



Llywodraeth Cynulliad Cymru  
Welsh Assembly Government

# National Pathology Framework

---

August 2008



NHS  
WALES  
GIG  
CYMRU



# **National Pathology Framework**

**Editor:  
Jennifer A. Frost**

**Edition 1  
August 2008**

# Contents

	<b>Page</b>
<b>Executive Summary</b>	<b>4</b>
<b>1 Introduction</b>	<b>5</b>
<b>2 The Future Delivery of Pathology Services in Wales</b>	<b>5</b>
<b>3 Pathology Services covered by this Framework</b>	<b>6</b>
<b>4 Performance Management</b>	<b>6</b>
<b>5 Guidance and Standards which impact on Pathology</b>	<b>7</b>
5.1 Healthcare Standards for Wales	7
5.2 National Service Frameworks	18
5.2.1 NSF for Children, Young People and Maternity Services	18
5.2.2 Coronary Heart Disease NSF	19
5.2.3 Diabetes NSF	20
5.2.4 Mental Health NSF	21
5.2.5 Older Persons NSF	22
5.2.6 Renal NSF	22
5.2.7 Cancer Standards	23
5.2.8 Blood Transfusion	25
5.2.8.i Traceability	26
5.2.8.ii Anti-coagulation Risk	26
5.2.9 Quality Requirements for Adult Critical Care in Wales	26
5.2.10 Toxicology	27
5.2.11 Healthcare Acquired Infection and Antimicrobial Resistance	28

	<b>Page</b>	
<b>6</b>	<b>Quality and Standards within Pathology</b>	<b>29</b>
6.1	Accreditation	29
6.2	Benchmarking	30
6.3	Security in Pathology Departments	31
6.4	Equipment	32
6.5	Standards, Protocols and Methods	32
6.6	Research and Development	33
<b>7</b>	<b>Appropriate Use of Pathology</b>	<b>34</b>
7.1	Planning and Delivery	34
7.2	Point of Care Testing	34
7.3	Electronic Pathology Handbook	35
7.4	Non-medical Referrals for Diagnostics	35
 <b>Appendices</b>		
Appendix A	Informatics	37
Appendix B	Pathology in Relation to Cancer Services	39
 <b>Bibliography</b>		 42

## **Executive Summary**

The National Pathology Framework (NPF) for Wales provides an overview of the standards applicable to the planning and delivery of Pathology Services in Wales at local, regional or national levels as appropriate. It should be read in relation to the recommendations as set out in 'The Future Delivery of Pathology Services in Wales'.

Evidence of compliance with the standards herein will help organisations meet the requirements of the Healthcare Standards for Wales.

The National Pathology Framework:

- Identifies the aspects of broader Healthcare standards that impact on Pathology and clarifies the quality standards to which Pathology services are expected to perform.
- Provides the context within which changes in laboratory organisation may be evaluated and the framework against which bids for capital expenditure can be evaluated.
- Provides guidance for Trusts and Local Health Boards (LHBs) and a performance management tool for Healthcare Inspectorate Wales and Regional Offices against which they can measure Trust and LHB performance in relation to Pathology Services.

Given that Pathology is involved in 70% of patient encounters with the Healthcare system the role of Pathology in the development, implementation and clinical audit of pathways of care should not be underestimated.

## **1. Introduction**

The National Pathology Framework(NPF) is a central component of the Pathology Modernisation Project which was set up as part of the Diagnostics Programme in response to 'Getting Results: a strategy for Diagnostic Services' <sup>(1)</sup>. The Framework sets out the national context and priorities for Pathology, providing a reference point for future development and identifying key performance indicators in specific areas of work.

The Framework references a wide range of standards and guidance including the overarching strategy for Health and Social Care in Wales, Designed for Life <sup>(2)</sup>. Service providers will be expected to demonstrate compliance with the standards herein.

The requirements described in the Framework identify the aspects of broader healthcare standards that impact on Pathology and clarifies the quality standards to which Pathology services are expected to perform.

The Framework provides a mechanism for assessing current and future services including but not exclusively, those that require investment in either capital or revenue. Service developments that are in line with this framework should be encouraged. Priorities for service delivery in different healthcare environments are described, but it does not define the organisational structures within which services will be delivered. The Framework specifically identifies the Pathology contribution to broader policies and guidelines such as the Healthcare and Cancer Standards and National Service Frameworks (NSFs).

Clinical audit, i.e., the evaluation and measurement by health professionals of how far they are meeting standards that have been set for their service, has an explicit role in Pathology in relation to Clinical Pathology Accreditation. There is also a contribution to be made by Pathology to clinical audit across wider healthcare services and patient pathways of care.

The contents of this document have been endorsed by the Pathology Modernisation Forum <sup>(3)</sup>, the Laboratory Services Subcommittee and its Specialist Advisory Groups of the Welsh Scientific Advisory Committee. They are evidence based, measurable and aligned with broader service development.

## **2. The Future Delivery of Pathology Services in Wales <sup>(3)</sup>**

The Future Delivery of Pathology Services proposes a way forward for the delivery of Pathology Services which builds on the collaborations that are already underway in order to address the development of integrated Pathology Services able to deliver the range and quality of service required by a changing health service.

### **3. Pathology Services Covered by this Framework**

The term “Pathology” describes clinically led diagnostic, laboratory and post mortem services based in Trusts in Wales. This includes direct patient care, interpretation and clinical liaison. The services cover a range of tests necessary for the diagnosis and monitoring of a wide range of clinical conditions so that the appropriate treatment can be given. Pathology also informs essential public health and population based services. The scope of this project therefore includes the following pathology services provided by the NHS in Wales:

Blood Transfusion	Clinical Chemistry
Cytology	Genetics
Haematology	Histopathology
Immunology	Microbiology
Tissue Typing	Toxicology

and cross discipline services including molecular diagnostics and point of care testing.

### **4. Performance Management**

Since the 1980s Performance Indicators have been used to examine and compare performance across NHS organisations. These indicators have focused on areas such as length of stay, costs per episode of patient care and number of staff employed. While these type of indicators focus on efficiency others have been developed to examine clinical performance. Although few of these indicators relate directly to Pathology, delivery in many areas will require a quality service from Pathology.

Wales has introduced a new approach to performance management in the NHS. “The Performance Improvement Plan for NHS Wales” <sup>(4)</sup> takes a holistic view of the services provided by an NHS organisation to its patients and the public, providing a structured focus on an organisation’s strategic and annual performance objectives, ensuring that responsibility for performance improvement is shared throughout NHS organisations.

Regional Offices have the lead responsibility for monitoring the performance of the NHS in Wales through the Performance Improvement Framework.

## **5. Guidance and Standards which Impact on Pathology**

### **5.1 Healthcare Standards for Wales**

The Healthcare Standards for Wales <sup>(5)</sup> came into effect from June 2005 and constitute a common framework of healthcare standards to support the NHS and partner organisations in providing safe, high quality care for all patients in Wales. Along with the development of National Service Frameworks and National Institute for Clinical Excellence (NICE) guidance, they form part of a sustained drive to remove inequalities in health across the breadth of Wales.

The standards are grouped into four domains:

- The Patient Experience – Support the provision of healthcare in partnership with patients, service users, their carers and relatives and the public.
- Clinical Outcomes – Healthcare decisions and services based on appropriately assessed research evidence of an effective outcome for patients and service users.
- Healthcare Governance – Providers and commissioners of Healthcare will have in place systems that support both managerial and clinical leadership and accountability centred on patient and service user needs and preferences.
- Public Health – Healthcare organisations will collaborate with relevant organisations and local communities to ensure the design and delivery of programmes and services to promote, protect and improve health, and tackle health inequalities and help people to live healthy and independent lives.

Good practice in Pathology and compliance with guidelines will enable NHS organisations to demonstrate compliance with these Standards. In many instances the Healthcare Standards map to the requirements of Clinical Pathology Accreditation (CPA) as illustrated below.

Pathology related quality requirement	Evidence
<b>Healthcare Standard Description</b>	<b>Corresponding CPA Standards</b>
<p><b>First Domain: The Patient Experience</b></p> <p><b>Standards to support the provision of healthcare in partnership with patients, service users, their carers and relatives and the public will be based on plans and decisions that respect diverse needs and preferences. Services will be user friendly and patient centred. Healthcare will be provided in environments that promote patient and staff wellbeing and respect for individual patients' needs and preferences in that they will be designed for the effective and safe delivery of treatment and care and are well maintained and cleaned to optimise health outcomes for patients.</b></p>	
<p><b>Standard 1</b></p> <p>The views of patients, service users, their carers and relatives and the public are sought and taken into account in the design, planning, delivery, review and improvement of health care services and their integration with social care services.</p>	<p>A2, A4, A7.3c, A11, G1.2, G2.2, H1, H2, H6.4 (Note 3)</p>
<p><b>Standard 2</b></p> <p>The planning and delivery of healthcare:</p> <ul style="list-style-type: none"> <li>a) reflects the experiences, views and preferences of patients and service users</li> <li>b) reflects the health needs of the population served</li> <li>c) is based on nationally agreed evidence and best practice</li> <li>d) ensures equity of access to services</li> </ul>	<p>A2, A4, A7.3c, A11, G1.2, G2.2, H1, H2, H6.4 (Note 3)</p>
<p><b>Standard 3</b></p> <p>Patients with emergency health needs access appropriate care promptly and within national time-scales set annually by the Welsh Assembly Government.</p>	<p>W4.1c, E5.1d, G1.2, G3, G5, H2.1b</p>

<p><b>Standard 4</b></p> <p>Healthcare premises are well-designed and appropriate in order to:</p> <ul style="list-style-type: none"> <li>a) promote patient and staff well-being;</li> <li>b) respect different patients' needs, privacy and confidentiality;</li> <li>c) have regard for the safety of patients, users and staff; and</li> <li>d) provide a safe and secure environment which protects patients, staff, visitors and their property, and the physical assets of the organisation.</li> </ul>	<p>A1.3c, A3.1f, A10.1, C1, C2, C3, C4, C5, D2.2c, F3.1b</p>
<p><b>Standard 5</b></p> <p>Healthcare services are provided in environments, which:</p> <ul style="list-style-type: none"> <li>a) are well maintained and kept at acceptable national levels of cleanliness;</li> <li>b) minimise the risk of healthcare associated infections to patients, staff and visitors, achieving year on year reductions in incidence; and</li> <li>c) emphasise high standards of hygiene and reflect best practice initiatives.</li> </ul>	<p>A1.3c, A3.1f, A3.1g, A10, C1, C2, C3, C4, C5, D3.2E, D3.2F, E3.1, E4, E5.1e, F2.1n, F3.1b</p>
<p><b>Standard 6</b></p> <p>Healthcare organisations, in recognising different language, communication, physical and cultural needs:</p> <ul style="list-style-type: none"> <li>a) make information available and accessible to patients, service users, their carers and relatives and the public on their services;</li> <li>b) provide patients and service users with timely information on their condition; the care and treatment they will receive as well as after-care and support arrangements; and</li> <li>c) provide patients and service users with opportunities to discuss and agree options relating to their care.</li> </ul>	<p>A3, E1, G1, G2, G3, G4, G5, H1.2</p>

<p><b>Standard 7</b></p> <p>Patients and service users, including those with long-term conditions, are encouraged to contribute to their care plan and are provided with opportunities and resources to develop competence in self-care.</p>	<p>Not applicable to Pathology and CPA standards.</p>
<p><b>Standard 8</b></p> <p>Healthcare organisations ensure that:</p> <ul style="list-style-type: none"> <li>a) staff treat patients, services users, their relatives and carers with dignity and respect;</li> <li>b) staff themselves are treated with dignity and respect for their differences;</li> <li>c) informed consent is obtained appropriately for all contacts with patients and service users and for the use of confidential patient information; and</li> <li>d) patient information is treated confidentially, except where authorised by legislation to the contrary.</li> </ul>	<p>No particular CPA standard relates to Standard 8a, b &amp; c. CPA standard A1.3c correlates with standard 8d.</p>
<p><b>Standard 9</b></p> <p>Where food is provided there are systems in place to ensure that:</p> <ul style="list-style-type: none"> <li>a) patients and service users are provided with a choice of food which is prepared safely and provides a balanced diet; and</li> <li>b) patients and service users' individual nutritional, personal, cultural and clinical dietary requirements are met, including any necessary help with feeding and having access to food 24 hours a day.</li> </ul>	<p>Not applicable to Pathology and CPA standards</p>
<p><b>Standard 10</b></p> <p>Healthcare organisations ensure that people accessing healthcare are not unfairly discriminated against on the grounds of age, gender, disability, ethnicity, race, religion, or sexual orientation.</p>	<p>Not applicable to Pathology and CPA standards.</p>

<p><b>Second Domain: Clinical Outcomes</b></p> <p><b>Healthcare decisions and services will be based on what appropriately assessed research evidence has shown will provide an effective outcome for patients and service users taking account of their individual needs and preferences. Patients and service users will receive services as promptly as possible, and will not experience unreasonable delay at any stage of service delivery or of their care pathway.</b></p>	
<p><b>Standard 11</b></p> <p>Healthcare organisations ensure that:</p> <ul style="list-style-type: none"> <li>a) clinical care and treatments are delivered by healthcare professionals who make clinical decisions based on evidence based practice;</li> <li>b) clinical care and treatments are carried out under appropriate clinical supervision and leadership;</li> <li>c) clinicians continuously update skills and techniques relevant to their clinical work including peer reviews; and</li> <li>d) clinicians participate in regular audit and review of clinical services.</li> </ul>	<p>A1.3a, B1, B2, B3.1g, B7.1d, B9, F3.1B, G5.3, H5, H6.5</p>
<p><b>Standard 12</b></p> <p>Healthcare organisations ensure that patients and service users are provided with effective treatment and care that:</p> <ul style="list-style-type: none"> <li>a) conforms to the National Institute for Clinical Excellence (NICE) technology appraisals and interventional procedures, and the recommendations of the All Wales Medicines Strategy Group (AWMSG);</li> <li>b) is based on nationally agreed best practice and guidelines, as defined in National Service Frameworks, NICE clinical guidelines, national plans and agreed national guidance on service delivery;</li> <li>c) takes account of patients physical, social, cultural and psychological needs and preferences; and</li> <li>d) is integrated to provide a seamless service across all organisations that need to be involved, including social care organisations.</li> </ul>	<p>A3.1c, A10.2, C4.2, C5.1b, C5.4, D2.3, G5.4</p>

<p><b>Standard 13</b></p> <p>Healthcare organisations, which either lead or participate in research, have systems in place to ensure that the principles and requirements of the research governance framework are consistently applied.</p>	<p>A10, B1.2, B1.5c, B1.5k, B9.1a, B9.2e, B9.5, F2, F3.2, F3.4, G5.4</p>
<p><b>Third Domain: Healthcare Governance</b></p> <p><b>Providers and commissioners of healthcare will have in place systems that support both managerial and clinical leadership and accountability centred around patient and service user needs and preferences. Working practices will be in place to enable probity, quality assurance, quality improvement and patient safety to be the central components of all routines, processes and activities.</b></p>	
<p><b>Standard 14</b></p> <p>Healthcare organisations continuously and systematically review and improve all aspects of their activities that directly affect the safety and health of patients, service users, staff and the public. They will not only comply with legislation, but apply best practice in assessing and managing risk.</p>	<p>A2, A4.3a, A5, A11, H1, H2, H3, H4, H5.3, H6, H7</p>
<p><b>Standard 15</b></p> <p>Healthcare organisations, recognising different language and communication needs, ensure that patients, service users, relatives and carers;</p> <ul style="list-style-type: none"> <li>a) can provide feedback on their experiences and the quality of services;</li> <li>b) have their complaints looked at promptly and thoroughly in accordance with complaints procedures;</li> <li>c) are given information about complaints advocacy support provided by Community Health Councils in Wales; and</li> <li>d) receive assurance that organisations act on any concerns and make appropriate changes to ensure improvements in service delivery.</li> </ul>	<p>A2, A7.3c, A11.1b, A11.1h, C1.4, H1.1a, H1.2, H2, H7.1d</p>

<p><b>Standard 16</b></p> <p>Healthcare organisations have systems in place:</p> <ul style="list-style-type: none"> <li>a) to identify and learn from all patient safety incidents and other reportable incidents;</li> <li>b) to report incidents to the National Patient Safety Agency's (NPSA) National Reporting and Learning System and other bodies in line with existing guidance;</li> <li>c) to demonstrate improvements in practice based on shared local and national experience and information derived from the analysis of incidents; and</li> <li>d) to ensure that patient safety notices, alerts and other communications concerning safety are acted upon within required time-scales.</li> </ul>	<p>A11, B1i, C5.3d, C5.5, H1.1a, H2.1a</p>
<p><b>Standard 17</b></p> <p>Healthcare organisations comply with national child protection and vulnerable adult guidance within their own activities and in their dealings with other organisations.</p>	<p>Not applicable to Pathology and CPA standards.</p>
<p><b>Standard 18</b></p> <p>Healthcare organisations have planned and prepared, and where required practised, an organised response to incidents and emergency situations, which could affect the provision of normal services.</p>	<p>C5.3, D2.2d, G1.1e</p>

<p><b>Standard 19</b></p> <p>Healthcare organisations ensure that:</p> <ul style="list-style-type: none"> <li>a) all risks associated with the acquisition and use of medical devices are minimised;</li> <li>b) all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed;</li> <li>c) quality, safety and security issues of medicines are managed; and</li> <li>d) the prevention, segregation, handling, transport and disposal of waste are managed so as to minimise the risks to the health and safety of staff, patients, the public and the safety of the environment.</li> </ul>	<p>A9.1e, A10.1e, C4.1g, C5.1f, C5.3f, C5.3g, C5.3i, D1, D3, E3.1g.</p>
<p><b>Standard 20</b></p> <p>Healthcare organisations work to enhance patient care and to continuously improve staff satisfaction by providing best practice in human resources management.</p>	<p>A2, A3, A4, A5, A7.3c, A11, B1.5, B2, B3, C2, C3, C5, F3.1b, G5, H1.2, H6.5</p>
<p><b>Standard 21</b></p> <p>Healthcare organisations:</p> <ul style="list-style-type: none"> <li>a) undertake all necessary employment checks and ensure that all employed or contracted professionally qualified staff are registered with the relevant bodies:</li> <li>b) require that all employed professionals abide by their published codes of professional practice and conduct and</li> <li>c) address where appropriate under-representation of minority groups.</li> </ul>	<p>A1.3a, A1.3e, B1.5b, B1.5c, B2.1, B2.2, B3.1, B4, B5, B6.2, B9, F3.1b, G5.3</p>

<p><b>Standard 22</b></p> <p>Healthcare organisations ensure that staff:</p> <ul style="list-style-type: none"> <li>a) are appropriately recruited, trained and qualified for the work they undertake;</li> <li>b) participate in induction and mandatory training programmes; and</li> <li>c) participate in continuing professional and occupational development.</li> </ul>	<p>A1.3a, A1.3e, B1.5b, B1.5c, B2.1, B2.2, B3.1, B4, B5, B6.2, B9, F3.1b, G5.3</p>
<p><b>Standard 23</b></p> <p>Healthcare organisations ensure that staff are supported by:</p> <ul style="list-style-type: none"> <li>a) processes which permit them to raise, in confidence and without prejudicing their position, concerns over any aspect of service delivery treatment or management; and</li> <li>b) organisational and personal development programmes which recognise the contribution and value of staff.</li> </ul>	<p>A1.3b, A7.2, A7.3b, A7.3c, A11, B1.5g, B1.5i, B3.1e, B3.1f, B3.1g, B5.1c, B5.1f, B7.1d, B8.1, B9.1b, C5.3d, H1.1a, H1.1b, H1.1c, H1.1g, H6, H7</p>
<p><b>Standard 24</b></p> <p>Healthcare organisations work together with social care and other partners to meet the health needs of their population by:</p> <ul style="list-style-type: none"> <li>a) having an appropriately constituted workforce with appropriate skill mix across the community and</li> <li>b) ensuring the continuous improvement of services through better ways of working.</li> </ul>	<p>A1.3a, A2, A3, A4, A5, A7, A11, B1, B2, B3, B7, B9, C1, D1, D2, D3, E1, E4, E5, F1, F2, F3, G1.2, G5.4, H1</p>
<p><b>Standard 25</b></p> <p>Healthcare organisations use effective information systems and integrated information technology to support and enhance patient care, and in commissioning and planning services.</p>	<p>D2, G2, G3</p>

<p><b>Standard 26</b></p> <p>Healthcare organisations have effective records management processes in place to ensure that:</p> <ul style="list-style-type: none"> <li>a) from the moment a record is created until its ultimate disposal, the organisation maintains information so that it serves the purpose it was collected for and disposes of the information appropriately when no longer required; and</li> <li>b) patient confidentiality is maintained.</li> </ul>	<p>A1.3c, A4.3d, A8, A9, B6, C4.1a, D2, G2.5, G3.1f, G3.1g, G4.1d, H2.1a</p>
<p><b>Standard 27</b></p> <p>Governance arrangements representing best practice are in place which:</p> <ul style="list-style-type: none"> <li>a) apply the principles of sound clinical and corporate governance;</li> <li>b) ensure sound financial management and accountability in the use of resources;</li> <li>c) actively support all employees to promote openness, honesty, probity, accountability, and the economic, efficient and effective use of resources;</li> <li>d) include systematic risk assessment and risk management and</li> <li>e) are integrated across all health communities and clinical networks.</li> </ul>	<p>A1.3b, B1, C5.3e, D1, D2, D3, E1, E3, E4, E5, E6, F1, F2, F3, G1, G5, H1, H2, H3, H4, H5, H6, H7</p>
<p><b>Standard 28</b></p> <p>Healthcare organisations:</p> <ul style="list-style-type: none"> <li>a) ensure that the principles of clinical governance underpin the work of every team and every clinical service;</li> <li>b) have a cycle of continuous quality improvement, including clinical audit; and</li> <li>c) ensure effective clinical and managerial leadership and accountability.</li> </ul>	<p>C5.3e, D1, D2, D3, E1, E3, E4, E5, E6, F1, F2, F3, G1, G5, H1, H2, H3, H4, H5, H6, H7</p>

<p><b>Fourth Domain: Public Health</b></p> <p><b>Healthcare organisations will collaborate with relevant organisations and local communities to ensure the design and delivery of programmes and services to promote, protect and improve health, and which will tackle health inequalities and help people to live healthy and independent lives.</b></p>	
<p><b>Standard 29</b></p> <p>Healthcare organisations promote, protect and demonstrably improve the health of the community served and reduce health inequalities by:</p> <ul style="list-style-type: none"> <li>a) collaborating and working in partnership with local authorities and other agencies in the development, implementation and evaluation of health, social care and well being strategies; and</li> <li>b) ensuring that needs assessment and sound public health advice informs their policies and practices.</li> </ul>	<p>A2, A3, A7.3c, A11.1b, A11.1e, A11.1f, B1.4a, B1.5c, B1.5n, C5.4, D2.3, E1, E4.2, E6, G1.2, H1, H2, H6.4</p>
<p><b>Standard 30</b></p> <p>Healthcare organisations:</p> <ul style="list-style-type: none"> <li>a) have systematic and managed disease prevention and health promotion programmes, which include staff, which meet the requirements of the National Service Frameworks, national plans and health promotion and prevention priorities; and</li> <li>b) take fully into account current and emerging policies and knowledge on public health issues in the development of their public health programmes, health promotion and prevention services and the commissioning and provision of services.</li> </ul>	<p>Not applicable to Pathology and CPA standards.</p>

<p><b>Standard 31</b></p> <p>Healthcare organisations:</p> <ul style="list-style-type: none"> <li>a) have plans in place to mobilise resources to protect the public in the event of significant infectious disease outbreaks and other health emergencies;</li> <li>b) identify and act upon significant public health problems and health inequality issues, with Local Health Boards taking the leading role;</li> <li>c) implement effective programmes to improve health and reduce health inequalities; and protect their populations from identified current and new hazards to health; and</li> <li>d) encourage and support individuals to recognise their own responsibilities in maintaining their health and well being.</li> </ul>	<p>C5 particularly C5.1f, E5.1f</p>
<p><b>Standard 32</b></p> <p>Healthcare organisations achieve the Corporate Health Standard, the national quality mark for workplace health, moving to a higher level on reassessment.</p>	<p>No particular CPA standard relates to Standard 32.</p>

## 5.2 National Service Frameworks (NSFs)

There are six NSFs in Wales that provide a systematic approach on which to tackle the agenda of improving standards and quality across health care sectors. They set national standards and define service models for a service or care group, put in place programmes to support implementation and establish performance measures against which progress within agreed timescales can be measured. All have implications for Pathology workload.

### 5.2.1 NSF for Children, Young People and Maternity Services in Wales <sup>(6)</sup>

The overarching aim is that children, young people and their families receive services that meet their particular needs. They are treated with respect by service providers and are provided with information and support appropriate to their needs and ability that assists them in making decisions about the care that they receive.

While most pathology tests are not age specific, there are

requirements in the NSF which will require a specific response from Pathology Departments.

Pathology related quality requirement	Evidence
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests.	Laboratory handbook guidance for age and condition appropriate tests agreement with commissioners to ensure that appropriate care pathways and point of care testing support are in place.

### 5.2.2 Coronary Heart Disease NSF <sup>(7)</sup>

The National Service Framework for Coronary Heart Disease was published by the National Assembly for Wales in July 2001 and an update in 2007 with detailed quality requirements is under consideration. 'Improving Health in Wales' recognised that many services need to be developed across organisational boundaries in order to deliver co-ordinated care for patients. Three Regional Cardiac Networks and a National Co-ordinating Group were established in Wales in September 2002 to take forward the implementation of the NSF for Coronary Heart Disease.

The delivery of coronary care services in line with the Standards published in the NSF has significant workload implications for Pathology Laboratories as shown below.

- Evidence-based programmes to address tobacco use, diet and physical activity (CHD Standard 1) will increase test referrals from primary care via the Quality and Outcomes Framework (QOF) and also increase demand for Point of Care Testing support from Pathology Departments.
- Risk assessments and treatment plans for those at high risk of developing coronary heart disease (CHD Standard 2) and all those who have been diagnosed as having the disease, will include laboratory measurements (e.g. lipids, glucose) as stipulated in the primary care QOF.
- Familial hypercholesterolaemia (FH) is a specific disorder that will directly involve pathology staff and laboratories in

diagnosis, monitoring and patient management including direct patient care.

- Laboratory measurements are key to the diagnosis and management of acute coronary syndromes (particularly troponin testing) and are also a fundamental part of monitoring and management of heart failure. The proposed use of BNP (B type natriuretic peptide) measurements would be a significant development requiring specific pathology services and resources but which might be expected to improve patient outcomes with appropriate onward referral to cardiac or respiratory services.
- Monitoring of warfarin therapy in patients with atrial fibrillation using INR testing requires specific pathology (haematology) input which may also involve assistance with POCT testing in primary care.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
<p>To ensure that patient care is supported by timely and appropriate laboratory tests including:</p> <ul style="list-style-type: none"> <li>• Provision of laboratory measurements as stipulated in the primary care QOF.</li> <li>• Compliance with Cardiac Networks Co-ordinating Group recommendations on the use of BNP as diagnostic test in patients suspected of having heart failure.</li> <li>• Use of laboratory or POCT monitoring of warfarin therapy.</li> </ul>	<p>In combination with local coronary care specialists, all laboratories should confirm that they are complying with the relevant standards.</p> <p>In agreement with commissioners to ensure that appropriate care pathways and point of care support are in place.</p>

### 5.2.3 Diabetes NSF <sup>(8)</sup>

The Diabetes NSF was published in 2002 and supplemented in 2005 by specific guidance on the management of Type 1 diabetes in children and young people in Wales <sup>(9)</sup>.

The NSF focus on early detection and active management of diabetes will improve patient outcome but result in increased referrals to Clinical Chemistry laboratories as shown below:

- Efforts to enhance the early detection of diabetes will result in a significant increase in fasting glucose measurements and also in glucose tolerance tests. The earlier detection of diabetes will increase the known prevalence of diabetes and therefore result in greater workload for monitoring diabetes care and complications.
- Tighter targets and recommendations for more frequent monitoring of glycaemic control and lipids (as well as liver function tests) will have an impact on laboratory workload.
- Screening for renal disease with provision of estimated Glomerular Filtration Rate will lead to greater need for monitoring for renal bone disease (Parathyroid Hormone), and renal anaemia (full blood counts, haematinics). There is likely to be a greater call for renal biopsies and renal imaging (especially ultrasound).
- The screening for microalbuminuria, apart from increasing urine albumin/creatinine measurements, implies Point of Care dipstick testing for blood in urine (unless this is performed in the laboratory), with appropriate support required. This will lead to more urine specimen being submitted for exclusion of infection. Greater use of Ace inhibitors will require support with urea and electrolyte measurement.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests.	In agreement with commissioners to ensure that appropriate care pathways are in place.

#### 5.2.4 Mental Health NSF <sup>(10)</sup>

Pathology tests are increasingly used in both diagnosis and long term patient management. Regional toxicology

laboratories are increasingly called on for 24/7 provision of drug testing and monitoring for diagnosis and rehabilitation.

Pathology related quality requirement	Evidence
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care Tests.	Laboratory handbook guidance for tests at local or regional laboratories. Agreement with commissioners to ensure that appropriate care pathways and point of care testing support are in place.

### 5.2.5 Older People’s NSF <sup>(11)</sup>

Long term chronic disease management involves repeated pathology input via a combination of laboratory and Point of Care tests.

Pathology related quality requirement	Evidence
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests.	Agreement with commissioners to ensure that appropriate care pathways and point of care testing support are in place.

### 5.2.6 Renal NSF <sup>(12)</sup>

The Renal NSF focuses on prevention rather than treatment, early diagnosis and better case management. This impacts on Pathology by requiring appropriate and timely monitoring of renal function with possible increased use of POCT and participation in renal MDT’s and includes:

- Pathology Laboratory Information Management Systems will need to allow automatic transfer of relevant haematology, biochemistry and microbiology tests results

to the treating renal unit, which may be distant from the location of both patient and laboratory.

- The standards for children with renal disease require creatinine to be measured in relation to specified age related normal values.
- Intervention will focus on those at high risk of developing kidney disease including provision of genetic screening for first degree relatives or renal patients.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
<p>To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests including:</p> <ul style="list-style-type: none"> <li>• IT that enables automatic transfer of laboratory results to appropriate clinical team</li> <li>• Appropriate creatinine measurements for adults and children</li> <li>• Genetic screening for first degree relatives of renal patients.</li> <li>• Monitoring for post operative infection.</li> <li>• Monitoring for acute rejection in the graft- A biopsy of the transplant, analysed by a histopathologist fully trained in renal transplant pathology, is required to confirm the diagnosis.</li> <li>• Treatment of rejection should be compliant with NICE guidelines</li> </ul>	<ul style="list-style-type: none"> <li>• Reference LIMS development</li> <li>• Demonstrate development in hand via LIMS procurement</li> <li>• Demonstrate compliance with standard methods for adults (and children when standard has been agreed)</li> <li>• In agreement with commissioners to ensure that appropriate care pathways are in place</li> </ul>

### 5.2.7 The Cancer Standards <sup>(13)</sup>

The Cancer standards published in 2005 are a series of topics that address the key organisational requirements for effective delivery of care and follow the main stages in the

patient journey. They describe the context to the specific standards and the appropriate monitoring criteria.

Pathology Services contribute to all stages in the provision of an integrated Cancer Service from screening of asymptomatic individuals, through diagnosis, typing and staging of precancerous lesions and established cancers to tailoring optimal therapy for individual patients.

They provide laboratory support for surgery, radiotherapy, chemotherapy and the newer approaches to therapy; the collection of accurate data for monitoring and managing the effectiveness of the service and Research and Development, including clinical trials. The long-term survival of cancer patients as a result of better diagnosis and new treatment modalities requires new inputs from pathology, e.g., routine investigations for tumour markers, and continued surveillance.

Specific standards which relate to pathology include:

**Standard 4.1** – All clinicians treating cancer should be part of the multidisciplinary team (MDT), and should have designated time to attend the MDT meeting.

**Standard 4.2** – The MDT should include a pathologist with designated time to prepare for and attend the MDT.

**Standard 5.7** – Results of diagnostic tests should be communicated to patients within 1 week of the last diagnostic procedure.

**Standard 8.1** – All pathology laboratories should participate in Technical External Quality Assessment (EQA), and Clinical Pathology Accreditation (CPA).

**Standard 8.2** – Reports on resection specimens should comply with all items of the pathology component of the all Wales Cancer Data Set.

**Standard 8.3** – Pathologists reporting cancer specimens should participate in an appropriate Histological EQA Scheme.

**Standard 8.4** – Each MDT has a mechanism for access to specialist opinion for histopathological diagnosis and classification of difficult lesions where appropriate.

Pathology related quality requirement	Evidence
<p>To ensure that patient care is supported by timely and appropriate laboratory tests.</p> <p>Cancer standards 4.1, 4.2 Multidisciplinary teams (MDT).</p> <p>5.7 Diagnostic test results to be communicated to patient within 1 week of diagnostic procedure.</p> <p>8.1, 8.2, 8.3, 8.4 Quality requirements Laboratories shall be CPA accredited, comply with All Wales Cancer data set requirements and participate in EQA schemes.</p> <p>Access to specialist opinion Each MDT has a mechanism for access to specialist histopathology expertise.</p>	<ul style="list-style-type: none"> <li>• Agreed Standard Operating Procedures with Cancer Networks.</li> <li>• Designated time identified histopathologists</li> <li>• Consultant job plans</li> <li>• Evidence of turnaround times.</li> <li>• Evidence of participation</li> <li>• Agreed reporting and second opinion procedures.</li> </ul>

### 5.2.8 Blood Transfusion Services and Hospital Transfusion Laboratories

The need to provide timely and safe transfusion support at the point of delivery of patient care continues to be a major factor in determining the organisation of haematology services. National and International initiatives designed to improve the quality of Blood Transfusion have major consequences for hospital transfusion laboratories and the Trusts they serve. These include the Serious Hazards of Transfusion (SHOT) <sup>(14)</sup> scheme, the WHC 2002/137 – Better Blood Transfusion – Appropriate use (BBT2) <sup>(15)</sup> and, from the 8<sup>th</sup> November 2005, the legal requirement on hospital transfusion laboratories to comply with the Blood Safety and Quality Regulations 2005 SI 50 (BSQR) <sup>(16)</sup>. These requirements mean that laboratories must have an

appropriate quality system in place. Haemovigilence reporting is now also a mandatory requirement.

### 5.2.8.i Traceability

It is now a legal requirement for hospital transfusion laboratories to maintain, for not less than 30 years, data to ensure full traceability of all blood and blood components. This applies from receipt by the hospital blood bank to transfusion of the individual receiving the blood component or the final fate if not transfused.

### 5.2.8. ii Anti-coagulation Risk

The National Patient Safety Agency (NPSA) is recommending that each NHS and independent organisation adopt nine recommendations to manage the risk associated with anticoagulants, thereby reducing the chance of patients being harmed in the future. These recommendations should be adopted by March 2008 <sup>(17)</sup>.

Pathology related quality requirement	Evidence
To ensure integrity of the blood supply, providing timely and safe transfusion support at the point of delivery of patient care and full traceability of all blood and blood components.	<ul style="list-style-type: none"> <li>• Traceability records</li> <li>• Evidence of SABRE/SHOT reporting</li> <li>• Self-inspection records</li> </ul>
To manage risk associated with anticoagulation therapy.	<ul style="list-style-type: none"> <li>• Staff competences</li> <li>• Audit of anticoagulant services and associated clinical procedures/policies.</li> </ul>

### 5.2.9 Quality Requirements for Adult Critical Care in Wales <sup>(18)</sup>

It is proposed that there be five recognised levels of adult general critical care in Wales. Patients' condition can be defined as increasing in severity from level 0, appropriately cared for in ordinary hospital wards such as are available in all acute hospitals and all general departments of surgery

and medicine, to levels 3 and 3T (Tertiary) where organ support and monitoring must be available for most body systems.

All hospital with an A&E department must be supported by full services and hospitals accepting major trauma or emergency surgical patients must be able to treat Level 3 patients. Level 3T units should act as tertiary referral units for patients with multiple organ failure and must have a significant teaching and training role.

The quality requirements for levels 1 and 2 include 24 hour access to blood transfusion services, biochemistry, haematology and microbiology laboratory services every day. Access to blood gas analysis must be 'rapid' at level 2 and 'immediate' at levels 3 and 3T together with 24 hour immediate access to blood transfusion services, biochemistry, haematology, microbiology and toxicology.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests.	Agreement with commissioners to ensure that appropriate care pathways and point of care testing support are in place.

### **5.2.10 Toxicology**

The principal providers of toxicology services are the three Regional Toxicology laboratories at Llandough, Bridgend and Bangor. Service provision for the management of patients who are suspected of having taken an overdose or therapeutic drug monitoring of certain compounds will require services to be available around the clock. This will challenge both staffing and equipment availability.

Pathology related quality requirement	Evidence
To ensure that diagnosis and long term patient care is supported by timely and appropriate laboratory based or Point of Care tests.	Laboratory handbook guidance for referral to local or regional services.  Agreement with commissioners to ensure that appropriate care pathways and point of care testing support are in place.

### 5.2.11 Healthcare Acquired Infection and Antimicrobial Resistance <sup>(19)</sup>

All NHS Trusts in Wales are required to participate in Surveillance programmes as agreed with the Welsh Healthcare Acquired Infection Programme. Current programmes include:

- Blood stream infections
- Surgical site infections
- Clostridium difficile surveillance
- Surveillance of hospital outbreaks
- Infection reduction programme

Pathology related quality requirement	Evidence
Participation in Surveillance programmes as agreed with WHAIP	Infection reports

## 6. Quality and Standards within Pathology

### 6.1 Accreditation

The Welsh Assembly Government, along with the Department of Health (England) and the Scottish Executive, requires diagnostic services to enrol in accreditation schemes where they exist <sup>(20)</sup>. For Pathology this means that all laboratories are required to be enrolled with Clinical Pathology Accreditation (CPA) <sup>(21)</sup>. Enrolled status is defined by CPA as having conducted a self-assessment against the CPA standards and submitted a completed application form and quality manual.

CPA accreditation covers the organisation and quality management of the laboratory and the resources required to ensure that pre-examination, examination and post examination activities of the laboratory meet the needs and requirement of the users. The CPA standards include a requirement for evidence of professional competence as appropriate for different staff groups. The Royal College of Pathologists suggests that professional performance can be defined as the quality of clinical practice in the workplace and can best be maintained through participation in CPD, clinical audit and audit of own performance, annual appraisal or individual performance review processes, receiving and acting on feedback and peer review processes, practicing to meet external clinical targets and ensuring the best possible clinical outcomes.

Compliance with the CPA standards signifies an ability of a laboratory, by appropriate certification or accreditation procedures to be found compliant with relevant ISO standards <sup>(22, 23, 24, 25, 26, 27)</sup>

At present providers are independently involved in pursuing CPA accreditation with an unnecessary level of duplication of effort. Increased use of standard protocols and sharing of Standard Operating Procedure formats would minimise 'wheel reinvention' and assist in harmonisation of staff training and development.

Pathology related quality requirement	Evidence
<ul style="list-style-type: none"> <li>• All Pathology laboratories to be CPA accredited.</li> <li>• Participation in relevant EQA schemes.</li> <li>• Participation in clinical and individual audit and performance review</li> <li>• Relevant professional staff registered with regulatory body and participating in CPD schemes.</li> </ul>	<ul style="list-style-type: none"> <li>• Evidence of enrolment with CPA.</li> <li>• If not yet accredited – plans in place to address predicted non-compliances.</li> <li>• All Pathology Departments must have an identified Quality lead with a protected time allocation.</li> <li>• EQA performance records.</li> <li>• Audit and performance review records</li> <li>• Staff records demonstrating registration status and CPD where appropriate.</li> </ul>

## 6.2 Benchmarking

Benchmarking provides a baseline assessment of workload, facilities and equipment and accreditation status against which organisational change can be evaluated.

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

- The National Pathology Alliance Benchmarking Service <sup>(28)</sup> run from Keele University covers all Pathology disciplines except genetics and has been developed in association with representation from a wide range of participating laboratories. The scheme allows participants to compare their performance with other laboratories both regionally and nationally – participating Trusts are 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 Hospital Portfolio – Pathology Module <sup>(29)</sup> 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.

A Benchmarking protocol is currently under development by the Pathology Modernisation project in collaboration with the Keele scheme and Wales Audit Office to provide a standard mechanism for comparing performance in key areas across the whole of Wales covering quantitative (efficiency) and qualitative (quality) components. Routine data collection and annual reporting can then be used to drive and audit changes in practice. Key performance indicators will take a common approach within each sub-discipline, allowing comparisons to be made between providers within Wales and beyond. Staff numbers and costs are also included together with some workforce planning data in relation to career pathways and consultant job plans.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
Participation in scheme(s) as agreed with Pathology Modernisation Project.	<ul style="list-style-type: none"> <li>• Completion of relevant annual data collections.</li> </ul>

### 6.3 Security in Pathology Departments

The nature of pathology and microbiology in particular, requires that departments take into consideration statutory requirements and recommendations made under the Anti Terrorism Crime and Security Act 2001 <sup>(30)</sup>, and other relevant Health and Safety legislation <sup>(31, 32)</sup>.

Pathology Departments are required to ensure the safety and security of all staff, equipment and controlled substances including micro-organisms by providing a robust controlled access system and personnel policies and procedures. In general, access should be allowed on a needs-only basis. There should be no automatic right of access for Trust staff who do not work in Pathology including staff that are required to visit Pathology on a daily basis. Where access to a person from an outside agency is permitted, the agency must confirm that the individual has had a standard CRB check with no relevant findings against his/her name.

Pathology related quality requirement	Evidence
Pathology Departments are required to ensure the safety and security of all staff, equipment and controlled substances including micro-organisms by providing a robust controlled access system and personnel policies and procedures.	<ul style="list-style-type: none"> <li>• Appropriate policies and training records.</li> <li>• Database of authorised entrants to Category 3 facilities.</li> </ul>

#### 6.4 Equipment

A greater degree of standardisation of equipment procurement processes across the pathology disciplines and providers will improve consistency and will help reduce procurement costs. This would also reduce training requirements for staff moving between providers. A National Investment Framework is being developed as part of the Pathology Modernisation Project which will help to support the above.

#### 6.5 Standard Protocols and Methods

In order to deliver consistent, quality services across Wales it is vital that commissioners and providers are able to refer to common agreed standards and protocols, set by professionals and evidence based. Building on work already undertaken and in a rolling programme of standards and protocol development, a *Scientific and Technical Standards* database based on evaluated methods will be developed.

Standard requirements for specimen collection, storage and transport will assist referring clinicians and will be embedded in the Laboratory Handbook component of the electronic test requesting and results reporting system (TR&RR) (See Appendix A).

Coding issues and agreement of common test profiles will be required in the development of the All Wales Laboratory Information Management System (LIMS) (See Appendix A).

<b>Pathology related quality requirement</b>	<b>Evidence</b>
As for CPA: <ul style="list-style-type: none"> <li>• Standards for test requests and specimen collection.</li> <li>• Standards Operating Procedures.</li> </ul>	CPA accreditation. If not yet accredited: <ul style="list-style-type: none"> <li>• Laboratory handbook.</li> <li>• SOPs and document control system.</li> </ul>

## **6.6 Research and Development**

Research and development underpin the ability of pathology services in Wales to provide high quality, evidence based services. The pool of resources in Wales is relatively small and R&D needs to be focused and co-ordinated, providing a sound evidence base for practice and a clear direction of the future, particularly with regard to molecular technology.

The links between academic and service research, development and teaching need to be recognised and their relationship needs to be clarified in a way that provides opportunities to professionals in all grades and locations and a means of transferring R&D outputs into routine service delivery.

R&D forms a significant part of the education and training of Healthcare scientists in Pathology and participation in R&D should be a part of their continuing professional development.

<b>Pathology related quality requirement</b>	<b>Evidence</b>
Participation in R&D both within the department and the Trust.	<ul style="list-style-type: none"> <li>• Research grants and publications</li> <li>• Staff training records</li> </ul>

## **7. Appropriate Use of Pathology**

### **7.1 Planning**

Currently, direct Commissioning of Pathology Services is limited to specialised services. Most Pathology services are funded as part of a Trust's annual financial allocation. There is however often a dislocation between demand and resource provision.

Future Pathology service models should take account of current and proposed changes in the structure of the NHS in Wales and the contribution of Pathology to Elective, Emergency and Unscheduled Care and Long Term Conditions Pathways.

### **7.2 Point of Care Testing (POCT)**

Point of Care Testing refers to analytical tests undertaken by non-laboratory staff outside a recognised diagnostic laboratory. These range from simple, disposable hand-held strip readers to desktop analysers. The appropriate use of POCT as an alternative to laboratory testing should be considered as a clinical governance issue and therefore be subject to examination of clinical effectiveness.

The use of POCT in either primary or secondary care locations and involving use of diagnostic equipment and procedures outside the diagnostic laboratory should be supported by an accredited pathology laboratory.

Point of Care Testing Guidance <sup>(33, 34)</sup> has been produced setting out standards for the appropriate delivery of POCT across Wales. This comprehensive All Wales Point of Care Testing Strategy includes a procurement strategy for POCT devices and consumables, guidance on training and competency for POCT device use and education and training courses for POCT trainers in line with National Occupational Standards. Laboratory arrangements are being put in place to support the POCT guidelines in anticipation of increased demand for near patient tests.

Pathology related quality requirement	Evidence
<ul style="list-style-type: none"> <li>• Each NHS organisation must have a Policy detailing the management of POC services within the organisation</li> <li>• Each department providing POCT support must have an identified POCT co-ordinator with protected time for POCT activity and participation in the Wales POCT Forum.</li> </ul>	<ul style="list-style-type: none"> <li>• All Pathology departments must have a Point of Care Testing Committee with the authority to regulate all POCT within the Trust</li> <li>• All Pathology departments must have a designated POCT Coordinator with a protected time allocation</li> <li>• LHBs: evidence that POCT carried out in services that they commission complies with the above requirements and recommendations in the POCT guidelines.</li> </ul>

### 7.3 **Electronic Laboratory Handbook and Test Requests and Results Reporting** <sup>(35)</sup>

An All-Wales electronic test requests and results reporting system is currently being piloted in a number of service areas. It is expected that this will be available for roll out across Wales during 2008. This will improve efficiency in the provision of healthcare in Wales due to decreased transcription of patient information and reduction in duplicate test ordering by clinicians unaware of requests from other care providers. The patient request and results information gathered will be a primary source for the Individual Health Record and other clinical systems as well as allowing organisations to monitor the usage of diagnostic services that they request and/or provide within and across the current organisational boundaries.

### 7.4 **Non-Medical Referrals for Diagnostics**

The modernisation of health and social care in Wales has led to changes in clinical practice and the development of extended roles for many clinical professions. New models of service delivery in some areas include the need for clinical professionals other than registered medical or dental practitioners to be able to request diagnostic investigations. Good Practice Guidance <sup>(36)</sup> has been produced and endorsed by the Joint Professional Forum of

Statutory Welsh Advisory Committees and is intended to facilitate local policies and procedures for non-medical / dental referral for diagnostic investigation.

## **Appendix A**

### **Informatics**

Informatics is at the heart of modern pathology and pathology data are a major component of the patient record. The Pathology Modernisation Project is working in collaboration with Informing Healthcare<sup>(37)</sup> to address the Informatics issues in Pathology in the context of information developments across the Health Service as a whole. In the short term three major approaches are under consideration.

#### **1. A New Laboratory Information Management System (LIMS) for Wales**

All but two Trusts in Wales have an iSoft Telepath System that is overdue for replacement. The Genetics Service does not currently have a system which compromises their ability to communicate across Wales and the UK. The delivery of the Pathology Modernisation agenda is dependant on the availability of a LIMS which will enable, along with associated business changes, pathology services (including the Genetics Service) to offer seamless patient care across Trust boundaries. The procurement and implementation of an All Wales LIMS is being jointly project managed by the Pathology Modernisation project and Informing Healthcare. The technical solution will need to support all levels of organisation and clinical structures on a local, regional or national basis.

#### **2. The Clinical Portal in Relation to Pathology**

Informing Healthcare is developing a Clinical "Portal" which will be a secure private web page giving healthcare staff a common way of accessing the various electronic systems that are used to support patient care. Parallel developments in an Individual Health Record and system architecture are establishing service-oriented standards compatible with the National Architecture approach.

Test requests and Result Reporting (TR&RR) and an Electronic Pathology User Handbook are being incorporated in the development of the Clinical Portal. This will give clear advice about the choice of laboratory test with additional information about clinical indications and result interpretation. Detailed requirements including specimen collection and delivery and diagnostic accuracy are included to ensure that the most appropriate tests are requested with minimal wastage of resources.

### **3. New Informatics Opportunities in Histopathology**

#### **3.1 On-screen reporting with linkage to CanISC data collection**

Data contained in histopathology reports are complex with more narrative content than most other pathology reporting. There is a need for efficient data transfer into other data systems, particularly CaNISC. An All-Wales solution, with linkage to existing the LIMS and consistent with the above projects is being developed in collaboration with IHC.

#### **3.2 Digital images**

Digital imaging systems in histopathology are not yet suitable for routine diagnostic use but invaluable for Multi-Disciplinary Team meetings, EQA and teaching. Systems are currently being installed in Cancer Bank locations and these can be used to develop opportunities for diagnostic use.

## Appendix B

### Pathology in Relation to Cancer Services

Pathology Services contribute to all stages in the provision of an integrated Cancer Service from screening of asymptomatic individuals, through diagnosis, typing and staging of precancerous lesions and established cancers to tailoring optimal therapy for individual patients. They provide laboratory support for surgery, radiotherapy, chemotherapy and the newer approaches to treatment; the collection of accurate data for monitoring and managing the effectiveness of the service and Research and Development, including clinical trials.

The Calman-Hine <sup>(38)</sup> and Cameron <sup>(39)</sup> Recommendations for Cancer Services required development of both core and specialist pathology services with consequent resource implications for manpower, equipment and technology. In particular, consultant staffing shortages in Histopathology and Haematology have not yet been fully addressed.

The development of networked national specialist laboratories for sophisticated diagnostic techniques in immunocytochemistry, cytogenetics, molecular diagnostics, and tumour markers suggested that these could usefully be recognised and resourced as All-Wales Reference Laboratories.

#### 1. Crosscutting issues:

##### 1.1 Communication and Information Technology

Redevelopment of Laboratory Information Management and Telepathology Systems must take into account the need for All-Wales communications, in particular, second opinion consultation and external quality assurance in Haematology and Histopathology. (See Appendix A).

##### 1.2 Provision of Specialist Cancer Laboratory Services

Certain specialist cancer pathology services require input from more than one pathology discipline or use common technology. For example, immunohistochemical, immunophenotypic, cytogenetic and molecular techniques in Haematology and Histopathology in the management of haematological malignancies.

1.3 The use of diagnostic molecular biological technologies in identifying *somatic* genetic abnormalities that contribute to the diagnosis of specific tumours is increasing in all four sub-specialties. It is appropriate that they are undertaken in a small number of appropriately accredited laboratories that are recognised for their expertise, co-ordinated to ensure an integrated All-Wales high quality service, and which form the critical mass necessary for

research and development. Consideration should be given to developing a single specialist pathology locus for these purposes.

## **2. Discipline Specific Issues – Clinical Chemistry and Immunology**

- 2.1** Core Biochemistry Services will need to support the monitoring requirements of patients receiving sophisticated cancer therapy, notably chemotherapy.
- 2.2** The establishment of an All-Wales Reference Biochemical Laboratory with a designated clinical biochemistry “Cancer Expert” could provide interpretative expertise, promote clinical education and support Research and Development of novel tumour immunotherapies and clinical trials throughout the Principality. The reference laboratory would have specialist input into tumour marker assays specialised immunological investigations and advice on management.

## **3. Discipline Specific Issues - Haematology**

- 3.1** Core Haematology Services will face increasing demands from the use of sophisticated therapies for a range of malignancies, especially in relation to radiotherapy and chemotherapy. There is an opportunity to develop All-Wales protocols for such support for cancer treatments.

Close collaboration between expert medically qualified consultants in Haematology and Histopathology is essential for the diagnosis of Haematological Malignancy as is access to sophisticated immunological and molecular technologies. This is now well developed within the All Wales Lymphoma Panel, although some funding issues remain.

## **4. Discipline Specific Issues – Histopathology/Cytopathology**

(excluding screening diagnostic services)

- 4.1** Involvement in site specific multidisciplinary teams is essential for histopathologists who must have the appropriate dedicated time for participation.
- 4.2** Access to a second opinion consultation service for difficult biopsies and unusual tumours is essential for all diagnostic histopathologists. The use of Telepathology has been developed by the All Wales Lymphoma Panel and demonstrated in Mid and West Wales; it will and will need to be extended. Specialised investigations and molecular diagnostics should be concentrated at a single site where there is the critical mass of specialist expertise.

## **5. Discipline Specific Issues - Microbiology**

Increased demands for core microbiology services will result from the use of sophisticated therapies for a range of malignancies, especially in relation to radiotherapy and chemotherapy. These will include pre-treatment screening, diagnosis and advice on the management of opportunistic and multi-resistant pathogen infections in immunocompromised patients, formulation of antibiotic policies and treatment strategies for the control of such infections in secondary care and in the community.

## **6. Discipline Specific Issues - Genetics**

Increasing understanding of the genetics of cancer and developments in Pharmacogenetics result in increasing involvement of the Genetics Service in both diagnosis and treatment, an example being NICE guidance on hereditary breast cancer.

## Bibliography

- | Ref | Documents  |
|-----|--|
| 1   | Welsh Assembly Government. Getting Results: A Strategy for Diagnostic Services in Wales, 2004  |
| 2   | Welsh Assembly Government. Designed For Life: Creating world class health and social care for Wales in the 21 <sup>st</sup> Century, 2006  |
| 3   | Diagnostic Services Programme, The Future Delivery of Pathology Services in Wales, 2007  |
| 4   | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , The Performance Improvement Plan for Wales, <i>date?</i>  |
| 5   | Welsh Assembly Government. Healthcare Standards for Wales – Making the Connections Designed For Life, 2005   |
| 6   | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , National Service Framework for Children, Young People and Maternity Services, 2005  |
| 7   | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , Coronary Heart Disease National Service Framework, 2001   |
| 8   | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , Diabetes National Service Framework, 2002   |
| 9   | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , Designed for the Management of Type 1 Diabetes in Children and Young People in Wales: Consensus Guidelines – Standards 5 and 6 Diabetes NSF |
| 10  | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , Revised National Service Framework for Adult Mental Health Services, 2005   |
| 11  | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , National Service Framework for Older People in Wales, 2006  |
| 12  | NHS Wales website <a href="http://www.wales.nhs.uk">www.wales.nhs.uk</a> , Designed to Tackle Renal Disease in Wales: A National Service Framework, 2007   |
| 13  | Welsh Assembly Government, National Standards for Cancer Services, 2005  |

- 14 Serious Hazards of Transfusion website, [www.shotuk.org](http://www.shotuk.org)
- 15 Welsh Assembly Government, Better Blood Transfusion, 2002
- 16 Department of Health, Statutory Instrument 2005 Number 50, Blood Safety and Quality Regulations, 2005
- 17 National Patient Safety Agency, Patient Safety Alert 18, 2007
- 18 Welsh Assembly Government, Designed for Life: Quality Requirements for Adult Critical Care in Wales, 2006
- 19 NPHS website [www.nphs.wales.nhs.uk](http://www.nphs.wales.nhs.uk)
- 20 Welsh Assembly Government, WHC (2004) 061 – Diagnostic Services Strategy
- 21 Clinical Pathology Accreditation (UK) Ltd website [www.cpa-uk.co.uk](http://www.cpa-uk.co.uk)
- 22 International Standards Organisation, ISO 15189:2007 Medical Laboratories – Particular requirements for quality and competence International Standards Organisation
- 23 International Standards Organisation, ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- 24 International Standards Organisation, ISO 9001:2000 Quality Management Systems - Requirements
- 25 International Standards Organisation, ISO 9000:2005 Quality Management Systems – Fundamentals and Vocabulary
- 26 International Standards Organisation, ISO 22870:2006 Point-of-care-testing (POCT) – Requirements for Quality and Competence
- 27 European Communities Confederation of Clinical Chemistry: Essential Criteria for Quality Systems of Medical Laboratories, European Journal of Clinical Chemistry and Clinical Biochemistry 1997;35:121-132
- 28 National Pathology Alliance Benchmarking Service website <http://www.keele.ac.uk/depts/hm/cml/benchmarkinghome.htm>
- 29 Healthcare Commission, Getting Results: Pathology Services

- in Acute and Specialist Trusts – Acute Hospital Portfolio Review, 2006
- 30 Home Office, Anti Terrorism Crime and Security Act 2001, part 7
  - 31 Home Office, Personnel Security Measures for Laboratories, 2005
  - 32 London First and National Counter Terrorism Security Office, Secure in the Knowledge, 2005
  - 33 Welsh Assembly Government, Point of Care Testing: The Use of Diagnostic Equipment and Procedures Outside the Diagnostic Laboratory, 2004
  - 34 Diagnostic Services Programme, Point of Care Testing Governance Policy – Why, When and How? A User Guide, 2008
  - 35 Informing Healthcare website [www.wales.nhs.uk/ihc](http://www.wales.nhs.uk/ihc)
  - 36 Welsh Assembly Government, Chief medical Officer letter, Statutory Health Professional Advisory Committees Good Practice Guidance, Non Medical / Dental Referral for Diagnostic Investigation, 2007
  - 37 Informing Healthcare website [www.wales.nhs.uk/ihc](http://www.wales.nhs.uk/ihc)
  - 38 Department of Health, A Policy Framework for Commissioning Cancer Services: A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales (Calman Hine Report), 1995
  - 39 National Institute for Clinical Excellence, Service Guidance for Improving Outcomes for People with Sarcoma (Cameron Report), 2003



