for patient, Rapid diagnosis or treatment, Transport of patient /specimens, patient visits/reduced consultations
  - b) For which group of patients will this POCT Scheme be used and approximately how many patients will this benefit?
  - c) Is this investigation currently provided by a different mechanism? If so how?
  - d) Why is the current method not adequate?
  - e) Have ways of reconfiguring the current method be explored
3. **Give details of all equipment and reagents required for this POCT scheme.**
4. **What is the cost of the proposed POCT?**

Capital Costs		Revenue costs		Professional costs	
Purchase/lease of POCT equipment		Consumables: reagents / calibrators etc		Staff training	
Ancillary equipment: centrifuges, incubators, pipettes etc.		routine maintenance (including service contract		Management of the POCT programme	
Working environment		Internal Quality Control material		Staff operator time	
Depreciation		EQA Subscription		Conforming to legal requirements	
Interfacing with information management systems		data-handling system		Laboratory support	
		Waste disposal			
<b>Total running costs</b>					
<b>Cost per patient</b>					

- a) Please provide a detailed breakdown including
  - b) How will these costs be met?
5. **Have you contacted the Laboratory Medicine Directorate for support in carrying out this POCT?**
6. **Quality Assurance**
  - a) How will Internal Quality Control (IQC) be performed
  - b) Which External Quality Assurance (EQA) scheme/s will you subscribe

- c) Who will provide the training and competency testing for users of the POCT scheme?
- d) Who will be undertaking audit of the service & how frequently

**7. How will this investigation be provided to patients if the POCT scheme is temporarily or permanently unavailable?**

**Appendix 3 SERVICE LEVEL AGREEMENT SPECIFICATION**

*This SLA requires a Quality Management system for the planned systematic approach to POCT. Details to be agreed between the user and the accredited laboratory.*

1. Specify each application, e.g. glucose testing in GP surgery: well person screening in Occupational Health Department, Diabetic clinic etc
2. Specify the site, e.g. Wards, Accident and Emergency, Outpatient clinics
3. Specify personnel involved
4. Specify the type of procedure
5. Specify the contact person for:  
IOC, EQA, QC record books, training, lead trainer, problem solving, maintenance, IT, contracts, Health and Safety.
6. Clearly specify the responsibilities of the accredited laboratory and users
7. Define the training procedure as indicated in the approved training documents.
8. Recording patient results  
There must be an agreed protocol to record all patient results, include date, time and operator so that a clear audit trail is established back to the patient.
9. Specify performance monitoring requirements
10. Specify cost for provision of accredited laboratory service.

**The agreement must be signed by both parties to form a binding contract.**

**Appendix 4 STAKEHOLDER INPUT**

This update was undertaken by the POCT Steering Committee, as part of the Pathology Modernisation Project. Representation on this Committee included:

Chemistry, Haematology and Microbiology Standing Specialist Advisory groups (SSAG).  
 All Wales Medicine Committee  
 General Practice  
 Local Health Boards - Torfaen / Blaenau Gwent/ Newport / Caerphilly/ Monmouth.  
 Informing Healthcare  
 Skills for Health  
 Wales External Quality Assessment Scheme  
 All Wales POCT Co-ordinators Group.

## References

1. Cochrane, A. Effectiveness and Efficiency - Random reflections on Health Services, 1972
2. Lord Carter of Coles Report of the Review of NHS Pathology Services in England, August 2006
3. Dame Ingrid Allen, The Future of Pathology Services in Northern Ireland, November 2006
4. Scottish Pathology Network website [www.pathologyscotland.org](http://www.pathologyscotland.org)
5. Wales Audit Office, Acute Hospital Portfolio, October 2006
6. Information provided by Dr Mark Hastings, National Public Health Service, September 2007
7. Information provided by Dr Hilary Fielder, Director of Screening Services, Velindre NHS Trust, September 2007
8. Information provided by Dr Ian McDowell, Clinical Director, Laboratory Medicine, Cardiff & Vale NHS Trust
9. Information provided by Mr Geoff Poole, Director, Welsh Blood Service, September 2007
10. Information provided by Dr Annette Thomas, Director, WEQAS, September 2007
11. Information provided by Dr Ian Frayling, Director All Wales Genetics Laboratory Service and Consultant in Genetic Pathology, Cardiff & Vale NHS Trust, September 2007
12. Information provided by Dr Paul Williams, Consultant Immunologist, Cardiff & Vale NHS Trust, September 2007
13. Information provided by Dr Keith Griffiths, Chairman North Wales Pathology Network and Consultant Biochemist, North West Wales NHS Trust, September 2007
14. Information provided by Dr Grant Robinson, Chairman South East Wales Pathology Forum and Consultant in Haematology, Gwent Healthcare NHS Trust, September 2007
15. Information provided by Mr Ray Rooke, Mid and West Wales Pathology Forum and Laboratory Manager, Swansea NHS Trust, September 2007
16. Welsh Assembly Government, Healthcare Standards – Making the Connections Designed for Life, May 2005
17. Department of Health, A Career Framework for Healthcare Scientists in the NHS, November 2005

## **Bibliography**

Beecham, J. Review of Local Service Delivery: Beyond Boundaries, 2006

Lord Carter of Coles. Report on the Review of NHS Pathology Services in England, 2005

Department of Health, Social Services and Public Safety for Northern Ireland. The Future of Pathology Services in Northern Ireland, 2006

Hall, R. Access and Excellence: Acute Health Services in Wales, 2000

Wanless, D. The Review of Health and Social Care in Wales, 2003

Welsh Assembly Government. A Question of Balance: A Review of the Capacity in the Health Service in Wales, 2002

Welsh Assembly Government. Getting Results: A Strategy for Diagnostic Services in Wales, 2004

Welsh Assembly Government. People, Places, Futures – The Wales Spatial Plan, 2004

Welsh Assembly Government. Healthcare Standards for Wales – Making the Connections Designed For Life, 2005

Welsh Assembly Government. Designed For Life: Creating world class health and social care for Wales in the 21<sup>st</sup> Century, 2006



