

Health Service Executive



Implementing a new system of service delivery for Laboratory Medicine Services



TEAMWORK
MANAGEMENT SERVICES

Report by Teamwork Management Services Limited



Draft Report for review at the HSE NHO Management Meeting on 30/04/07
Confidential until submitted to Health Service Executive Board

Health Service Executive

Implementing a new system of service delivery for Laboratory Medicine Services

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The key messages

This report proposes a new system of service delivery for laboratory medicine services in Ireland. It is patient centred, builds upon recognised international practice, raises the quality of patient care and safety and complements Ireland's health service 2010 transformation programme. The report:

- Expands and provides dedicated highly automated processing capacity in up to 3 new laboratories for patients' tests from the GP and the community;
- Provides much better patient access to local centres for taking blood samples and collecting specimens;
- Expands the use of local and acute hospital point-of-care testing, convenient for patients;
- Supports regional hospitals and tertiary hospitals with dedicated 'hot' laboratories;
- Develops the expert advice of Laboratory Medicine staff to support and manage patients with complex conditions;
- Uses 'leading edge' logistics and information technology to improve end-to-end quality and efficiency of processes;
- Integrates professional development, innovation, research and development into pathology service delivery; and
- Creates a single Health Service Executive framework for all the health-related laboratory services in Ireland.

The results will be profound: much better laboratory medicine services for patients and clinicians; far fewer laboratories; a smaller technical and support workforce; and a more cost effective service.

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The crucial role of pathology in patient care

Our remit and approach

We were commissioned by the Health Service Executive to determine the most appropriate structure and arrangements for the delivery of laboratory medicine services. We have identified international practice in laboratory medicine services, examined the benefits and risks of the current system, developed a new system for Ireland, including criteria for size and location, and prepared an action plan.

Our focus has predominantly been on the primary, community and acute laboratory medicine system of test processing and clinical advice. Our understanding of the current circumstances has been informed by:

- Familiarisation visits to 19 hospital laboratories as a representative cross-section of the whole service (see Appendix 3);
- The collection of data from every hospital based laboratory medicine laboratory;
- Fact-finding interviews with a number of national organisations (see Appendix 2); and
- A review of published healthcare reports and policy documents provided by the Health Service Executive (see Appendix 4).

We were asked to prepare this report on an independent basis without formal engagement and consultation with the public, patients, staff and other stakeholders in laboratory medicine services.

We were also asked to comment upon the interface between the clinical laboratory services and other health related laboratory services, namely the:

- Pathology screening services;
- Public health (clinical and population microbiology) laboratory service; and
- Official Food Safety Laboratories (OFSL), comprising 7 public health laboratories dedicated to microbiological food safety and the containment of food related disease outbreaks and 3 public analyst laboratories, responsible for confirming chemical food and water safety.

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People we have met during this review have consistently recognised the need to change the way in which the current system is managed and delivered.

Laboratory medicine is critical to supporting high quality patient care

Laboratory medicine services are critical to supporting the delivery of high quality patient care. They themselves need to operate to internationally recognised standards to ensure the quality and accuracy of their contribution to patient care.

The responsibilities are wide ranging and need to be available on a 24/7 basis, depending upon the urgency of the clinical need. They include:

- Enabling the clinician to confirm or exclude the presence of significant disease as the source of a patient's complaint;
- Providing guidance on likely clinical outcomes of disease;
- Monitoring the progress of chronic disease or long term condition;
- Providing expert advice in the management of patients with more complex conditions;
- Being directly responsible for the delivery of patient care in a growing number of complex conditions;
- Supporting research and development into new laboratory tests, systems and processes;
- Maintaining standard operating procedures and meeting quality assurance standards in laboratory services; and
- Supporting undergraduate teaching, postgraduate teaching and professional development.

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Outline of the future clinical and laboratory medicine model

Globally, many different countries and health care systems have recognised the need for fundamental change in the way health services are presently delivered in order to respond to a number of common severe pressures and drivers for clinical change ^{1 2 3}, including:

- The need to incorporate the rapidly increasing progress in healthcare knowledge and expertise into normal clinical practice;
- The impact of patient knowledge, demands and their rising expectations; and
- Keeping pace with demographic changes, for example, the greatly increasing growth in the health and social needs of the elderly.

The common response, in Ireland as well ^{4 5 6}, has been to develop a new clinical model that puts the patient at the centre of service planning and delivery, with the primary objective of delivering care 'at home, or as close to home as is clinically safe and appropriate'. In other words, delivery is now being designed around the patient, not around the service, or its staff or its estate. The Health Service Executive recognises that there is currently inappropriate use and over reliance on acute hospital services which often creates inconvenience for patients and clients which unnecessarily overloads hospitals. In addition accessing high quality acute hospital care can be difficult ⁷.

¹ National Framework for Service Change in the NHS in Scotland. 'Drivers for change in Healthcare in Scotland'. National Planning Team, July 2005.

² Common vision for the Canadian Health system, 2004.

³ Implementing the New Zealand Health Strategy, 2005.

⁴ Health Service Executive Service Plan, 2005-2008.

⁵ Improving Safety and Achieving Better Standards: An Action Plan for Health Services in the North East. Report to the Health Service Executive, July 2006.

⁶ A New Direction for Healthcare in the North East, Health Services Executive, July 2006.

⁷ Health Service Executive Transformation Programme 2007-2010, December 2006.

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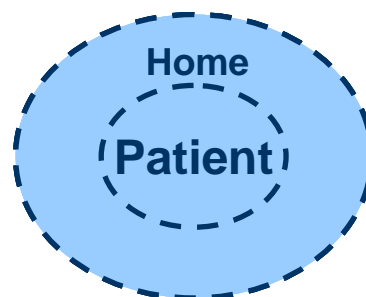
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In summary, this means that the Health Service Executive is embarking upon clinical service reorganisation to improve the quality of:

- Self care, through more support in the home and more patient and carer empowerment, involvement and responsibilities;
- Routine local care through better general practice, primary care, community⁸ and ambulance services; and
- Specialist care through consolidating that expertise into well staffed, well equipped larger hospital units.

To define the future of laboratory medicine, we first need to describe the future clinical model. The pictorials below build up that clinical model and, alongside it, introduce the key features of the future supporting laboratory medicine service, based upon our assessment of international best practice, described later in the report.

Figure 1: The patient at home: The future clinical model and supporting laboratory medicine service



24/7 Clinical services in the home

Self care, chronic disease management, home telecare, 'smart' homes, social housing schemes, primary care, community care, social care, ambulance emergency care management, etc

Laboratory medicine at home

Point-of-Care Testing⁹ (self care and emergency assessment), Phlebotomy, Sample processing by the 'cold' laboratory¹⁰.

⁸ For example, the PCCC strategy for Ireland is to have a clinical network of some 400 – 500 community care teams in place over the next five years, mostly co-located with general practice/primary care, each team serving a local population of some 50,000.

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The patient at home

Much work is being done to release patients from the traditional constraints imposed upon them, to support them to become more independent and responsible for managing their disease. The expert patient has arrived and the era of personalised medicine is imminent. Education, empowerment, innovation, point-of-care testing and implantable devices are leading a revolution in personal care capabilities and competencies.

Therefore, it will become the 'norm' for more and more patients to manage themselves in their own home environment, particularly for chronic disease and long term conditions, through supported self care and selected point-of-care testing.

The 'at risk' elderly population will maintain their independence through home telecare surveillance, smart homes and social housing schemes.

Where there is an acute emergency, the call for help will be triaged so that an Emergency Medical Technician can respond, undertake a clinical assessment, appropriate investigations, including point-of-care testing, and ideally arrange next steps in order to keep the patient safely out of hospital, rather than automatically deliver the patient to the nearest accident and emergency department.

This approach is reflected in the recent Health Service Executive investment in upgrading the numbers, skills and competencies in the pre-hospital ambulance services, such that the patient benefits from a much better quality of first emergency response¹¹.

⁹ We use the term point-of-care testing to mean laboratory tests performed by non-laboratory staff (typically medical and nursing) at or near the site of patient care in the primary care sector and outside the main laboratory in hospital departments. The types, test repertoire, training, deployment and quality assurance of point-of-care test analysers is controlled by the Laboratory Medicine Service, responsible for implementing a national Point-of-Care Testing strategy.

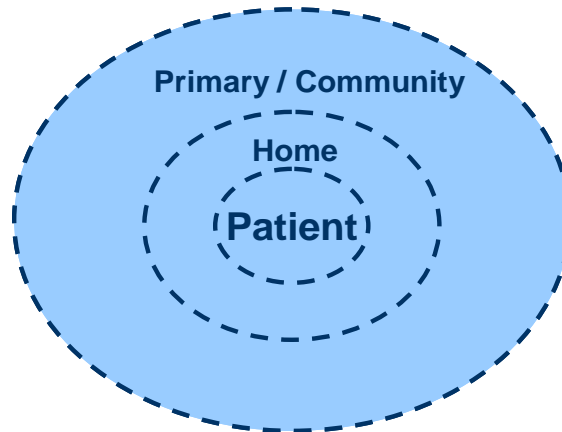
¹⁰ We use the term 'cold' laboratory throughout this report to refer to the development of centralised laboratories designed to process high volumes of routine or 'cold' samples, both for blood sciences, microbiology, histology and cytology generated by general practice, primary care and community care. These laboratories will include automated sections, with cross discipline working. They are supported by dedicated logistics solutions for timed sample collection, transport, tracking and delivery. The standard turnaround time for the automated test repertoire is typically less than 4 hours from receipt of sample. The 'cold' laboratory may be 'standalone' or co-located with a 'hot' laboratory. It may also be responsible for more specialised esoteric tests or national reference functions, depending upon how the national Laboratory Medicine Services strategy co-ordinates its approach in these areas of its business.

¹¹ This development programme is already underway in Ireland and started rolling out in 2005 when the first 50 Emergency Medical Technicians completed their training.

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Figure 2: The patient at home, supported by primary care and community services



24/7 General practice, primary care and community services

Access to GP, nursing and community clinics, domiciliary services, support for self care, chronic disease, long term conditions, intensive case management, maternity and child health, mental health, special needs, etc.

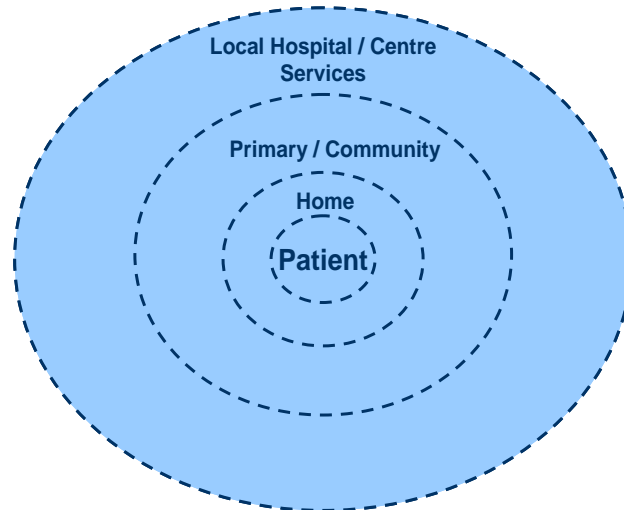
Laboratory medicine in general practice, primary care and community

Phlebotomy and sample collection, point-of-care testing (routine and urgent), sample processing by the 'cold' laboratory.

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Figure 3: The patient at home, supported by primary care, community services and the local hospital/centre services



Clinical services at the local hospital

Specialty out patient clinics, diagnostics, planned care, community beds (non-acute), 24/7 minor injuries and illness service.

Laboratory medicine at the local hospital

Point-of-care testing, Phlebotomy, Sample collection point, Processing by the 'cold' laboratory.

The local hospital

The local hospital will provide a range of services appropriate to the size of the local population. These will include:

- Planned care (Out-patient specialty clinics, minor local procedures, day surgery, etc);
- Diagnostics (point-of-care testing, radiology, ultrasound, endoscopy, sample collection service, etc);
- Urgent care (Nurse led minor injuries, Illness service; observation bay; point-of-care testing, etc); and

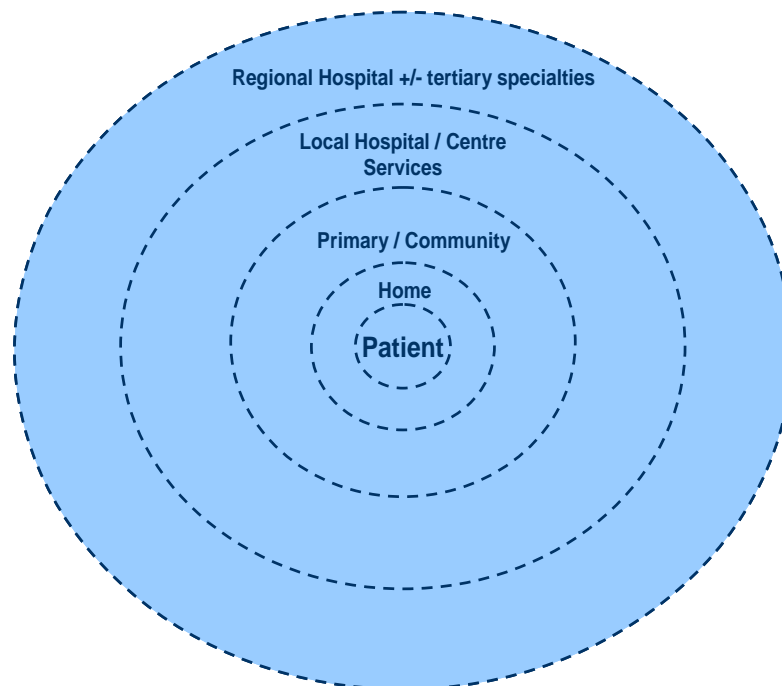
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- Non-acute beds (rehabilitation, step down, intermediate care, palliative care, etc).

The vast majority of patients, who only need access to routine planned care, routine diagnostics and minor emergency services, will be managed within their local environment, either in home or at their local hospital or centre.

Figure 4: The patient at home, supported by primary care, community services, local hospital services, the regional hospital ¹² and the tertiary specialty centres



24/7 Acute clinical services at the regional hospital +/- tertiary specialties

Patients will only go to the regional hospital for treatment that cannot be provided at the local hospital. Consultants are always available to manage the more major emergencies and complex elective conditions.

¹² 'Regional hospital' refers only to the size of the typical catchment population of 300,000 to 500,000 for a large acute hospital with Accident and Emergency, Critical Care, Emergency specialties, etc. It is therefore responsible for also supporting local hospitals within that catchment population, but it has no specific geographical meaning.

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The regional hospital is supported by a national network of tertiary specialties, where patients will be referred on to when there is insufficient expertise and workload to justify such services at the regional hospital. On occasion, some tertiary specialties may be co-located with the regional hospital, depending upon tertiary planning strategies.

Laboratory medicine services at the regional hospital

Laboratory medicine service on site, comprising:

- *Phlebotomy service, sample collection system, 'hot' laboratory¹³, Urgent point-of-care testing; and*
- *Clinical pathologists providing expert advice, direct patient care and operating across the clinical networks.*

The regional hospital

The regional hospital will therefore be the site that is fully staffed and equipped to provide high quality, round-the-clock care for those patients in need of acute emergency care and complex planned care, conditions that cannot be managed safely at the local hospital level.

Normally all the acute specialties will be based here, including accident and emergency, critical care, coronary care, general medicine and sub-specialties, general surgery and sub-specialties and women and children's services.

They will provide advice and expertise to the network of local hospitals within their region. The patients will be transferred nearer home, to their local hospital as necessary, once the acute phase of their episode of care is completed.

¹³ We use the term 'hot' laboratory throughout this report to describe the laboratory facility that processes all samples generated by patients attending the regional hospital, out patients and when admitted for emergency care or complex planned care. There is cross-discipline working in place, during normal working hours as well as out-of-hours, with full advantage being taken of common analyser platforms to support common working practices. The distribution and authorised use of urgent point-of-care testing represents additional 'remote laboratory capacity', designed to optimise patient care at the bedside, at the same time as sensibly relieving the need for the laboratory itself to do the analyses.

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The supra-regional tertiary clinical specialty centres

Finally, there is the national network of supra-regional tertiary clinical specialty centres, taking referrals from the regional hospital for conditions that qualify as tertiary care with regard to the numbers of patients and the level of clinical and laboratory medicine expertise required to provide high quality management and satisfactory clinical outcomes. The regional hospital itself may also be co-located with some of these tertiary specialties, depending upon national service planning strategies.

The role of the more specialised laboratories in the future pathology model

So far, the laboratory medicine model has described point-of-care testing, the 'cold' laboratory and the hospital 'hot' laboratory. We have indicated that they may be standalone or co-located, depending upon how the national strategy is applied. We now add in the more specialised laboratories to complete the description of the future laboratory medicine model. In principle, the specialised laboratories must all satisfy:

- The need for the much lower numbers of the more esoteric or more complex tests to be 'distributed' in a coherent manner across the whole laboratory system:
 - This needs a small number of laboratories to be nominated as 'specialised' in a particular test repertoire, or, (if the tests have additional criticality, rarity or have a strong public health dimension), to be the one designated 'national reference' laboratory ¹⁴;
 - Such laboratories are the repository of expert knowledge on that subject, a source of expert advice and a link to international laboratories working in the same arena;

A larger 'hot' laboratory may have additional responsibilities, for example when co-location is essential to support specialist clinical services on-site, or it may attract wider laboratory roles, such as being co-located with a 'cold' laboratory, being selected as one of a small number of specialised referral centres for a defined range of additional esoteric tests, or being appointed as a national reference laboratory, depending upon how the national Laboratory Medicine Services strategy co-ordinates its approach in these areas of its business.

¹⁴ Development of Microbiological Reference Laboratory Services in Ireland. Draft Report of the Microbiological Reference Laboratory Group, Health Service Executive, 2006 (work in progress).

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- There needs to be a critical mass of the volumes of each particular test, such that each laboratory can do daily analyses to ensure a clinically satisfactory speed of turnaround and results reporting and successfully concentrate the appropriate expertise to quality assure the process and to advise upon external quality assurance;
- The need for some specialised laboratory functions to be specifically co-located with particular clinical services, for example, haemopoietic (blood) disorders; and
- The need for the academic laboratory to be able to discharge its responsibilities for teaching, postgraduate fellowships and research and development.

These requirements give rise to several perfectly reasonable combinations of functions, co-locations and standalone solutions, all compatible within the overall model.

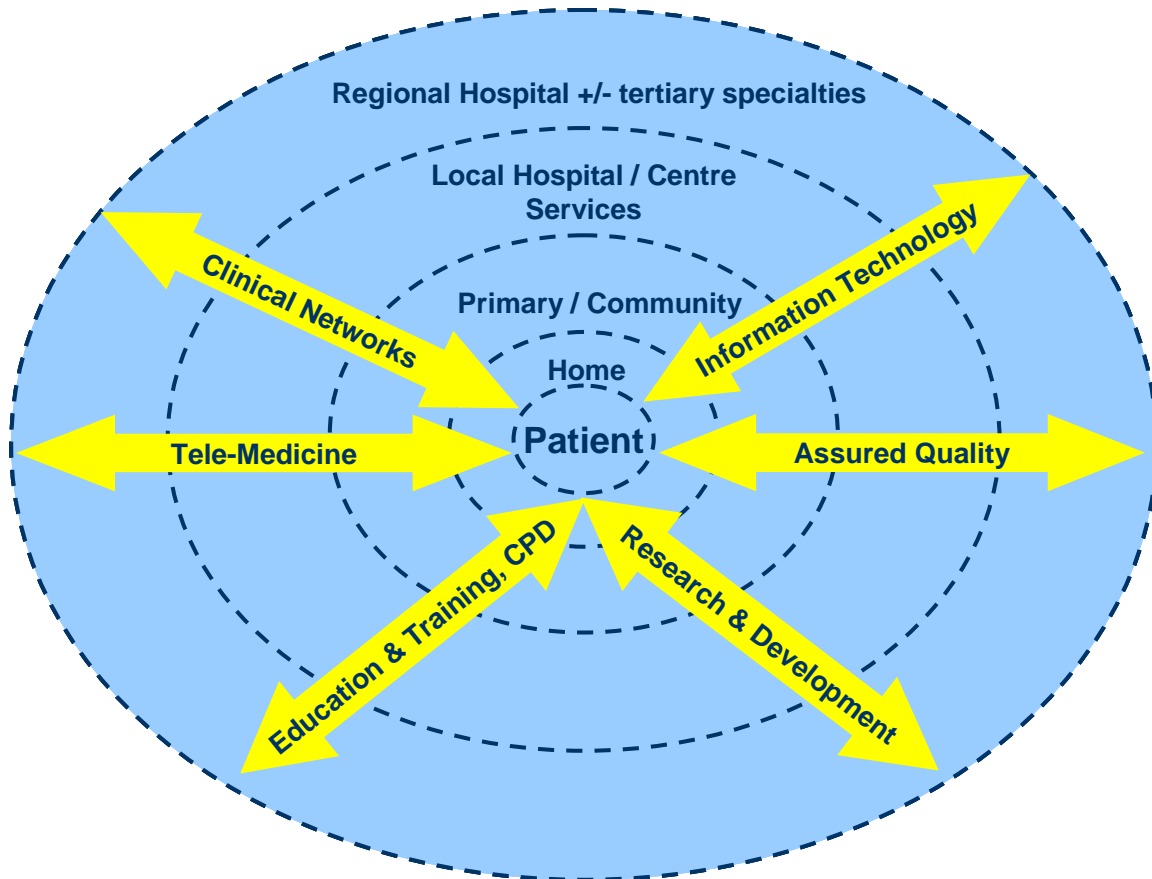
For example, both the 'cold' laboratory and 'hot' laboratory may each have specialised roles or qualify as a designated national reference laboratory. Typically, the academic laboratory will be co-located with a regional hospital and its 'hot' laboratory.

National reference laboratories do not need to be co-located with hospitals, except where their function is critical to supporting a particular clinical service or where it is logical to group similar laboratory functions together on the one site.

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Figure 5: The single infrastructure of the future clinical and supporting laboratory medicine models



The common infrastructure for the future models

A graphical representation in Figure 6 depicts the 'glue' that binds together all the components of the future clinical and pathology models, namely:

- Clinical networks;
- Assured quality;
- Education, training and continuous professional development;
- Research and development;
- Information technology; and
- Telemedicine.

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This means that the patient receives a seamless service at all points of the patient journey, however many staff and organisations contribute to the acute event or on-going management.

The models are designed around building critical mass for health professionals to:

- Better assure the quality of patient care and reduce the unnecessary variations in clinical and laboratory medicine service practices by developing:
 - Larger clinical teams and virtual teamworking;
 - Best practice clinical and diagnostic pathways;
 - Systematic peer review;
 - Effective clinical governance;
 - New education, training and professional development programmes to support new practices in laboratory medicine, for example standardising multi-disciplinary working and implementing the new sub-specialty activities arising out of innovative technology applications;
- Build effective clinical networks to formally link across other networks, clinical services, specialties and disciplines to:
 - Stimulate change;
 - Develop professional relationships;
 - Transcend bureaucratic boundaries in patient care;
 - Ensure equitable access to expert advice and care, irrespective of time and distance;
 - Develop a uniform approach to education, training and continued professional development;
 - Develop a national structure to co-ordinate all laboratory medicine services activities in research and development;
 - Develop a uniform approach and co-ordinated distribution of workload, quality assurance and other responsibilities across all national reference laboratories including clinical, public health and public analyst services;

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- Invest in unique patient identification and common information technology infrastructure to enable the development of the electronic patient record and effective clinical and laboratory medicine links and communications; and
- Invest in innovative techniques, such as telemedicine, telecare, telediagnosics, tele-dermatology, laboratory automation, robotics, information management, remote reporting and telepathology to improve the quality of patient care, laboratory medicine service delivery and overcome the constraints of lack of on site staff, time and distance considerations.

With the outline model now defined, it is important to understand how it would work in practice. We describe three typical patient scenarios below, following their care pathways to illustrate how the patients interact with more patient centred clinical and supporting laboratory medicine services, compared to what happens at the moment with today's arrangements.

Scenario 1: Tommie gets over his heart attack

Tommie, his GP and his consultant at the regional hospital were all pleased with the new blood test arrangements. Tommie can now get back to the farm in half an hour. The new laboratory information technology system meant that his GP now gets the results much quicker and the consultant could keep track of the results as often as he needed - much less chasing around for results or having to arrange for repeat tests.

Since his heart attack, Tommie had slowly got back to work on the farm, helped by his son, Sean. The heart consultant at the regional hospital had put him on a series of tablets. He took them regularly, but two of them need regular blood tests. The first is a statin capsule for his raised blood fats and the second is called warfarin because they found he had an irregular heart-beat. The statin result was fed back to his GP, but each week, Tommie had found himself having to wait at the hospital for the warfarin result and then get his tablets in the correct dose.

Tommie's problem was getting to the regional hospital, which serves a rural population of 300,000, for his blood tests. It took ages there and back. If his son Sean drove him, they were usually back mid-afternoon, but this took Sean off the farm all day once a week. If Tommie got buses, he was not back till evening and his wife felt this was bad for him.

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After the local PathPoint centre ¹⁵ opened, in the village pharmacy, all Tommie had to do was to drop in, where a trained phlebotomist took his blood. Each day the blood tests are collected and taken away for processing. Tom wasn't sure where, but he knew he was now getting a real fast service. All Tommie had to do was either phone up the pharmacy or pop in the next day to pick up the exact dose of the warfarin tablets from the pharmacist for the next week.

Scenario 2: Maeve doesn't look well

After it had all happened, Maeve's GP had told her mum that the new PathPoint centre at the local hospital had made all the difference. Looking back, Mum had been terrified when she got the result on her daughter Maeve. Maeve, aged 4, hadn't looked well for a week. She hadn't been sleeping; she had a head-ache and looked a bit flushed. Mum had taken her temperature and it was high. She had a fever. The GP referred her to the minor injuries and illness service at the local hospital. The service is for assessing children as well as adults. Yes, apart from her high temperature, there was nothing else to find on clinical assessment. The Advanced Nurse Practitioner (ANP) took blood from Maeve and ran it through a 'Point-of-care' analyser, linked 'on-line' to the laboratory at the regional hospital.

The white count was not right. The ANP immediately rang the duty haematologist at the regional hospital for advice. It was at least a two hour drive away. He was able to look on-line at the result and said he felt there was a risk this was leukaemia. He made a few calls whilst the ANP sat down with Maeve on her lap. She explained to mum that if this was leukaemia, there was a good chance Maeve would be cured. However, the local hospital did not have an acute leukaemia unit. The local haematologist was getting Maeve a bed at the regional hospital.

Dad arrived from work a few minutes later, at the same time as the ambulance pulled in. Maeve and Mum got to the regional hospital, where the duty haematologist was waiting to meet them and get on to business. Dad left Maeve's brothers with their aunt and joined mum that evening. The following day Maeve started treatment. Three months later, the bone marrow transplant was a success.

That was all 9 years ago. After the transplant there were weekly blood tests, all Maeve and her mum did was to pop in to the PathPoint centre for the bloods to be taken. They were processed at the 'cold' laboratory and looked at on-line by the GP and the Regional Leukaemia Unit. They were needed less and less frequently.

Maeve was growing into a normal, argumentative teenager, but she enjoyed her 6-monthly visits to the Unit. She always went shopping with Mum afterwards.

¹⁵ 'PathPoint Centre' - The term Teamwork have coined to refer to a distributed network of local access points for patients to attend for phlebotomy, to drop off specimens for collection and to access other services, such as ECG, Holter monitoring, etc.

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Scenario 3: Brian becomes an intelligent customer

Brian's GP started calling him an 'intelligent customer' after the new local PathPoint centre opened. Now, any patient could simply drop in and get their bloods taken or bring in other samples for taking to the big laboratory, where all the GP tests were now done.

Brian was diagnosed with diabetes three years ago when he was 22. He had moved to Dublin to take up a job in an international bank. He hadn't been feeling well for months. He was losing weight and always felt thirsty. Things came to a head after a boozy evening in Temple Bar with his hurling team-mates. Brian had ended up in the accident and emergency centre at the regional hospital, in a coma.

Brian had an uncle and a cousin with diabetes. He was comfortable in learning how to inject Insulin. He even took to pricking his finger and letting blood drip on a testing stick. What he couldn't stand was the frequent visits to the local diabetic clinic. Most of it seemed to revolve around hanging around the hospital, waiting for the formal blood sugar, creatinine and HbA1C. He seemed to know more about the results than some of the junior doctors.

Once the new PathPoint centre opened, he would call in on the way to work from his flat. There was no wait. The phlebotomist took a tube of blood, stuck on a plaster and he was off. A day later, the lab sent him an e-mail with the results. Each month they sent him his serial tests. Brian's GP and the consultant diabetologist also got the results on line. Occasionally Brian would get an e-mail or a cell-phone text, asking him to call into to the GP after work. The GP could usually advise Brian on the Insulin adjustment. Occasionally, there'd be an e-mail from the diabetologist, fine tuning his regime.

The strange thing was, when he went back to Cork for Christmas he met his cousin Mark. They compared notes. Mark's GP had exactly the same system. Mark's visits to the hospital in Cork had diminished as well.

Last time they met, Brian told his GP that he'd got onto the Bank's hurling team.

'We're off to Boston on tour in the spring.'

'There's lots of local PathPoint centres in Boston' the GP said, 'I'll let you know where they are.'

Having described the global shape of the future clinical model and supporting pathology services, in the next section we describe our approach to international best practice and summarise our findings in relation to laboratory medicine service developments.

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Identifying international practice

THE KEY MESSAGES

Implementing internationally recognised best practice developments in laboratory medicine is all about the service playing its full role in a health system organised to ensure that all patients are treated by clinical staff who are supervised, well trained, up to date with their skills, working in a multi-disciplinary team.

Best practice in the laboratory medicine is also about a single, co-ordinated system for:

- Dramatically improving the total end-to-end quality, processing and turnaround times by managing the large volumes of routine patient tests generated from primary and community care through dedicated ‘cold’ laboratories, supported by total quality management and logistics solutions;

As well as:

- Providing optimal support to the patients in the regional hospitals receiving acute ‘round-the-clock’ care through:
 - Dedicated ‘hot’ laboratories;
 - More access to clinical laboratory medicine advice and more direct care of the complex patient; and

As well as:

- Using point-of-care testing in a managed way, in acute hospitals, in local healthcare settings and in the patient’s home, wherever it is clinically appropriate and cost effective.

We now set out our approach to identifying best laboratory medicine services for the future, our findings and our views of what best practice is really all about.

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Our best practice credentials

Our stance on best practice

Teamwork has developed a unique understanding and expertise in mentoring health planners and hospitals through the whole best practice cycle, from understanding, to clinical engagement, action planning and on into implementation.

This experience has given us the inside track when it comes to helping clients to take the best practice agenda forward. In essence:

- Best practice is about people, about clinical engagement and about persuading clinical staff to 'own' the change;
- Best practice is not often about bricks and mortar. Optimising care is about changing professional behaviour. Changing the estate is the by-product of changing the people, not the other way around;
- It is therefore a process, not a solution in itself. It is driven by the evidence of benefits of change and the patient needs, NOT by the needs of the service or its staff or its estate;
- It is a catalyst, it enlightens and motivates the operational workforce to work differently, certainly more effectively, and in a dynamic, seriously progressive manner;
- What constitutes best practice is not necessarily a clear-cut, black and white argument. Even after consulting the range of international evidence available, there often remains a professional judgement to be made;
- Best practice is dynamic. In our experience, each new programme being developed adds a new twist to the story. It is not just about reproducing developments piloted elsewhere; and
- Finally, in our experience, it has often been possible to achieve substantial clinical progress towards best practice within very short timescales. Quick wins are a key element of the roll out of best practice.

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Our own experience in assisting organisations to deliver best practice

Our views expressed on best practice are not just derived from desktop research and analysis. We argue that our comments have added weight as a result of working with frontline staff of many different organisations seeking to deliver today's best practice. While our experience is largely drawn from England and Wales, the principles for redesigning healthcare are readily transferable. We have included some examples of these as follows:

Developing laboratory medicine services:

UCLH – We undertook a feasibility study to establish the first joint venture arrangement between a major teaching hospital and an independent sector laboratory medicine provider in England. We also developed the terms of engagement between the two parties and expected benefits accrued to each party. This lab has been operational since January 2004 and has delivered in excess of the benefits and savings identified at the feasibility stage.

Hammersmith – We developed the strategy and vision for the development of laboratory medicine services in north west London at the heart of which was the establishment of a central, highly automated laboratory, servicing four other acute hospitals. This included the centralisation of all microbiology, histopathology and cytology on to the central site. We subsequently developed the output based specification for the Trust to proceed with OJEU advert to take forward the modernisation plans.

Portsmouth – We supported the development of a central, automated laboratory for 'blood sciences' along with rationalisation of cellular pathology and microbiology in preparation for its major Private Finance Initiative development.

Winchester and Southampton Health Economy – We supported the health economy to develop options for an integrated laboratory medicine service and the strategic vision for services for a population of some 730,000. The development of laboratory medicine services is part of the overall plans for the delivery of sustainable, affordable, and efficient health services across the locality.

Incorporating best practice into health strategies for the future: Sandwell and west Birmingham, Coventry and Warwickshire, North Wales, Isle of Wight

Improving the health system: Healthcare Commission

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Emergency Care: Southport, Morecambe Bay, West Hertfordshire, Carmarthenshire, Swansea

Planned Care: Diagnosis and Treatment Centres, Cancer networks, Vascular networks, Cardiac networks, Out-patient services

Building up local services: Southport; Innovations in Primary Care, taking on acute functions (UK Primary Care Development Programme)

Developing specialist acute care in regional hospitals: Neonatal services, Greater Manchester (neonatology), Swansea (acute services), Wolverhampton (acute services), Southampton (acute services), Leeds (trauma and orthopaedics), London (acute services, theatre services, workforce reviews)

Our approach to identifying international best practice developments in laboratory medicine services

We derived our view of international best practice from a study of what is happening in a representative cross-section of countries, regions, specific laboratory systems and services noted for their fresh approach to laboratory practices.

More specifically, we looked at Australia (Queensland and New South Wales), Canada (British Columbia), Germany, Japan, New Zealand, United Kingdom (England, Scotland, Wales, and Northern Ireland) and the USA.

We used a combination of examination of the relevant international literature, government reports, evidence based studies, direct enquiries, personal communications and web site research.

What does international best practice look like?

We were able to identify a range of common global themes that give a clear snapshot of current international best practice in laboratory medicine services and demonstrate the overall strategic direction of travel for the future.

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THE KEY MESSAGES

Our findings confirm that many countries are reviewing their current laboratory medicine services and developing new strategies for improvement. This global direction of travel is about implementing:

- A new laboratory medicine system based upon complementary:
 - 'hot' laboratories responsible for acute secondary and tertiary patient care;
 - 'cold' laboratories that are custom designed, central, and use the latest generation of automation, robotics and dedicated information technology to manage large volumes of routine samples ¹⁶;
 - Point-of-care;
- 'Patient centred' laboratory medicine services and networks; and
- Telepathology and other new technologies and analytical techniques.

Background: On-going review and strategic change

There are numerous examples of regions and countries in the middle of wide ranging systematic reviews of present laboratory medicine services as a prelude to major strategic change¹⁷. They are on-going and long term in their nature.

For example, the Department of Health programme for laboratory reform in England was originally launched in 1999 and is an illustration of the long term nature of change ^{18 19 20 21 22}.

¹⁶ Report of the Review of NHS Pathology Services in England. Chaired by Lord Carter of Coles, An Independent Review for the Department of Health, UK, August 2006. This is also the conclusion reached by Lord Carter and he states '....that laboratories were typically formed into networks comprising "hot" laboratories which provide the essential support for acute activity (accident and emergency, critical care), which therefore requires co-location with acute hospitals; "cold" laboratories which process high volumes of routine tests, which have no requirement for co-location with other hospital activities; and specialised or esoteric laboratories which provide analysis of less common, more complex and usually more expensive tests'.

¹⁷ For example, in British Columbia, England, Wales, Scotland and Northern Ireland.

¹⁸ Modernisation of Pathology Services (August 1999) NHS Executive, HSC 1999/170. The modernisation programme is launched with £28 million invested in 39 demonstration projects.

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The British Columbia Laboratory System²³ in Canada, responsible for looking after a population of around 4.12 million, and three years into their change process, have identified some key attributes of their new strategic model of delivery, including:

- Reformed laboratory medicine services will be a provincially coordinated, regionally integrated model;
- Within this model, the province, the Health Authorities and individual laboratory facilities will each have clear roles and responsibilities;
- The reformed laboratory medicine services sector must be a seamless system in which hospital laboratories and non-hospital laboratories are complementary partners serving the health care needs of individual patients;
- The reformed laboratory medicine system must preserve the strengths of the current system;
- The level of service provided to smaller, remote and/or isolated communities must be customized to fit their unique needs; and
- The model must be robust enough to accommodate future laboratory-related scientific and technological developments, i.e. it must be designed for both the present and the future.

That is, the service must build upon current strengths, be integrated across the province, seamless across the health sectors, future-proofed and customised as necessary to meet local needs.

¹⁹ Pathology – The Essential Service (2002) Draft Guidance on Modernising Pathology Services – Consultation Document, Department of Health.

²⁰ Modernising Pathology Services (February 2004) Department of Health. Further consultation resulting in issuing of updated strategy.

²¹ Modernising Pathology Services: Building a Service Responsive to Patients (September 2005), Department of Health. Further update issued.

²² Report of the Review of NHS Pathology Services in England (August 2006). Chaired by Lord Carter of Coles. An Independent Review for the Department of Health. Resulted in setting up of 12 pilot projects to ‘road-test’ the recommendations of the review and gather improved data on activity, cost and performance of pathology services.

²³ Canada: British Columbia Provincial Laboratory Coordinating Office <http://www.plco.ca>.

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Examples of new laboratory medicine systems operating today

There are many international examples of new laboratory medicine systems, based upon the advantages of separating ‘hot’ and ‘cold’ sample processing.

For example:

- In the USA, there is a major independent laboratory medicine service provider operating large central laboratory facilities in most major cities across the US. One of the largest, in Teterboro, New Jersey, processes in excess of 39,000 requests per day, offering routine testing for GPs and for referred esoteric tests from hospital based laboratories;
- Among hospital based laboratories in the USA, the development of consolidated laboratory medicine networks (CLN) has also led to the separation of ‘hot’ and ‘cold’ work ²⁴. CLN is a system in which many of the non-urgent laboratory tests that in the past were performed in separate hospital laboratories are now being sent to a core laboratory. Regional laboratories in a network are functioning as “urgent test” laboratories only for time dependent tests. For example, the Columbia Hospital Laboratory Network for California ²⁵, the Detroit Medical Center ²⁶, and the North Shore/ Long Island Jewish Medical Center CLN that has been established since 1998 and has a network of 15 hospitals served by a core laboratory ²⁷;
- Japan has always had large very high volume automated central laboratory medicine facilities, able to process more 60,000 routine requests per day;

²⁴ Takemura, Y., and Beck, R. J., 2001, Laboratory testing under managed care dominance in the USA. *Journal of Clinical Pathology*, 54, pp. 89-95.

²⁵ Lu, S. et al Outreach, consolidation and networking: Columbia’s approach to successful integration of laboratory services in California. *Clinical Laboratory Management Review*, 1996 Sep-Oct; 10(5):507-510, 512-517.

²⁶ Detroit Medical Center (DMC) University Laboratories (<http://www.dmc.org/univlab/default.htm>). The core laboratory is located in the University Health Center of Detroit Receiving Hospital University Health Center (<http://www.drhuhc.org>). The DMC hospitals have rapid response laboratories.

²⁷ The North Shore/Long Island Jewish Medical Center Health System Laboratories with a core lab based at Lake Success, New York and all the other hospitals have a rapid response laboratory performing tests needed within four hours (<http://www.northshorelij.com>).

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- In Germany, a central independent laboratory medicine laboratory in Augsburg deals with over 50,000 routine patient requests per day. There are also sufficient requests for more esoteric (rarely requested) tests to achieve the same turnaround times as for routine tests;
- In the UK, there is a central laboratory medicine facility in London providing over 8.5 million tests per annum at relatively low cost and high efficiency;
- Another major independent diagnostics supplier with laboratory medicine facilities operates internationally, with large central facilities in Australia, New Zealand, Germany, USA, Singapore, Malaysia and UK, providing services for both primary and fast throughput for esoteric testing;
- Queensland, Australia, runs three similar laboratory medicine systems to meet all the requirements for its 4 million population:
 - 1. The public sector laboratory medicine service operates under the aegis of the Queensland Health Pathology Service (QHPS)²⁸. The service has 4 central laboratories based in and around Brisbane and linked to 33 other 'hot' laboratories throughout the State. The central laboratories are also the national referral centres for various tests;
 - 2. There is an independent service provider with its main central laboratory in Brisbane and 31 consultant pathologists and scientific/technical based there. It receives all the 'cold' tests for processing and maintains a network of 25 'hot' laboratories. There are also over 200 specimen collection centres located throughout Queensland and northern New South Wales; and
 - 3. There is a second independent service provider maintaining another central laboratory in Brisbane, staffed with 34 consultant pathologists and scientific/technical staff, and linked to 21 smaller 'hot' laboratories, all linked electronically. All 'cold' samples are processed in the central laboratory which deals with about 15,000 patient requests per day. This equates to about 15 million automated assays, and 300,000 histopathology requests per year.

²⁸ The Queensland Health Pathology Service (QHPS) <http://www.health.qld.gov.au/qhps/pathology.asp>.

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The patient benefits accruing from new laboratory medicine systems

The separate approach to the handling of 'hot' and 'cold' sample processing has enabled the traditional hospital laboratory to concentrate on meeting the demands of patient care in the acute hospital, processing the hospital 'hot' samples without the competing pressures of the routine workload.

Equally, the 'cold' laboratory has been free to provide much more patient centred services and a guaranteed standard of service for routine care, with total end-to-end quality assurance, fast turnaround times, rapid results reporting and a paradigm shift in productivity. At the same time these improvements have been recognised to deliver substantial economic savings ^{29 30 31}.

The common characteristics of a 'cold' laboratory

The past five years has seen an explosion on pre-analytical, analytical and post-analytical cross discipline laboratory equipment, led by the instrument suppliers leading to changes in laboratory medicine practices in blood sciences. Advances in the automation of elements of microbiology and cellular pathology processing are imminent.

This has driven the development of fully automated facilities that require fewer manual interventions, reduce errors and can quickly process very large numbers of a wide repertoire of tests. More than 10,000 tests per hour can be processed by the larger analysers and reports generated by the information technology systems.

²⁹ For example, the University College London Hospitals NHS Foundation Trust's Annual Report and Summary Financial Statements 2005/2006 (19 June 2006) as presented to Parliament pursuant to Schedule 1, paragraph 25(4) of the Health and Social Care (Community Health and Standards) Act 2003 states that its joint venture with a private company for pathology test processing has delivered savings of £1 million.

³⁰ The NHS Greater Glasgow and Clyde health area is to save £9 million over the seven years of its managed service contract for pathology services with an private sector equipment supplier (reported in Medical Laboratory World magazine 'Managed Services: Managed Benefits', 27 July 2006, accessible from <http://mlwmagazine.com>).

³¹ Lord Warner commented at the time of publication of the Report on the Review of NHS Pathology Services in England (August 2006) on the need to look for substantial efficiency gains, of at least 10%, through new ways of working that can be fully implemented in 2008/09.

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The standard time from sample receipt to report authorisation is four hours.

The success of 'cold' laboratory medicine systems has been largely based upon a number of key characteristics:

- Building new, large, custom designed, central facilities that:
 - Use the latest multi-analysers, capable of 'cross discipline' work across the blood sciences (haematology, biochemistry, endocrinology, immunology and viral serology);
 - Minimise the duplication of laboratory equipment;
 - Use system automation, robotics and information technology ³² to process the samples according to rules based operating procedures that reflect best practice for patient management and quality of care;
 - Minimise the need for manual intervention throughout the whole process from test ordering, through logistics, automated handling, automated testing and electronic requesting and results reporting, and also therefore less potential for human error in the system;
 - Deliver the economies of scale through high volume annual outputs of 8 to 10 million results or more;
 - Offer the clinician and responsible bodies analysis and reporting facilities for clinical audit, feedback and clinical governance purposes;
 - Fully meet all requirements of accreditation standards;
 - Have the capability to be operated on a 24/7 shift basis;

³² A modular pre-analytics system installed at the Central Manchester and Manchester Children's University Hospitals NHS Trust has led to significant improvements in sample handling. 'Automation: Robolab' 1 February 2005 (reported in Medical Laboratory World magazine <http://www.mlwmagazine.com>).

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- Implementing total logistics solutions, from the provision of local sample collection points for patients scattered over large geographic areas to regular timed delivery to the central laboratory to meet locally acceptable service performance standards^{33 34}; and
- Private sector investment, enterprise and management to overcome resistance to service change, and to stabilise costs through a competitive, commercial tariff system.

Patient centred laboratory medicine services

This is a key element of the new strategy being developed to improve the interaction of the patient with the laboratory medicine services and the overall quality of patient care.

Organisationally, there is now a clear focus on the provision of local centres for specimen collection to make patient access to laboratory medicine as close to home as possible.

Clinically, there are strategies in place for developing much more patient independence through self care programmes, raising the quality of care through best practice clinical and diagnostic pathways and formal clinical networks to create strong, effective, multi-disciplinary teams.

³³ Report of the Review of NHS Pathology Services in England (August 2006). Chaired by Lord Carter of Coles. An Independent Review for the Department of Health. This report states that some 50% of private sector laboratory costs are in specimen collection and management.

³⁴ Acceptable turnaround times (TAT) differs significantly by country. For example, in Brazil, phlebotomy is performed in patient service centres operated by laboratories. Couriers come every two hours and specimens are delivered to the core (central 'cold') laboratory throughout the day. Results are ready and transmitted to referring physicians within four to six hours of the blood being drawn. In the US physicians will draw blood in their offices. The laboratory sends couriers out to the physicians' offices at the end of the day. The specimens are tested at night and the results are electronically transmitted to the referring physician's office the next morning. (Reported in Medical Laboratory World magazine, 'In my view: Robert Michel', 10 August 2004, accessible from <http://www.mlwmagazine.com>). Robert Michel is editor-in-chief of The Dark Report (<http://www.darkreport.com>), a monthly US publication that provides business intelligence to laboratory administrators and pathologists.

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Provision of patient centres for specimen collection

Managing the complex logistics for automated laboratories has also led to investment in patient friendly services for phlebotomy and specimen collection. No less than 85% of all British Columbians (3.5 million people) live within 5 kms of a specimen collection station. In urban centres such as Greater Victoria or Vancouver, nearly 100% of the population lives within 5 kms³⁵. In Brisbane, there are over 200 collection centres distributed throughout Queensland and northern New South Wales³⁶.

Supporting self care^{37 38}

Supporting the patient at home is at the heart of service change.

Health planners are developing programmes to create ‘expert patients’, to make use of access to broadband and innovative technologies, such as telecare in the home and to stimulate the application and further development of physiological measuring and diagnostic devices to empower the patient and develop self care.

Point-of-care testing

Point-of-care testing has a history of supporting self care, particularly in diabetes and anti-coagulant monitoring.

Clinical reviews³⁹ have found that point-of-care testing offers numerous clinical and organisational benefits. The use of point-of-care testing improves the patient’s quality of life, helps optimise drug treatment, reduces the number of clinic and GP visits, reduces the requirement for blood products in anti-coagulated patients, reduces the number of hospital admissions and reduces the length of stay in hospital.

³⁵ Canada: British Columbia Provincial Laboratory Coordinating Office <http://www.plco.ca>.

³⁶ Personal communication.

³⁷ Supporting long term conditions to self care. Improving Care, Improving Lives. DoH UK February 2006.

³⁸ Supporting self care. A practical option. Diagnostic, Monitoring and Assistive Tools, Devices, Technologies and Equipment to support Self Care. DoH, UK August 2005.

³⁹ Clinical review. Point-of-Care Testing. C.P. Price, British Medical Journal, 322: 1285–1288, 2001.

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One review concluded that ‘although the cost of producing a result at the point-of-care may be greater than for laboratory testing, point-of-care has wider patient, operational, economic and societal benefits’⁴⁰. Another review⁴¹ reported that there may be significant cost savings for other aspects of the patient's care.

The Australian Government is to report in 2007 on the findings from its long-term point-of-care testing trial. Issues under evaluation include the clinical and cost effectiveness of point-of-care testing, and patient satisfaction when compared with pathology laboratory testing⁴². The trial covers some 60 GP practices and around 5,500 patients.

A further review identified 500 individual point-of-care devices in operation in a laboratory medicine partnership across two hospitals in England. The service was commended by Clinical Pathology Accreditation (UK) Ltd. More than 2,000 staff have attended induction and update courses. Over 160 urinalysis instruments have been supplied to GP surgeries. Full blood count and chemistry analysers in accident and emergency and medical assessment units enable patients to be tested much faster. An audit showed a 75% reduction in time spent by junior doctors in requesting and retrieving blood test samples⁴³.

A pilot study has identified that patient waiting times in anticoagulation clinics has substantially reduced waiting times, with 100% of patients being seen within 20 minutes through the implementation of point of care testing⁴⁴.

⁴⁰ Status of Point-of-Care Testing: Promise, Realities and Possibilities. P St Louis. Clinical Biochemistry 33: 6, 427-440, 2000.

⁴¹ Statland, B. E., and Brzys, K., May 1990, Evaluating STAT testing alternatives by calculating annual laboratory costs (Bedside Diagnostic Testing). Chest, 97 (5), pp. 1985-1991.

⁴² Australian Government, Department of Health and Ageing, Point-of-Care Testing trial (<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pathology-poctt-info.htm-copy3>).

⁴³ Partnership Pathology Services (PPS) development between Frimley Park Hospital and Royal Surrey County Hospitals (reported in Medical Laboratory World magazine, ‘Pathology modernisation: Better together’, 1 June 2005, accessible from <http://mlwmagazine.com>).

⁴⁴ Learning from Pathology Service Improvement Sites and Improvement Examples, August 2006, NHS Cancer Services Collaborative Improvement Partnership.

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Reduced morbidity and a reduction of the stay in the critical care unit or the hospital can more than offset any apparent incremental bedside testing costs. The reduction in the length of hospital stay has been seen as one of the main advantages of point-of-care testing⁴⁵.

Despite these clinical and other benefits, point-of-care testing:

- Is mostly used in the hospital setting to support:
 - urgent care in critical care units and accident and emergency departments; and
 - planned care services responsible for diabetic control, anticoagulant monitoring, etc;
- Has developed outside the acute sector in a haphazard fashion, usually outwith the control of the hospital laboratory;
- Been problematic in relation to maintaining quality assurance albeit specific clinical standards having been developed for the usage of point-of-care testing^{46 47 48};
- Has not been connected to laboratory information technology systems;
- Suffered from lack of a formal strategy and defined budget; and
- Has yet to become a core integral component of most laboratory services and systems.

⁴⁵ Price, C. P., May 2001, Regular review: Point of care testing, BMJ, 322, pp.1285-1288.

⁴⁶ Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline, June 1999, AST2-A Vol. 19, No. 9, Clinical and Laboratory Standards Institute ISBN 1-56238-375-2.

⁴⁷ Management and Use of IVD Point-of-care Test Devices, Medical Devices Agency, March 2002, Bulletin MDA DB2002(03).

⁴⁸ Nichols, J., Jan 2006, Tips for Managing your POCT Program. Medical Laboratory Observer, 38 (1), pp. 16-18.

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Notwithstanding, point-of-care analysers, both desktop and hand-held, continue to be developed by the industry, with increasing ease of use, sophistication and widening repertoire of tests. Also, some laboratory medicine services and systems have developed specific point-of-care testing strategies and guidelines^{49 50 51 52 53}. A recent systematic review of the scientific literature and practice guidelines, 'Evidence Based Practice for POCT' makes recommendations on optimal use of POCT for improving patient outcome⁵⁴.

In summary, point-of-care testing is here to stay. It is flourishing, will expand in importance, capacities and its reach. For example, the World Health Organisation has endorsed the global use of HIV rapid testing in the fight against the disease⁵⁵.

Returning to the outline of the future clinical model as described in an earlier section, the clinical strategy is patient centred, with the patient at home as the optimal circumstance. It is difficult to argue against the managed, judicious, and appropriate use of point-of-care testing to support a variety of clinical circumstances, at all levels, including:

- Patient independence and self care⁵⁶;
- The primary care/community team undertaking home visits or in local clinics;
- The Emergency Medical Technician in conducting the first emergency response;

⁴⁹ Point-of-Care Testing Guidelines. Washington State Clinical Laboratory Advisory Council. 2000. Revised March 2005.

⁵⁰ Guidelines on Point-of-Care Testing. The Royal College of Pathologists, UK March 2004.

⁵¹ Canterbury District Health Board Point-of-Care Policy, New Zealand, 2004.

⁵² Review of the role and value of near patient testing in general practice. Report to the Pathology and Diagnostics Branch, Commonwealth Department of Health and Aged Care, Australia 2004.

⁵³ Evidence Based Practice for Point-of-Care Testing. The National Academy of Clinical Biochemistry. Presented to annual meeting, July 2004.

⁵⁴ Available from the National Academy of Clinical Biochemistry (NACB) which is an academy of the American Association for Clinical Chemistry (AACC) (<http://www.nacb.org>).

⁵⁵ Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach. World Health Organisation, 2005.

⁵⁶ Patient self testing is a reliable and acceptable alternative to laboratory INR monitoring. C Gardner et al. British Journal of Haematology 128: 2, 242-247, 2005.

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- The Advanced Nurse Practitioner, for example, undertaking clinical assessments in the minor injuries and illness service;
- The local hospital environment;
- To support 'hot' laboratory services where there are low volumes of urgent requests outside of normal working hours; and
- To support critical care and resuscitation environments.

It can be argued that it is time for point-of-care testing to be formally adopted within the overall future best practice strategy for laboratory medicine services to complement the 'hot' and 'cold' elements of the system.

Use of Patient Care Pathways

Evidence based 'best practice' care pathways are well recognised to improve the quality of patient care and reduce variations in clinical practice and many organisations are devoted to improving the quality of care through improved care pathways as the instrument of change ^{57 58 59 60 61}.

There is a recognised need for a complementary, more evidence based laboratory medicine approach to be developed ⁶² in order to support evidence based clinical medicine through better decision making, better use of tests and better interpretation and action as a result.

⁵⁷ NHS National Institute for Health and Clinical Excellence, UK <http://www.nice.org.uk>.

⁵⁸ Scottish Intercollegiate Guidelines Network (SIGN), NHS Quality Improvement, Scotland <http://www.sign.ac.uk>.

⁵⁹ NHS National Library for Health – Protocols and Care Pathways Specialist Library <http://www.library.nhs.uk/pathways>.

⁶⁰ US Veterans Administration. Diabetes Mellitus Clinical Practice Guidelines http://www.oqp.med.va.gov/cpg/DM/DM_base.htm.

⁶¹ US Veterans Administration. Pre End Stage Renal Disease Clinical Practice Guidelines http://www.oqp.med.va.gov/cpg/ESRD/ESRD_Base.htm.

⁶² Evidence-based Laboratory Medicine: Supporting Decision Making. C.P. Price, Clinical Chemistry. 46:8 1041-1050, 2002.

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Furthermore, with the aim to deliver care ‘at home, or as close to home as possible’, there is need for these hospital orientated care pathways to also describe what should best happen outside that environment, to support the GP, primary care and community teams when it comes to the appropriate use of investigations and the frequency of such requests, particularly in the monitoring of long term conditions.

Care pathways are also being used in conjunction with financial incentives to encourage clinicians to use the pathways and therefore make appropriate use of laboratory medicine services in their delivery of patient care. For example:

- In the USA, the Health Maintenance Organisations use financial incentives to ensure the appropriateness of laboratory medicine requests⁶³; and
- In the UK, the new General Medical Services contract has been developed along similar lines⁶⁴. The contract includes ‘Quality Indicators’ for repetitive testing which potentially increases their remuneration if laboratory medicine is used appropriately, in line with best practice.

From these initiatives to improve the quality of patient care and monitoring, it can be safely argued that there will be a rise in community-based laboratory medicine demand from these international moves to manage chronic disease and long-term conditions outside the acute sector.

Development of formal pathology networks

Rationale

We found that all the countries and systems we studied agreed in principle about the need to develop integrated services around formal laboratory medicine networks, for a variety of reasons:

- As an improver of overall service quality, operating through agreed best practice patient care pathways;

⁶³ Examples of Health Maintenance Organisations in the USA include, Kaiser Permanente (<http://www.kaiserpermanente.org/>), Health Insurance Plan of New York (HIP) (<http://www.hipusa.com>), FirstCare (<http://www.firstcare.com/>).

⁶⁴ General Medical Services contract is available from the Department of Health’s website at: <http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/PrimaryCare/PrimaryCareContracting/GMS/>.

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- As a promoter of professional relationships and peer review in this and across disciplines;
- As a mechanism to facilitate the building of critical mass and economies of scale in service delivery;
- As a forum for change and problem solving; and
- As a vehicle for directing the interests of individual organizations to focus on a more strategic level of engagement.

Networks are an effective management tool for overall laboratory medicine reform and can evolve as they mature. Networks have been shown to integrate laboratory medicine into wider service developments and decrease inappropriate variations between services by encouraging peer review.

Establishing multi-disciplinary teams engages the whole laboratory medicine workforce in a series of common reform policies, including care pathway development, clinical risks, performance management and peer review.

Networking has also enabled the development of single solutions for common infrastructure problems best dealt with in the context of supporting a population of at least a million rather than for individual organisations, for example in developing the unique patient identifier, in standardising document scanning and archiving and in developing innovations, such as telepathology.

Some examples

The interim report ⁶⁵ and the final report ⁶⁶ on The Future of Pathology Services in Northern Ireland services has recommended that there should be a single, managed network for the provision of the full range of pathology services for the population of 1.7 million across Northern Ireland.

⁶⁵ Review of Clinical Pathology/Laboratory Services – Understanding Today and the Challenges for Tomorrow - Interim Report of Progress, Department of Health, Social Services and Public Safety, August 2006. This report is available from http://www.dhsspsni.gov.uk/hss/clinical_pathology_review.htm.

⁶⁶ The Future of Pathology Services in Northern Ireland, Department of Health, Social Services and Public Safety, November 2006.

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In Scotland ⁶⁷ for example, there were two regional laboratory medicine networks established in 2003 for its population of 5.1 million. In May 2006, an overarching national Scottish Pathology Network (SPAN) was put in place for histopathology and cytopathology.

In England, The Essential Service Draft guidance on modernising pathology services (Department of Health, 2002) indicated that an optimal population size for pathology networks should be greater than that served by a district general hospital to provide the basis for effective and efficient pathology services. The Modernising Pathology Services report (Department of Health, 2004) suggests that an effective network should cover a natural population taking into account existing and planned clinical services in acute and non-acute settings, other clinical networks (e.g. cancer networks), and patient flows.

These pathology clinical networks should also take into account support to specialised services. Based on the Review of Commissioning Arrangements for Specialised Services (independent review requested by Department of Health, May 2006), specialised services are those provided in relatively few specialist centres to catchment populations of more than a million people ⁶⁸.

Current pathology networks in England and their catchment populations include:

- Coventry and Warwickshire Pathology Network (www.uhcnhs.uk) – 1 million;
- PathLinks – 1.1 million;
- Teespath (www.teespath.co.uk) – 1.1 million;
- South West London Pathology Network – 1.3 million;
- Kent and Medway – 1.6 million;
- Cumbria and Lancashire – 1.9 million; and
- Cheshire and Merseyside – 2.4 million.

Networks vary in size from a catchment population of 1 million to over 2.5 million.

⁶⁷ Scottish Pathology Network (SPAN), NHS Scotland. Launched May 2006.
<http://www.pathologyscotland.org>.

⁶⁸ Statutory Instrument No. 2375, The NHS (functions of SHAs and PCTs and Administration Arrangements) (England) Regulations 2002.

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The impact of cancer networks on laboratory medicine

Cancer clinical networks have accelerated the pace of development of the haematology and histopathology element of pathology networks and stimulated the expansion of the pathology services in the provision of direct patient care.

It has brought attention to the need for the histopathologist to work differently, to respond to the need to build a greater critical mass to facilitate sub-specialisation and to support automatic peer review as a member of the multi-disciplinary cancer team.

This has created practical problems for consultants used to working single-handedly or in small groupings. Centralisation of histopathology services is an established feature of service development. For example:

- One trust in the UK has a single group composed of 10 wte consultants serving its 1.6 million catchment population ⁶⁹;
- Another group has managed difficulties in recruitment to smaller laboratory medicine services by merging its cellular pathology from six sites into one large service on a single site and serving a population of some 1.1 million ⁷⁰; and
- Another service ⁷¹ has demonstrated that it is possible and acceptable to deliver a full sub-specialty cancer service in the district general hospital setting with a team of 5 wte histopathologists, based on an equitable, predictable distribution of the workload and the sub-specialty lead responsibility.

⁶⁹ Kent and Medway Pathology Network
http://www.kmpathology.nhs.uk/local_nhs_services/pathology.asp.

⁷⁰ PathLinks – Greater Lincolnshire
<http://www.nlg.nhs.uk/departments/intro.asp?id=69&division=path+links&department=Path+Links>.

⁷¹ Short report: Sub-specialisation in cellular pathology in the District General Hospital setting – the Warwick experience. D.S.A.Sanders et al. Journal of Clinical Pathology, 59:884-886, 2006.

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Microbiology

There are similar arguments in relation to the practical difficulties for single-handed consultants and the provision of clinical microbiology. Consultant microbiology requirements in the networks need to be assessed to ensure there are sufficient resources for infection control supervision at each of the hospital sites, antibiotic policy implementation and easy access to clinical microbiology advice.

There is also an argument raised for more direct patient involvement, in line with the primary objective of the clinical microbiologist to improve infectious disease management, supported by investment in more rapid testing and evaluation of tests in terms of clinical outcome, rather than simply continuing the same level of input into the daily running of the laboratory⁷².

Public Health microbiology

In the USA, there is a well defined overarching structure, the 'Laboratory Response Network' (LRN), approved in April 2006⁷³.

It integrates into a single reporting framework all laboratories, including clinical, public health, environmental, food, veterinary, agriculture laboratories, i.e. all laboratories that, in the broadest sense, are capable of either analysing or referring specimens or samples that may contain microbial agents or biological toxins function, are designated as 'sentinel' laboratories of the LRN.

Each state has a designated LRN reference laboratory. Routine assays of human specimens for the presence of microbial agents are an activity that places all clinical laboratories in a position to serve in a sentinel capacity for the Laboratory Response Network. Two categories of sentinel clinical laboratories are recognised, basic and advanced, depending upon their analytical capacities.

⁷² Changing needs, opportunities and constraints for the 21st century microbiology laboratory. J.V. Eldere, Clinical Microbiol Infect. 11 (Suppl 1): 15-18, 2005.

⁷³ Defining Clinical Sentinel Laboratories in the Laboratory Response Network (LRN) LRN Leadership Council, CDCP, Atlanta, USA, Approved April 2006.

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The impact of new technologies

The introduction of novel technologies in laboratory medicine, as in radiology, has allowed clinicians to report on data collected or analysed at distant sites and to share that report on-line using digital technology.

The base hospital for a pathologist is no longer driven by a need to be near analysers or technicians. Economies in co-locating equipment, such as a 'blood' laboratory for haematology and biochemistry analysers, no longer equate with economies in co-locating the clinicians who rely on them, particularly when they are reporting on 'cold' specimens.

Telepathology services and developments

There is clear evidence of the feasibility, clinical safety and effectiveness of telepathology. A review of 32 published trials in 2001 ⁷⁴, looking at all areas of diagnostic telepathology, including intra-operative frozen sections, routine and referral cases, concluded that:

- All the necessary technology for telepathology was available;
- The diagnostic accuracy is comparable to glass slide diagnosis;
- In many contexts, there is a clear cut economic argument in favour of telepathology; and
- The technique should now be integrated into mainstream histopathology.

In the USA, implementation of telepathology as part of the laboratory medicine service has allowed the Veterans Integrated Service Network (VISN-12) to reach the goal of providing a single standard of accurate and timely laboratory medicine service, even at small sites that lack an on-site pathologist ⁷⁵:

- Telepathology has been an integral component within the geographically dispersed 8 hospital laboratory network;

⁷⁴ Telepathology: current status and future prospects in diagnostic telepathology. S.S. Cross, et al. *Histopathology* 41: 91–109, 2001.

⁷⁵ Combined robotic and non-robotic telepathology as an integral service component of a geographically dispersed laboratory network. B.E. Dunn, et al. *Human Pathology*, 32: 12, 1300–1303, 2001.

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- The telepathology network is used routinely to support the consolidation and centralisation of primary diagnosis and clinical consultation in surgical pathology, gross examination and documentation of surgical pathology and autopsy specimens; and
- The telepathology system is also used for the interpretation of protein electrophoresis and immunofixation gels, support for consolidated microbiology laboratories for diagnostics and teaching, review of problematic peripheral blood smears and body fluids and distance learning.

Still in the USA, telepathology was used to enable the provision of a high quality, full dynamic telepathology service to a remote hospital to replace a resident pathologist ⁷⁶.

In Scotland, the Scottish Pathology Network has a procurement project ⁷⁷ to provide a digital pathology workstation for every consultant pathologist with a view to the sharing of digital imaging, access to second opinions, peer review and to support multi-disciplinary team meetings, particularly for the cancer network.

Horizon scanning

Research and development is advancing rapidly and across a wide front. They have the capacity, if translated into mainstream laboratory medicine practice, to once more revolutionise analytical techniques, in a similar manner to the impact of the latest generation of automated analysers.

It is therefore important that the strategy for laboratory medicine services remains flexible and future proofed in its approach to change. Table 1 below is not designed to be comprehensive, but to provide a flavour of the breadth and depth of current research developments and to estimate, if possible, the potential impact on laboratory practice and the benefits to patients.

⁷⁶ Routine surgical telepathology. Dunn et al Department of Veterans Affairs, 1999.

⁷⁷ Scottish Pathology Network Pathalba project, to provide access to pathology expertise, irrespective of geographical location <http://www.pathologyscotland.org/index.php?page=pathalba>.

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Table 1: Future changes in laboratory medicine ⁷⁸

Change	Impact on current lab practice	Benefits to patients
<p>1. Cellular science – e.g. reporting through use of satellite communication, remotely controlled microscopy, artificial intelligence microscopy, high-speed, hyper-band internet communication and remotely accessible telepathology workstation platforms. Also impact of nuclear magnetic resonance microscopy.</p>	<p>Reduces the reliance on a Consultant Histopathologist to provide an opinion in isolation or at the site of operation. Artificial intelligence microscopy will filter out routine resulting and refer on abnormal results for a Consultant opinion. Microscopy will be able to be performed at any location and second opinions from ‘remote’ specialists will be available over the net. Eliminate need for Consultant attendance at multi-disciplinary teams.</p>	<p>Improve quality and speed of opinion. Specialist opinion more readily available and allow more time for the really ‘difficult’ cases to be correctly diagnosed.</p>
<p>2. Blood sciences – e.g. integrated open-design modular laboratories; nano-technology, bio-robots, and micro device detection systems; personal profile chips; phenotypic monitoring gene chips.</p>	<p>The integrated modular automated laboratories are virtually available now, and it is what we are recommending for the main central facilities. The latest analysers are cross-discipline and together with the pre-analytical robotics, allow blood sciences to be integrated into one department (from at least 3 as now).</p> <p>Tracking now available to link major equipment platforms with robotic sorters to virtually eliminate manual intervention in the production of test results. This reduces the number of qualified scientific staff required and changes the skill mix. Greater emphasis can be placed on Quality Management and Clinical advice.</p>	<p>A far greater repertoire of assays is available on a routine basis which improves turnaround times and reduces time for diagnosis. Standard times from sample receipt to result authorisation is less than 4hrs for the majority of high volume automated blood science assays.</p>

⁷⁸ Adapted from ‘Understanding disease: A Centenary Celebration of the Pathological Society’ edited by P.A. Hall and N.A. Wright, Chapter 18: Professor J.J. O’Leary, Pathology 2026: The future of Laboratory Medicine and Academic Pathology, August 2006, ISBN 047003220.

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Change	Impact on current lab practice	Benefits to patients
3. Clinical microbiology and infectious disease – e.g. enhanced microbiological, virological and mycological susceptibility testing, direct molecular microbiological epidemiology organism and strain identification; hand-held microbiology detection devices.	Introduction of molecular technology allows results that may have taken several days (or weeks in the case of TB) to be available in a few hours. MRSA screening of patients before entry into hospital is now available, with results in 4 hours.	Patients benefit by having a safer environment in Hospitals and faster diagnosis of disease which provides for quicker intervention.
4. Diagnostic molecular pathology – e.g. whole genome proteomic chips, protein array technology, patient specific and disease monitoring chips, individual ‘lab-on-chip’ devices’ for disease monitoring.	Places emphasis on screening / prevention rather than cure, as many diseases are genetic and can now be predicted.	Faster intervention, following early diagnosis and allows a far more individual patient centred management arrangement for those where the disease cannot be prevented.
5. Cytogenetics – e.g. 24 colour chromosome analysis of solid tumours, more widespread interphase Cytogenetics, fine genome mapping and locus specific sequencing.	Greater investigative power for the clinicians which should indicate effective treatment pathways.	Better outcome for patients following more effective treatments.
6. Devices – e.g. microfluidic devices, nano-medicine, nano-robots, biosensors, passive monitoring of microdelivery systems, active real-time autonomous metabolic control.		
7. Information technology – e.g. bioinformatics, computational biology, systems biology, terrestrial communication, satellite communication, virtual laboratories, monitoring of remote devices.	Greater communication bandwidths etc will allow for diagnostics and treatments to be performed nearer to the patient with seamless data transfer between sites.	Patient diagnostics, monitoring and treatment on a more personal level.
8. Forensicogenomics – e.g. SNP genotyping, Hap Map, CODIS.		

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Change	Impact on current lab practice	Benefits to patients
<p>9. Stem cell biology and biobanking – e.g. tumour stem cell biology, adult stem cell biology, mouse ES stem cell biology, cell entrapment technology.</p>		

Following the identification of best practice, the next section considers benefits and risks of the current system of laboratory management services.

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Benefits and risks of the current system

KEY MESSAGES ABOUT THE CURRENT SYSTEM

The benefits of the current system include:

- All hospitals with accident and emergency, critical care and major surgery facilities, and, if available, maternity and paediatrics, are supported by hospital laboratories;
- Sufficient arrangements for the quality of processing of individual tests, as far as we were able to ascertain; and
- Numerous examples of good clinical and organisation practice, including clinical networking, 'hub and spoke' arrangements and use of point-of-care testing.

The risks and problems of the current system include:

- Whole system quality is not good enough, there are some laboratories with no disciplines accredited, there are some laboratories with only a few individual disciplines accredited and no laboratories where all the disciplines are accredited;
- 'Hot' and 'cold' tests from hospitals and GPs are processed together and delivered in a 9-5 timeframe, with limited work processed outside this period at premium cost;
- Much clinical focus is on core test processing and reporting tasks with limited time available for more direct patient clinical input and research and development;
- Heavy administrative burden associated with the lack of a unique patient identification system, outdated laboratory information technology systems and poor connectivity; and
- Future healthcare models indicate major changes in the location of healthcare delivery with much more care being provided at or close to home, which will increase the demand from primary care.

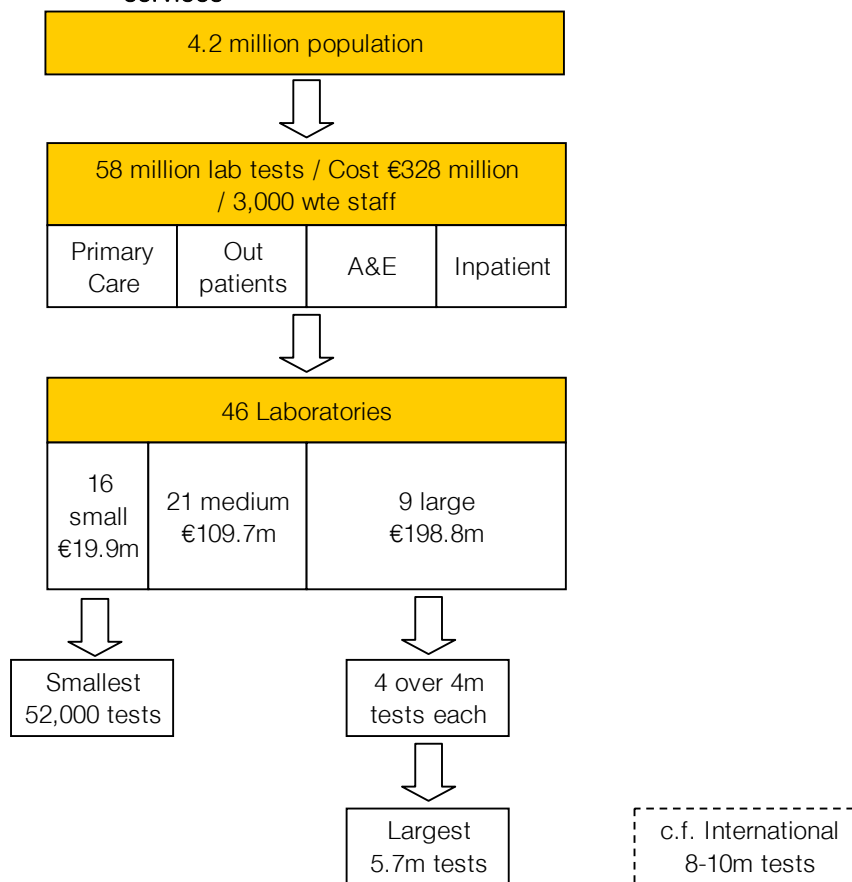
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This section reports our findings of the current circumstances in laboratory medicine and reviews the recommendations and work in progress in relation to the microbiology reference laboratories and the food safety laboratories.

An overview of the structure of the current organisation of clinical laboratory medicine services is set out in Figure 5. This excludes tests provided to the private sector estimated to cost €5m per annum. The data represents annual activity of 58 million lab tests per annum. Further information supporting this is included later in this section.

Figure 5: Organisation of current Health Service Executive clinical laboratory services



We encountered numerous examples of good practice in place. This included effective clinical networking, such as in clinical haematology and neuropathology, use of point-of-care to support front-line and out-of-hours laboratory services, and 'hub and spoke' arrangements between laboratories, with GP work, microbiology and histopathology at the hub, supported by the laboratory information management system (LIMS) connected by a local area network (LAN) to the other systems at the spokes.

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The Health Service Executive recognises the challenge of change in response to a global recognition that conventional approaches to health and social care delivery are unsustainable with current systems unable to cope, financially unsound and unable to provide quality care ⁷⁹.

With this background, we now set out a brief overview of the current hospital laboratory system and then focus on the main benefits and risks under the following groupings:

- Whole system quality is not good enough;
- Limitations in the current organisation of hospital laboratories; and
- Issues for the Public Health and Food Safety Laboratories.

Whole system quality is not good enough

We have drawn together several issues which impact on end-to-end quality of the system. All of these are effectively included under the formal accreditation programmes.

KEY SYSTEM RISKS IN DELIVERING END-TO-END QUALITY

The overall proportion of individual laboratory medicine disciplines that have achieved accreditation status is low.

Unsatisfactory end-to-end information systems:

- Lack of the ability to uniquely identify a patient creates major difficulties in effectively managing and tracking individual patient tests and results in delays, inefficiencies and duplication of tests between primary and secondary care;
- Laboratory information management systems (LIMS) are generally old with poor functionality and limited connectivity;
- Electronic reporting of GP results, while increasing, is limited;
- Statistics from LIMS systems are inadequate for in-depth analysis and clinical audit; and
- Disease specific protocols are not in place for best practice test

⁷⁹ Health Service Executive, Transformation Programme 2007-2010, December 2006.

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requesting.

Collection logistics mean that specimens from some GPs are only collected from once daily to twice weekly which impacts on the speed of processing and reporting back to patients.

The general condition of the laboratory estate is poor:

- Typically out-moded, out of date, traditionally designed, with large corridors, often around a central light well;
- Lack of flexible space or adequate space to incorporate and integrate departments into an open plan system, to introduce shared sample handling and office space for consultants; and
- Most microbiology laboratories are poorly designed and have inadequate category 3 containment facilities.

The current position on accredited disciplines as at 13 September 2006 is set out in Table 2.

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Table 2: Accredited disciplines by lab size as at 13 September 2006

Metric	Small	Medium	Large	All
Number of labs in each category	16	21	9	46
Total number of disciplines	37	91	48	176
Status: Accredited >>>				
Biochemistry	0	1	0	1
Haematology – Routine	0	1	2	3
Immunology	0	0	2	2
Microbiology – Bacteriology	0	0	2	2
Histopathology (incl. Non-gynae cytology)	0	1	2	3
Cytology	0	0	2	2
Status: Conditional Approval >>>				
Biochemistry	0	0	3	3
Haematology – Routine	0	0	1	1
Immunology	0	0	0	0
Microbiology – Bacteriology	0	1	2	3
Histopathology (incl. Non-gynae cytology)	0	0	1	1
Cytology	0	0	0	0
Status: Awaiting Assessment >>>				
Biochemistry	1	5	1	7
Haematology – Routine	1	6	1	8
Immunology	0	0	0	0
Microbiology – Bacteriology	1	5	2	8
Histopathology (incl. Non-gynae cytology)	0	5	1	6
Cytology	0	3	1	4

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

None of the disciplines based at small laboratories are accredited, with only 3 out of 91 disciplines at medium sized laboratories accredited. 10 of the 48 disciplines at large laboratories have accreditation.

From the laboratory information returns we are aware that there is work in progress to increase the number of disciplines that will achieve full accreditation status, with a number of disciplines having conditional approval and a further number awaiting assessment. The workload associated with the levels of accreditation achieved is presented in Table 3.

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Table 3: Workload by accreditation status

Metric	Lab size =	Small	Medium	Large	All
Number of labs in each category		16	21	9	46
Total workload	Tests/Requests	6,191,893	19,083,594	32,915,267	58,190,754
Accreditation Status >>>					
Accredited	Tests/Requests	0	557,499	1,495,418	2,052,917
Conditional Approval	Tests/Requests	0	103,690	9,542,121	9,645,811
Awaiting Assessment	Tests/Requests	99,437	2,348,607	3,031,766	5,479,810
Percentage of workload >>>					
Accredited	%	0%	3%	5%	4%
Conditional Approval	%	0%	1%	29%	17%
Awaiting Assessment	%	2%	12%	9%	9%

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

In summary, 30% of the total tests and requests processed in laboratory medicine disciplines are either accredited, have conditional approval or awaiting assessment.

While we have highlighted a significant number of risks, nothing was brought to our attention which suggested any specific concerns about the quality of processing of individual tests.

We noted that biochemistry departments generally had the most recently re-furnished laboratory space and most of the large/university laboratories had started to introduce pre-analytical and robotic systems.

Most of the medium and large laboratory sites have relatively new analytic equipment in their haematology and biochemistry departments. These analysers often have much greater capacity than necessary for the workload, with duplication in Immunoassay analysers almost universal across all laboratories.

Large biochemistry analysers, or multiples of smaller ones, have been installed to enable the workloads to be completed in the restricted 9 to 5 routine working hours' period. Effectively these analysers are only being fully utilised from 9 to 5 and therefore, for extended working day work patterns, there are too many analysers. New pre-analytical robotics is being installed in the much larger biochemistry laboratories, but they are only being used for that discipline, even though they are multi-functional.

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Chronic problems with sample delivery to the laboratory

There was a common feeling of long-standing dissatisfaction and frustration with the present arrangements for the transport of specimens to the laboratory. There is no standardised service, many collection timings do not meet the clinical needs and are too infrequent, specimens are often not fit for analysis by the time they arrive at the laboratory and there are health & safety and other regulatory implications.

From the GP and primary care point of view, the problems are therefore regarded as serious. It has reached the stage of needing to consider a new strategic approach to manage the complex logistics.

Limitations in the current organisation of hospital laboratories

Configuration of current hospital laboratories

A summary of some metrics derived from the laboratory information collected for the laboratories is presented in Table 4, based on information provided by the individual hospitals as part of the review process. No detailed validation of the information has been undertaken other than to ensure that returns were received from all 46 hospital laboratories. It was not the intention of the review to undertake a benchmarking exercise on the operational efficiency of the existing individual laboratories.

The information on the laboratory metrics presented within the following tables is based on information received as at 13 September 2006. In addition, the Health Service Executive estimates that it procures laboratory tests from the private sector to a value of approximately €5m. The detail and costs of these tests are excluded from the analysis in Table 4 below.

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Table 4: Summary metrics from data collection

Metric	Lab size =	Small	Medium	Large	All
Number of labs in each category		16	21	9	46
Workloads >>>					
Biochemistry and Immunoassay	Tests	5,007,934	15,302,537	26,866,293	47,176,764
Haematology – Routine	Tests	1,088,237	2,589,704	4,001,274	7,679,215
Immunology	Tests	0	91,785	370,036	461,821
Microbiology – Bacteriology	Tests	91,117	894,392	1,394,403	2,379,912
Histopathology (incl. Non-gynae cytology)	Requests	4,605	124,302	187,512	316,419
Cytology	Requests	0	80,874	95,749	176,623
Total		6,191,893	19,083,594	32,915,267	58,190,754
Staffing >>>					
Medical Scientists / Biochemists	wte	107.4	704.1	1,095.0	1,906.5
Other Staff	wte	50.6	326.1	723.9	1,100.6
Total	wte	158.0	1,030.2	1,818.9	3,007.1
Costs >>>					
Pay	€	10,235,904	61,543,055	105,973,690	177,752,649
Non-Pay	€	9,691,994	48,111,723	92,862,560	150,666,277
Total	€	19,927,898	109,654,778	198,836,250	328,418,926
Out-of-Hours/On-call payments	€	1,876,249	8,756,057	13,764,604	24,396,910
Out-of-Hours/On-call as a % of total pay	%	18%	14%	13%	14%

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

The small, medium and large classification of laboratories is based on Health Service Executive categorisation⁸⁰. A summary of laboratory disciplines by size of laboratory is presented in Table 5.

Table 5: Additional metrics on current laboratory services

Metric	Small	Medium	Large	All
Number of labs in each category	16	21	9	46
Disciplines >>>				
Biochemistry	15	21	9	45
Haematology - Routine	16	21	9	46
Immunology	0	5	8	13
Microbiology - Bacteriology	4	21	9	34
Histopathology (incl. Non-gynae cytology)	2	17	9	28
Cytology	0	6	4	10
Total Disciplines	37	91	48	176

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

⁸⁰ Report of the Medical Laboratory Service Group, October 2001. Chaired by Liam Dunbar.

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The 16 small sized laboratories are predominately multidisciplinary (haematology, blood transfusion, and biochemistry) providing a comprehensive service to the local hospital including blood transfusion requirements. Blood pack wastage appeared to be higher as there is no blood tracking in place and near-dated blood packs cannot be returned to the Irish Blood Transfusion Service (IBTS) or another laboratory. The on-call service within these smaller laboratories is also multi-disciplinary but expected to provide a wide range of assays usually for the accident and emergency department. There is little use of point-of-care testing equipment to provide urgent results.

For the 21 medium sized laboratories, virtually all provide haematology, blood transfusion, biochemistry, microbiology and histopathology. Five sites also have an immunology service.

The 9 large laboratories have all disciplines plus some specialist assays, relevant to the particular hospital clinical need. Of the large laboratories, 4 perform more than 4 million tests per year. The largest laboratory, measured by number of patient reportable tests does 5.7 million tests per annum. This compares with international experience which suggests a minimum number of between 8 to 10 million tests per annum in an automated multi-discipline facility, 500,000 requests in microbiology and 100,000 requests in histopathology.

Out of the 34 microbiology laboratories, only 5 handle more than 125,000 requests per annum. None of the 28 histopathology laboratories have 100,000 histopathology requests per annum.

Point of care testing at acute hospitals

In addition to laboratory processed tests, point-of-care testing devices are also available on acute hospitals sites outside the laboratory environment. A summary of the distribution of point-of-care testing devices is shown in Table 6.

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Table 6: Point-of-care testing device distribution by laboratory size

Metric	Small	Medium	Large	All
Number of labs in each category	16	21	9	46
Point-of-care testing devices >>>				
Glucose meters	16	21	9	46
Blood gas analysers	11	20	9	40
Simple coagulo-meters/INR monitors	2	3	5	10
Complex coagulo-meters/thromboelastographs	1	1	1	3
Full blood count (FBC) analysers	0	0	1	1
Haemoglobin analysers	4	5	6	15
Glycosylated haemoglobin HbA1c analysers	5	7	1	13
Cardiac Troponin (I or T) analysers	10	7	3	20
Urinanalysis	11	18	8	37
BNP and Drugs	10	4	3	17

Competing processing of hospital and GP tests

Primary and community care services currently do not have exclusive laboratory medicine processing facilities. There are in excess of 18.5 million primary care test requests. Increasing workload, particularly from the primary care patients, is now close to exceeding the current 9 to 5 capacity in several laboratories.

The tests originating from primary and community care (mainly routine 'cold' requests) are processed in hospital based laboratories alongside tests from outpatients, and the more urgent requests generated from within the hospital such as accident and emergency departments and inpatient ward areas.

A detailed breakdown of the source of the laboratory medicine request is presented in Table 7 with between 26% and 36% of the workload being generated from GP and community care settings.

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Table 7: Source of request

Metric	Lab size =	Small	Medium	Large	All
Number of labs in each category		16	21	9	46
Workload source >>>					
Accident & Emergency	Tests/Requests	913,903	2,327,337	2,311,542	5,552,782
Inpatient	Tests/Requests	2,876,709	7,133,604	12,877,415	22,887,728
GP	Tests/Requests	1,614,559	6,824,276	10,011,259	18,450,094
Outpatient	Tests/Requests	695,048	2,046,045	4,391,100	7,132,193
Other	Tests/Requests	91,674	752,332	3,323,951	4,167,957
Total	Tests/Requests	6,191,893	19,083,594	32,915,267	58,190,754
% of workload >>>					
Accident & Emergency	%	15%	12%	7%	10%
Inpatient	%	46%	37%	39%	39%
GP	%	26%	36%	30%	32%
Outpatient	%	11%	11%	13%	12%
Other	%	1%	4%	10%	7%
Total	%	100%	100%	100%	100%

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

However, this proportion of work originating from GP and community care settings is not uniform across all disciplines. A detailed breakdown by discipline is presented in Table 8. It shows that the proportion of GP related work can vary by size of laboratory as well as by discipline.

Table 8: GP workload by discipline

	Biochemistry & Immunoassay	Haematology - Routine	Immunology	Microbiology - Bacteriology	Histopathology (incl. Non-Gynae Cytology)	Cytology
Small >>>						
Average	25%	25%		37%	2%	
Lowest	2%	4%		32%	2%	
Highest	50%	50%		50%	2%	
Medium >>>						
Average	36%	27%	29%	27%	5%	48%
Lowest	2%	4%	20%	1%	1%	5%
Highest	61%	48%	62%	64%	15%	97%
Large >>>						
Average	30%	24%	30%	24%	5%	67%
Lowest	16%	13%	15%	13%	2%	67%
Highest	59%	52%	49%	47%	8%	67%
All >>>						
Average	31%	27%	30%	28%	5%	56%
Lowest	2%	4%	15%	1%	1%	5%
Highest	61%	52%	62%	64%	15%	97%

This table excludes Public Health, Public Analyst and Microbiology Reference laboratories

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The lack of comprehensive logistical support impacts on the timely delivery of samples from GP to laboratories. In some instances this encourages more patients to attend hospital out patient phlebotomy units rather than using the local service. Issues of 'un-funded, under-managed demand and continual increases in GP requirements' were identified by many laboratories.

Inflexible organisational and working arrangements within laboratories

Issues identified with inflexible organisational and working arrangements within laboratories are summarised below.

INFLEXIBLE ORGANISATIONAL AND WORKING ARRANGEMENTS

Separate sample handling departments in each discipline within the same laboratory.

Prioritisation of hospital requests over GP tests.

Duplication of similar equipment across disciplines.

Assays retained in a discipline when they could be more efficiently done in another discipline.

Biochemistry and endocrinology process tests separately although common tests are available on the main biochemistry automated platforms.

Laboratory management ability to implement changes to improve efficiency is limited.

Expensive arrangements for test processing outside the 9 to 5 period, although the recent Social Partnership Agreement proposes changes to existing work patterns.

Funding disincentives include:

- Funding currently from hospital budgets with no mechanism to connect funding with activity volumes;
- Cumbersome process for replacing laboratory equipment; and
- Phlebotomy with some patients going to hospital to avoid paying a GP handling fee for taking a sample.

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Future healthcare models require new laboratory configurations

Current alignment of laboratories with accident and emergency units

The current hospital medicine laboratories support the existing configuration of hospital clinical services. The current structure of hospitals with departments identified as accident and emergency, together with supporting onsite laboratories is set out in Table 9.

This indicates that, in the present laboratory medicine system, laboratories have traditionally 'partnered' small hospitals with small clinical workloads and therefore also have small laboratory workloads. This fragmented distribution results in multiples of duplicated equipment and an overall increase in staff numbers.

The present distributed system of laboratory medicine is out-of-step with the long term direction of travel for future clinical services.

There are new and planned European Union directives which have a major impact on pathology including further working time issues. More specifically, for blood transfusion services, there is a requirement for all hospital blood transfusion departments to be accredited to ISO-15189 standards. Bearing in mind that most laboratories are not presently accredited, this is a significant risk to the current service.

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Table 9: Emergency Department – New Attendances 2005

No.	Hospital	Hospital Network	Lab Size	Attendances
1	UCH - Galway	04 West/North West	Large	52,188
2	Cork University Hospital	02 Southern	Large	50,095
3	Waterford Regional Hospital	01 South Eastern	Large	49,702
4	Regional Hospital - Dooradoyle	07 Mid Western	Large	48,157
5	Beaumont Hospital	10 Dublin North East	Large	44,258
6	Adelaide & Meath, Tallaght	06 Dublin Midlands	Large	43,754
7	Temple Street Children's Hospital	10 Dublin North East	Medium	41,560
8	St. James Hospital	08 Dublin South	Large	40,410
9	Mater Misericordiae Hospital	10 Dublin North East	Large	39,856
10	Our Lady of Lourdes, Drogheda	03 North Eastern	Medium	35,858
11	St. Vincent's Hospital Elm Park	08 Dublin South	Large	33,460
12	NCH, Tallaght	06 Dublin Midlands	Large	29,192
13	Connolly Hospital - Blanchardstown	10 Dublin North East	Medium	29,155
14	MRH - Mullingar	06 Dublin Midlands	Medium	28,928
15	Letterkenny General Hospital	04 West/North West	Medium	28,543
16	Wexford General Hospital	01 South Eastern	Small	28,115
17	Kerry General	02 Southern	Medium	27,922
18	St Luke's Hospital - Kilkenny	01 South Eastern	Small	27,028
19	Mayo General Hospital	04 West/North West	Medium	26,419
20	OLHSC, Crumlin	06 Dublin Midlands	Medium	26,354
21	MRH - Tullamore	06 Dublin Midlands	Medium	26,216
22	Sligo General Hospital	04 West/North West	Medium	26,175
23	St. Columille's Hospital	08 Dublin South	Medium	23,306
24	Naas General Hospital	06 Dublin Midlands	Medium	23,201
25	MRH - Portlaoise	06 Dublin Midlands	Medium	22,340
26	Mercy Hospital	02 Southern	Medium	21,245
27	Ennis General Hospital	07 Mid Western	Small	19,583
28	Royal Victoria Eye and Ear	08 Dublin South	Small	19,100
29	South Infirmary Royal Victoria	02 Southern	Medium	18,801
30	Louth County Hospital	03 North Eastern	Small	18,754
31	Cavan General Hospital	03 North Eastern	Medium	18,098
32	Our Lady's Hospital - Navan	03 North Eastern	Small	16,647
33	Our Ladys Hospital - Cashel	01 South Eastern	Small	14,627
34	St. Michaels Hospital D'Laoire	08 Dublin South	Medium	12,865
35	Mallow General Hospital	02 Southern	Small	11,406
36	South Tipperary General Hospital	01 South Eastern	Small	11,390
37	Roscommon County Hospital	04 West/North West	Small	10,972
39	Nenagh General Hospital	07 Mid Western	Small	9,434
40	Monaghan General Hospital	03 North Eastern	Small	7,812
41	Bantry General Hospital	02 Southern	Small	4,229
	Total			1,067,155

Source: Performance Monitoring Unit, National Hospitals Office, HSE.

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Future healthcare models point towards much more care being provided at, or closer to, home in primary and community care settings or in specialist regional hospitals for seriously ill patients. In particular, the minor urgent care in accident and emergency departments and routine planned care and outpatients is likely to be provided in local settings. Many of the tests in these areas, which are currently considered hospital tests, may in the future be primary and community tests, which will not necessarily require processing at a hospital laboratory.

There is potential for a substantial proportion of the currently estimated 13 million A&E and outpatient ordered tests to be requested in the future from a location outside of an acute hospital.

As and when future healthcare models for improving patient care are implemented, the associated hospital based laboratory medicine service will need to change to support such services. Not all current hospitals will meet the future healthcare models for acute hospitals. In the short and medium term, 'hot' laboratories will continue to be required wherever hospital based accident and emergency and critical care services are required.

One immediate and specific example of this is the gynaecological cytology screening programme. The workload is currently divided between 10 different laboratories and performs about 176,000 screens per annum. Turnaround times for this service are very variable, ranging from about 3 weeks at best to more than 3 months at worst. The Irish Cervical Screening Programme review makes recommendations on improving this service ⁸¹.

Clinical focus on core test processing and reporting

The combination of many sites with a strong discipline focus on test processing within 9–5 together with information technology limitations, limits the amount of clinical time available to further enhance patient care and undertake research and development.

⁸¹ Implementation Plan for National extension of Irish Cervical Screening Programme 2007-2010. Irish Cervical Screening Programme, May 2006.

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The Public Health and Food Safety Laboratories

We have reviewed the present circumstances in relation to the present Public Health and Food Safety laboratories, as expressed in reports that we have received ^{82 83}.

In relation to the food safety laboratories in Ireland, the review makes 18 comprehensive recommendations covering the framework, management, facilities and staffing, range of service and information sharing.

The recommended direction of travel is entirely in keeping with the proposed new system of service delivery for laboratory medicine. The review highlights, for example, the need for a:

- Unified multi-site network for a single, more client focused, integrated Food Safety Laboratory Service (FSLs) by integrating the organisation of the public health (microbiology) and public analyst (chemical analysis) laboratories;
- Responsible Health Service Executive director/coordinator; and
- Unified approach to reserved budgeting, training, specialisation, risk management, out-of-hours working, research and development, information technology and international links.

In relation to the microbiological reference laboratories in Ireland, this review is on-going. It does not set out to describe current services or formally list the present reference laboratories. It aims to redefine the service, the standards for such facilities, the organisms to be targeted, the latest list of notifiable diseases, the selection criteria for an appropriate reference laboratory service and the procurement process. In summary:

- Two kinds of clinical laboratory are recognised, 'primary' (front-line) hospital based laboratories and 'reference', where the primary laboratory is unable to carry out the analysis due to the rarity and complexity of the microbial agent, where detailed identification is necessary, for validation of initial analysis and for analyses that have significant public health dimensions;

⁸² Strategic Developmental Review of Health Board Food Control Laboratories. Report to the Health Service Executive, July 2004.

⁸³ Development of Microbiological Reference Laboratory Services in Ireland. Report of the Microbiological Reference Laboratory Group. DRAFT 3 – Work in Progress.

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- Some comments are made in the draft report about existing reference laboratories, for example, the National Virus Reference Laboratory, National TB Reference Laboratory, National MRSA Reference Laboratory, the Interim Salmonella Reference Laboratory and the E. Coli Reference Laboratory;
- Numerous recommendations are made for developing more reference laboratories. This is in relation to specific organisms, for example Neisseria, Treponema, Chlamydia serotyping, the detailed identification of Campylobacter species, the typing of Cryptosporidium species and Legionella; and
- The review also illustrated the dynamic nature of notifiable diseases, with 23 new diseases being added to the list in 2004, emphasising the need for any strategic planning to be flexible and responsive to the changing microbiology scene.

These two reports demonstrate that the natural affinity between clinical microbiology, within the 'hot' laboratory, and the clinical orientated public health reference laboratories, in contrast to the more natural 'gap' that exists with the Food Safety Laboratories due to difference in roles and responsibilities.

Following on from the review of benefits and risk of the present system, the next section considers an optimum model for laboratory services.

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Developing a new system

THE KEY MESSAGES

Developing a new system for laboratory medicine aims to further improve patient care through:

- Providing a better service to primary care through dedicated ‘end to end’ provision;
- Enabling additional input by laboratory medicine clinicians into patient care, training and research and development;
- Focusing hospital based laboratory medicine services on the urgent ‘hot’ tests required for the clinical activity of the hospital it serves;
- Using point-of-care testing appropriately; and
- Improving guarantees on turnaround times and quality through accreditation and efficiency gains.

The system creates a single framework to oversee the activity and responsibility of all the health related laboratory medicine services in Ireland.

The system combines the provision of test results and clinical interpretation via pathology clinical networks, utilising appropriate point-of-care testing, ‘hot’ laboratories for acute hospital patient care and primary care ‘cold’ laboratories.

The optimal laboratory medicine model for clinical services delivers on three levels:

1. A ‘near patient and local hospital’ level, whereby the system enables:
 - The responsible clinician to make timely, accurate clinical decisions for the patient, both urgently and non-urgently, in order to complete an initial diagnosis and then act appropriately to manage the patient’s condition; and
 - The responsible patient or carer to safely and professionally monitor their chronic condition.

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2. A 'regional hospital' level, whereby the system provides:
- 24/7 expert pathology services with input into the clinical management of the more complex patient, including having direct clinical responsibility.
3. A 'national' level, whereby the system provides:
- Appropriate clinical management of population and environmental health services and advice.

The Health Service Executive, in transforming services by 2010, has clearly identified the need to build sustainable capacity which provides easier access and better care and services for patients⁸⁴. There is recognition of the need to radically change the way services are organised and delivered.

We have developed a new system for laboratory medicine as follows:

- Overall national system for laboratory medicine;
- Regional pathology clinical networks;
- Clinical services model for laboratory medicine;
- Types of future laboratories; and
- Criteria for determining size and location of future laboratories.

⁸⁴ Health Service executive Transformation Programme 2007 - 2010

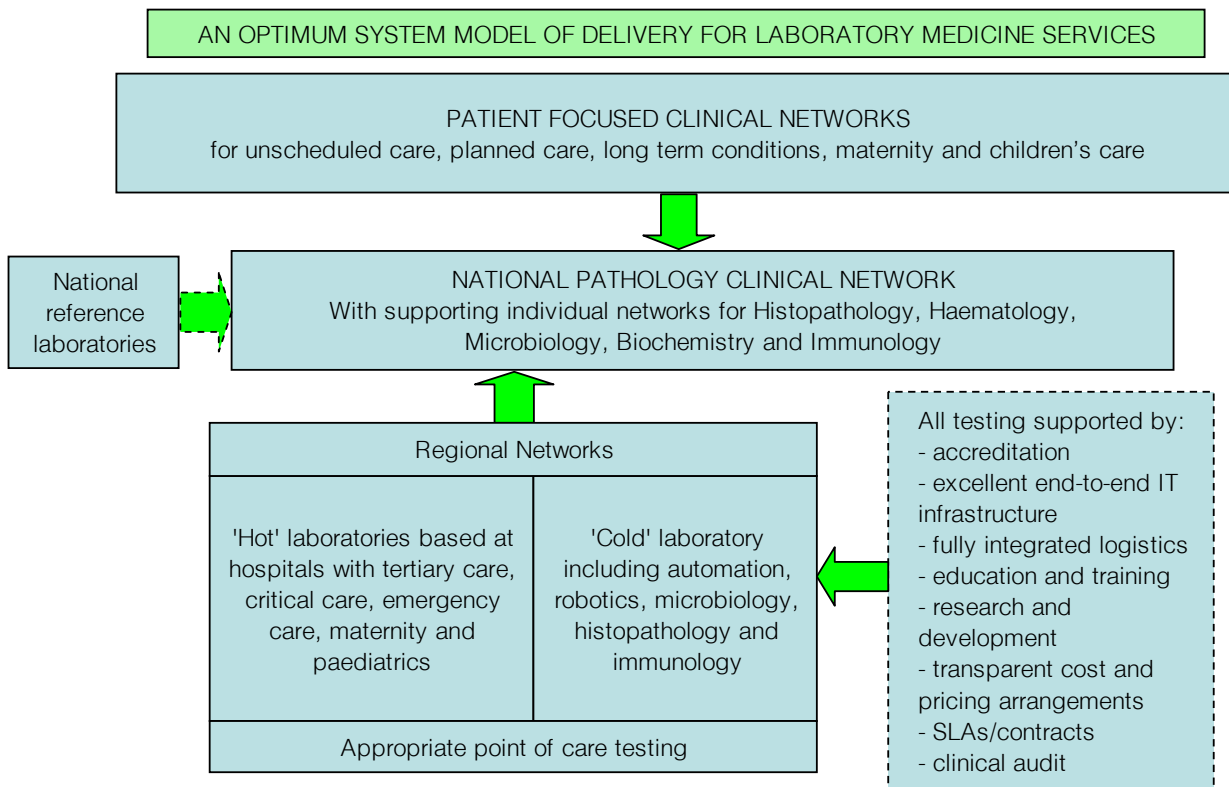
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The overall national system for laboratory medicine

At a national level, we have developed a laboratory medicine system as set out in Figure 6.

Figure 6: An optimum laboratory medicine services system



The development of a healthcare system focused around the patient, with more care being delivered at, or closer to home, or in specialist regional hospitals, will lead to major change in the requirements for laboratory medicine, with a major increase in tests undertaken in primary and community care settings, and a requirement for more specialist advice and urgent test processing to support hospitals with critical care and emergency care.

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This system combines clinical pathology networks serving the patient focused clinical networks, providing basic routine and advanced complex clinical laboratory medicine advice, together with a network of national reference laboratories, 'cold' laboratories, 'hot' laboratories at acute hospitals with secondary, tertiary, critical and emergency care, and appropriate use of point-of-care testing.

All testing in the system is supported by accreditation, excellent end-to-end information technology, European Working Time Directive compliant staff rotas, fully integrated logistics, transparent cost, pricing and service level agreements and clinical audit.

The system proposes bringing together all health-related laboratories ('hot', 'cold', clinical reference, public health and public analyst) under one national framework for laboratory medicine.

Pathology clinical networks

We identified that clinical networks typically cover a population of between 1 and 2.5 million people. Ireland currently has a population of 4.2 million which is projected to increase to 5.1 million by 2021. This suggests that there is potential to establish up to 3 new regional pathology clinical networks with each network covering between 1 and 2.5 million people. Such networks will support specific clinical networks. For example, gynaecological cytology screening is suited to being clinically managed and operationally processed on a central network basis linked into a national reporting and recall system.

Criteria for network development are based upon a system that provides the following advantages:

- Standardised and inter-connected IT solutions for the whole network, allowing for unique patient identification, electronic requesting and reporting from wherever the sample originates from;
- Improved efficiency and cost effectiveness across the network, with integrated logistics;
- Guaranteed future proofing with flexibility for change processes and increasing workloads;
- Availability of clinical laboratory medicine advice on a 24/7 basis, with larger groups of consultants allowing for sub-specialisation;
- Increased opportunities for research and development, staff training, continuing professional development and clinical audit;

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- Central management system with standard operating procedures and requesting protocols across the network;
- Whole network medical laboratory accreditation; and
- Ability to support the varying clinical needs of the hospitals and primary care in the network.

Pathology networks can provide the framework for developing modern proactive laboratory medicine services.

Meeting the needs of the users

The clinical view of 'near patient and local hospital' laboratory medicine

For the responsible clinician

In essence, the optimal laboratory medicine model mostly needs to provide a 'near patient and local hospital' service enables the responsible clinician, in conjunction with other complementary investigations, to make timely, accurate clinical decisions for the patient in order to complete an initial diagnosis and then act appropriately, either to:

- Reassure the patient;
- Control, stabilise and monitor the on-going clinical circumstance; or
- Deliver a satisfactory resolution and final clinical outcome.

In these circumstances, therefore, the clinical user is looking for a laboratory medicine service that satisfies clinical quality standards, based on a service level agreement that ensures:

- Sample collection is local, free at point of delivery and does not require travel to a crowded hospital out-patient department for phlebotomy;
- Test results, including point-of-care testing, are fully quality assured and backed by accreditation;
- The turnaround time for both 'hot' and 'cold' results is guaranteed from all laboratories, so that there is no delay that may potentially harm the quality of patient management; and

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- There is timely access to expert laboratory medicine advice, including guidance on the appropriate use of tests and the interpretation of the occasional result that is not understood by the clinical user or does not fit the clinical picture.

For the responsible patient or carer

- An appropriate level of training and understanding of test results has been received;
- That point-of-care testing is appropriate, accurate and quality assured; and
- Direct access to clinical pathology advice supports the feeling of independence.

For the 'regional hospital'

In addition to the routine services outlined above, a more advanced laboratory medicine service needs to be available to deliver the whole range of more complex laboratory medicine management, namely:

- Direct patient care and clinical responsibility in complex haematological, metabolic, infective and other conditions;
- Expert advice to support the clinical management of patients with more complex conditions, including seriously ill patients and in the critical care environment; and
- Histopathology advice and expertise into cancer and other multi-disciplinary meetings.

Education and training for the new system

There is a long established education and training system in Ireland leading to a career in Laboratory Medicine Services. It produces over 200 graduates each year to maintain the current trained scientific workforce, reported as 1,906.51 wte in our survey, as at September 2006. After graduation, there is no co-ordinated approach or reserved budget in laboratory medicine to support continuous professional development.

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The present primary curriculum appears to produce the right workforce to deliver current services, i.e. to support the ‘silo’ system, where it is the common working practice within the one laboratory to have multiple streams of single discipline activities, non-automated processing routines, duplicated analytical capacity and ad-hoc development of new tests and processes.

This is out-of-step with the new proposed system of service delivery. We recommend that the Health Service Executive, in order to discharge its responsibilities for facilitating education and training⁸⁵, and working in conjunction with the responsible education and training bodies, establishes a review to:

- Align future education and training with the future laboratory medicine model;
- Develop a national level retraining programme for present staff in post in preparation for the new working practices; and
- Introduces a national framework for a uniform approach to post-graduate continuous professional development, appropriately funded and specifically targeted at enhancing the individual’s skills, competencies to the benefit of the quality and range of service delivery.

In step with an update of education and training, we recommend that the Health Service Executive undertakes a study of the future workforce requirements, taking account of:

- The new proposed national framework for laboratory medicine;
- The new opportunities to drive forward the point-of-care testing, ‘hot’, ‘cold’ and ‘reference’ elements of the service;
- The new opportunities for more sub-specialty work and the mainstreaming of new analytical processes and technologies;
- The impact of full automation and robotics; and
- The impact of cross-discipline working.

⁸⁵ Interim Policy to the Board of the Health Service Executive, from the Education, Training and Research Committee, 2005.

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Research and development for the new system

All laboratory staff and services have a role to play in research and development, from the small laboratory unit to the large University departments.

The Health Service Executive has an explicit responsibility to facilitate research and development across the whole health service, including pathology. An interim policy framework was recently established to enable the Health Service Executive to move this agenda forward ⁸⁶.

With this objective in mind, we therefore recommend that the Health Service Executive incorporates the research and development function into the proposed national framework for laboratory medicine in order to ensure that:

- Working in conjunction with the responsible research bodies, there is a clear overall direction of travel for research and development programmes and that they are directly relevant to the advancement of both health care and laboratory medicine;
- There are no barriers to the integration of research and development programmes with front-line clinical and laboratory services;
- Any approved research and development funding is conditional and time-limited, i.e. dependent upon the quality of research outcomes, productivity and relevance to improving health care and Laboratory Medicine practices.

⁸⁶ Interim Policy to the Board of the Health Service Executive, from the Education, Training and Research Committee, 2005.

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Types of future laboratories

Point-of-care testing

It is recognised that point-of-care testing is still not integrated as a mainstream element of the laboratory services. However, there is significant potential for point-of-care testing to support the declared clinical strategy to manage many more patients at home, or close to home in the community and local hospital setting, as well as in certain situations in the regional hospital. It is therefore anticipated that appropriate use of point-of-care testing will expand significantly. All health service point-of-care usage will be integrated into the clinical pathology regional network.

'Hot' laboratories

There is a need for present hospital laboratories to examine the constraints to the streamlining of present working practices and to develop a targeted programme of change in line with the proposed new strategy. Such a programme would need to robustly address the particular issues of removing unnecessary individual practices between disciplines, of introducing cross-discipline working on a 24/7 basis and removing inefficiencies in the use of equipment.

In other words, 'hot' laboratories will need to refresh their approach to efficiency and productivity. Significant gains have been made through the adoption of appropriate automation⁸⁷ and the growing trend⁸⁸ in the implementation of lean thinking techniques⁸⁹ to improve efficiency and reduce error rates (Lean and Six Sigma) to create opportunities and capacity to seek new, extended roles within the new laboratory medicine system.

⁸⁷ Implementation of a modular pre-analytics system in the Autolab within the Central Manchester and Manchester Children's University Hospitals NHS Trust has cut the turnaround times for Accident and Emergency 'STAT' samples by up to 50% (reported in Medical Laboratory World magazine, 'Automation: Robolab', 1 February 2005, accessible from <http://www.mlwmagazine.com>).

⁸⁸ Robert L. Michel and Sylvia Christensen, '2006 Trends in Clinical Pathology Laboratory Management: Eleven Trends that Highlight Rapid Changes in Healthcare and Laboratory Medicine', Trend #9 Six Sigma and Lean Push into Pathology Laboratories. Dark Daily Special Report 2006, accessible from <http://www.darkdaily.com>.

⁸⁹ Examples at Broomfield, Lincolnshire, and Royal Shrewsbury hospitals in the UK (reported in Medical Laboratory World magazine, 'FiLM 2005: Lean and mean', 1 March 2005, accessible from <http://www.mlwmagazine.com>. FiLM is the annual Frontiers in Laboratory Medicine conference organised by the Association of Clinical Biochemists and The Dark Report).

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Notwithstanding, they will always be required wherever there is a hospital delivering acute secondary care, tertiary care, critical care, emergency care and complex surgery. The requirements of paediatrics and maternity will also need to be considered dependent on service models. Turnaround times for urgent and fast acute tests will typically be less than two hours with some performing a limited menu of tests in a 15 to 45 minute time frame ⁹⁰.

In terms of staffing, there will be a minimum requirement for 8 qualified staff to support the smallest of these laboratories while achieving European Working Time Directive compliance ⁹¹. At this level the staffing needs to be multidisciplinary.

Regional hospitals with much heavier 'hot' laboratory demands will require a greater staff complement. The service would also need sample reception and data input staff (the numbers are dependent on order-comms installation) with additional resources for extra requirements associated with any special clinical needs of the hospital. There will be variations in the size and complexity of these 'hot' laboratories across each pathology network.

'Cold' laboratories

'Cold' laboratories include the automation of routine blood sciences, plus blood transfusion, special haematology and biochemistry, microbiology, immunology, histopathology departments, with specialist tests (in some) and national reference laboratories (in some). In addition, some of these laboratories would have integrated research and development, and further education facilities.

Standard turnaround times for the automated test repertoire will be less than four hours from receipt of sample. The volume of tests being processed through 'cold' laboratories will support the development of service level agreements, protocols, laboratory audit, education and training, and research and development.

⁹⁰ These tests include blood gases, electrolytes, blood cell counts, coagulation times, cardiac markers and simple urinalysis. The results are primarily provided to the operating rooms, emergency department, intensive care units and the code team for medical emergencies where fast results are needed for acute care. Mayo Clinic USA, Clinical Core Laboratory Services <http://www.mayoclinic.org/labmed-pathology-rst/clinlabservices.html>.

⁹¹ Council Directive 93/104/EC. Official Journal of the European Community 1993; L307:18-24.

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These 'cold' laboratories would incorporate the primary care, GP and community laboratory medicine services for the network, subject to the mode of delivery decided during EU tender procedures and without compromising service levels to the GPs as a result.

One laboratory, working 24/7, and processing more than 50,000 tests per day, has identified the requirement for 38 wte staff ⁹².

Another service covering three hospitals in South Wales indicates that it requires 24 wte staff to process 920,000 functional requests per annum ⁹³.

From knowledge of existing 'cold' laboratories, it is estimated there will be a requirement for up to 48 technical, scientific and support staff to manage the automated section of a cold laboratory (see Table 10) processing 8 to 10 million tests a year, assuming order communications and electronic reporting is in place, dependent upon levels of robotics and degree of automation.

Consultant advice for the automated laboratory will be required from a consultant haematologist, consultant chemical pathologist or consultant clinical biochemist, consultant immunologist and consultant virologist. These have not been included in Table 10.

Table 10: Indicative staffing numbers and skill mix for automated section of a cold laboratory

Staff grade	wte
Principal Clinical Biochemist	2
Laboratory Manager / Deputy Manager	2
Medical Scientist (Chief) / Biochemist (Principal)	4
Medical Scientist, Chief (sample handling)	1
Biochemist / Medical Scientist (Senior)	10
Biochemist / Medical Scientist	15
Medical Scientist, Trainee	4
Medical Laboratory Aide (lab based)	10
Total	48

⁹² Stake your life on a LIMS, Peter Rees (April 2004) accessed at <http://www.scientific-computing.com/scwmaraapr04lims.html>.

⁹³ Automation: Robolab as reported within Medical Laboratory World magazine on 1 February 2005, accessible at <http://www.mlwmagazine.com>.

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Reference laboratories

Specialist national reference laboratories are required for cytogenetics, molecular genetics and public health microbiology, among others.

Specialist tests which have developed in current laboratory medicine departments in response to hospital clinical need or research and development activity, are part of a network laboratory repertoire, and can be made available to laboratory networks.

A reference laboratory may be part of a 'cold' laboratory or may be part of a larger 'hot' laboratory. This will depend on how the proposed new national strategy for laboratory medicine coordinates its approach in this area of its business.

Criteria for determining the size of laboratories

Key questions for this review include the criteria for deciding how many laboratories would be required for the current and future laboratory medicine workloads. These criteria assume that all laboratories are supported by the infrastructure outlined in the proposal for the whole system. The current workload is 58.2 million tests and requests, excluding point-of-care testing.

Point-of-care testing

A development plan for the judicious use of point-of-care testing will need to be developed as this supports the transfer of more care to home and local settings.

Specific criteria to consider in determining the usage of point-of-care include:

- Immediate diagnosis of an urgent condition;
- Impact in altering the quality of patient treatment (e.g. warfarin dosage, diabetic control);
- Reduction in GP, OP clinic, hospital and other contacts;
- Governance arrangements; and
- Value for money.

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'Hot' laboratories

'Hot' laboratories will vary in size, test repertoire and complexity according to the range of acute clinical activity in the hospital they are supporting. As a minimum, these laboratories will support every hospital location with secondary care, tertiary care, critical care, and emergency care.

There are good clinical reasons for limited acute microbiology assays being performed in some 'hot' laboratories in certain circumstances, as with biochemistry, laboratory haematology and blood transfusion. This decision is dependent upon the hospital clinical speciality, pathology consultant advice and circumstances surrounding service levels.

'Cold' laboratories

For these 'cold' laboratories, which may be integrated, we have separately identified the criteria for determining size from those for location.

Criteria for determining the number of 'cold' laboratories

We have identified the criteria in Table 11 as relevant in determining the number of 'cold' laboratories.

Table 11: Criteria for determining optimum number of 'cold' laboratories

No.	Criterion
1	Extent of alignment with current and future development of patient focused clinical services
2	Automatability of the workload across pathology disciplines
3	A minimum volume of 8 to 10 million automated tests per annum for each laboratory for optimum efficiency
4	Contingency and back-up / disaster recovery arrangements
5	Value for money and competition
6	Flexibility for future expansion

The rationale for each of these criteria is examined further below.

Extent of alignment with current and future development of patient focused clinical services

For current services, separate 'cold' laboratories could meet the need of the vast majority of the 18.5 million existing GP test referrals per annum.

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Future clinical models look to provide far more services locally. The majority of minor accidents and minor injuries currently managed in accident and emergency departments, together with some of the outpatient activity, may be undertaken in local settings with the supporting laboratory medicine tests being provided from the 'cold' laboratories and point-of-care testing. While we cannot be precise on the number of pathology tests which may in future be requested from primary and community care, it is likely to be more than half of the current 7 million outpatient tests processed from these areas in the acute hospital laboratories plus the current 18.5 million GP tests.

Automatability of the workload across laboratory medicine disciplines

A 'cold' laboratory will be suitable and appropriate for all the major laboratory medicine disciplines. There will be different levels of appropriate centralisation across disciplines. Large central facilities utilising total laboratory automation systems (with intelligent data managers) are already proven for routine high volume blood sciences requests.

For microbiology, there is commonality in automated test processing, for the higher volume viral serology, and hence many of these are suitable for centralisation in the automated section. Large central microbiology facilities can handle over 500,000 requests per year with proven demonstrable economies of scale and cost effective use of automated equipment. 50% of requests from GPs include microbiology assays. Operationally, to share common logistics, these microbiology facilities should be co-located with a 'cold' primary care laboratory medicine service facility.

A minimum volume of 8 to 10 million automated tests per annum for each laboratory

Currently the vast majority of the reported 18.5 million routine test requests originating from primary and community care could be processed in separate 'cold' laboratories.

Operational contingency arrangements

Operational contingency arrangements need to be considered in terms of whether a single automated 'cold' laboratory presents an unnecessarily high level of operational and strategic risk. High level risk assessment suggests that inevitably just having one 'cold' laboratory in a country presents a higher level of risk than having at least two 'cold' laboratories.

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Value for money and competition

More than one provider of 'cold' laboratories in the country may improve the competitive performance, particularly after the award of an initial contract. Careful consideration will need to be given to the potential advantages and disadvantages of awarding one, two or more contracts for processing routine tests.

Flexibility for future expansion

Implementation of the new laboratory medicine solutions would need to consider the potential for future expansion of the 'cold' automated laboratories to meet increasing year-on-year demand from primary and community care (10% ⁹⁴ per annum) and the potential for an initial increase of up to 30% due to high quality service provision.

However, once an efficient high volume automated laboratory facility has been established, such increases in volume do not require proportionate increases in staff, (except in the manual areas such as sample reception). Future planning for 'cold' laboratories should ensure that there is sufficient floor space, modular equipment platforms, and the most up to date Laboratory Information Management System and associated information technology systems are installed.

Proposal on the optimum number and location of 'cold' laboratories

Having considered carefully the factors outlined above, we would suggest, based on current volumes, there is an immediate case for up to three separate 'cold' laboratories for routine tests generated from primary and community care, with one to service Dublin, one the south and one the west.

We recommend that this is further tested in the proposed business case for automated laboratories.

⁹⁴ Report of the Review of NHS Pathology Services in England. Chaired by Lord Carter of Coles, An Independent Review for the Department of Health, UK, August 2006.

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Criteria for location

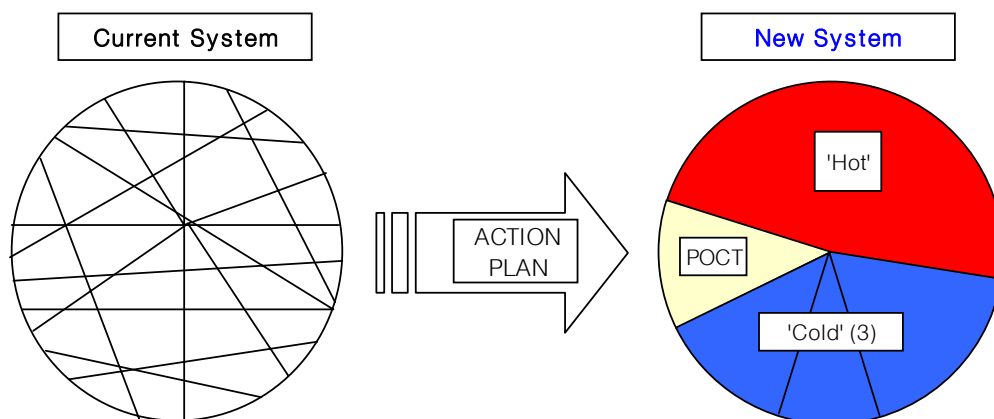
Location criteria to consider for the 'cold' laboratories include:

- Transport logistics and sample arrival time of transporting sufficient primary and community samples to the 'cold' laboratory;
- Cost effectiveness of the solution taking into account the benefits of synergy with co-location. This includes considering:
 - Opportunity to co-locate new 'cold' laboratories with an existing hospital on-site laboratory with high workload;
 - Relationship with 'hot' laboratories and point-of-care facilities within the laboratory medicine network;
 - Location of reference test facilities;
- Sufficient space for an appropriate new laboratory facility; and
- Current location of active academic, teaching and research and development, and potential for future development.

Current and future system of clinical laboratories

We have illustrated the change in clinical laboratories from the current to the new system in Figure 7.

Figure 7: From the current to the new



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Each local community will continue to have a laboratory medicine service, but not necessarily delivered by a local laboratory. The new system will be delivered by a combination of point-of-care testing, 'hot' laboratories co-located on each regional hospital, 'cold' laboratories, supported by logistics, automation and robotics to process the many millions of routine tests and a single network of coordinated reference / academic laboratories for clinical and public health purposes.

By the end of the transformation programme, there will be a 'hot' laboratory dedicated to serving each of the acute regional hospitals. Based on a regional hospital serving a catchment population of between 300,000 and 500,000, then, statistically, there will be between 8 and 14 regional hospitals with associated 'hot laboratories'.

The vast majority of routine tests will be processed by up to 3 new 'cold' laboratories.

Summary of impact of implementing the new system

We have brought together the key changes from implementing the new system in Table 12.

Table 12: Summary of the impact of implementing the new system on clinical services and supporting Laboratory Medicine Services

Aspect of service	Today	End Point of Transformation
HOSPITAL SERVICES		
Local hospitals undertaking acute emergency in-patient care	Many	None
Local hospitals, undertaking only non-acute community care	Few	Many as this will be the future core business for most existing local hospitals
Minor injuries & illness services	None	Based in each local hospital / centre
Accident & Emergency services	46	Few, possibly 8 - 14 only, sited in designated acute regional hospitals
LABORATORY MEDICINE SERVICES		
Number of 'hot' laboratories	42	These will be co-located with the 8 - 14 designated acute regional hospitals
Number of 'cold' laboratories	0	Up to 3 new highly automated laboratories, possibly provided by the private sector
All health-related reference & referral laboratories	Fragmented	Coordinated national network

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Aspect of service	Today	End Point of Transformation
Use of Point-of-Care testing	Limited, unplanned	Comprehensive, single national strategy for acute and primary care
Clinical pathology staffing	Often single-handed	Coordinated teamworking across clinical networks based in regional hospitals
Total staffing	3,007 staff (wte)	Substantial reductions. Absolute requirements dependent on new service procurement and workforce plans
Cost of HSE clinical pathology laboratory services	€328m	Substantial savings through market pricing, automation, changes in workforce profiles and procurement
Continuous professional development	Ad hoc	Integrated into service delivery plans
Turnaround times for reporting 'cold' tests	Very variable	Guaranteed
Turnaround times for reporting 'hot' tests	Guaranteed	Guaranteed
Laboratory Information Management System	Out-of-date	New national network system
Order communications and electronic reporting	Not available	As part of national network system
All laboratories fully accredited	No	Yes
Overall quality of test analyses	Satisfactory	Satisfactory
Service is 'patient centred'	No	Yes
Number of local phlebotomy /specimen collection points	Not enough	Many more
Need for tests to be unnecessarily repeated	Regularly	No
Specimen collection and delivery system	Very variable, unsatisfactory	Guaranteed

Specifically in relation to the laboratory medicine workforce there will be:

- An end to consultants working in professional isolation. Every consultant, wherever their base, will operate under the jurisdiction of a formal clinical network;
- A substantial reduction in the total number of the technical workforce needed in the future, as a result of the reduction in the number of laboratories and the gain in efficiencies and productivity made possible by the 'cold' laboratory concept;

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- Substantial changes in laboratory practices, with automated platforms requiring cross-discipline working and new patterns of work; and
- New opportunities in relation to laboratory medicine careers, professional development and research.

Having worked through an optimum model for laboratory medicine services, the next section sets out the action plan for delivering this.

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Action plan for implementing the new system

THE ACTION PLAN IS ALL ABOUT

Widespread engagement of the laboratory medicine staff in implementing a major programme of work, based on best practice, to implement new service models to support changes in the delivery of primary and secondary healthcare to improve patient focused care.

THE ACTION PLAN IS NOT ABOUT

Developing more of the same, maintaining the status quo, or leaving the issues for others to deal with.

The scale of healthcare change up to 2010 will be substantial and there is a big agenda of work to be delivered in laboratory medicine to support and ensure the achievement of the improvements in healthcare which patients anticipate and expect. This will mean clinicians, scientists and all staff engaged in laboratory medicine being prepared to challenge the current situation, to work differently, to ignore the confines of present disciplines, sites, estate and information technology, and to work towards implementing the changes outlined in this report, notwithstanding obvious pressures to maintain the status quo.

The action plan has been shaped to enable the engagement of staff at all levels and provides a framework for the Health Service Executive to take forward the active participation of as many staff as possible in the future development of laboratory medicine.

The action plan which follows sets out:

- A 3 month immediate work programme for the Health Service Executive;
- A further 9 month work programme for the Laboratory Medicine Services Steering Group;
- A first 12 months work programme for the pathology clinical network group and regional laboratory medicine services networks; and
- Medium term plans for years 1 to 5.

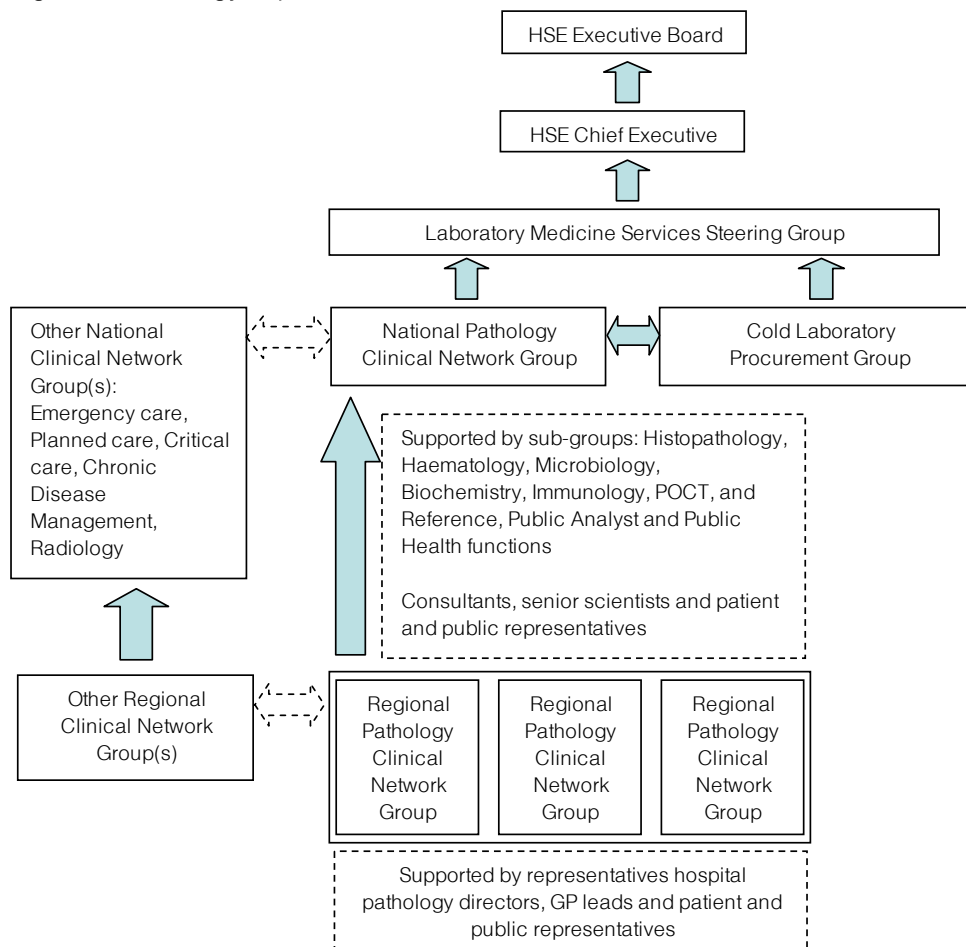
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3 month immediate work programme for the Health Service Executive

Establish an implementation structure for leading and directing the implementation work requirements for Laboratory Medicine Services. We have illustrated our suggestion for this structure as in Figure 8.

Figure 8: Pathology implementation structure



We suggest the following actions for implementing this structure in the first three months:

- Establish the membership of the Laboratory Medicine Services Steering Group;
- Establish the terms of reference and scope of the Laboratory Medicine Services Steering Group, giving due consideration to including reference laboratories and public health and public analyst laboratories;

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- Appoint a Programme Director for Laboratory Medicine Services to oversee the whole programme of change;
- Appoint a supporting programme manager working to the Director responsible for programme management;
- Establish the terms of reference and membership for the Pathology Clinical Network Group and specialist sub-groups for histopathology, haematology, microbiology, biochemistry, immunology and point-of-care testing;
- Establish the terms of reference and membership for the Regional Pathology Clinical Network Groups;
- Establish the terms of reference and membership of the 'Cold' Laboratory Procurement Group; and
- Establish a budget and secure investment to support the implementation of the proposed actions.

Subsequent 9 month programme for the Laboratory Medicine Services Steering Group

On the basis that the Steering Group will be in place within three months and the immediate work programme above implemented, we have suggested below the following work programme for the first nine months:

- Engage with and encourage the rapid development of the pathology clinical network group and the regional groups, in particular with attention to workforce planning, training and education needs, standardisation of equipment and procurement;
- Assuming the Health Service Executive is satisfied with the business case for 'cold' laboratories, approve the formal procurement;
- Ensure that the crucial importance of the unique patient identifier to laboratory medicine is recognised in the Health Service Executive's plans;
- Review services provided by all current hospital laboratories with a view to streamlining current working practices, setting a direction of travel towards routine cross-discipline working on a 24/7 basis and advising upon a national level retraining programme to support the objective;

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- Review services provided by reference laboratories and the recommended food safety laboratory service and integrate into a single framework;
- Review and develop a uniform approach and set of criteria for the designation, purpose and strategic deployment of national clinical reference laboratories;
- Commission through the clinical pathology network group and the regional networks, plans for the implementation of the laboratory information management system (LIMS) to other laboratories taking into account the proposed future system for laboratory medicine. In particular, review specifications to ensure integration capability with any new national electronic patient record system and order and reporting communications;
- Commission through the clinical pathology network group and the regional networks a three year programme for research and development including identifying infrastructure needs; and
- Commission the clinical network group and the regional pathology network groups to develop the strategic direction for new investment in laboratories and, in particular, the relationship between emerging and existing regional hospitals and their requirements for developing hospital 'hot' laboratories.

A first 12 months work programme for the national pathology clinical network group and regional laboratory medicine service networks

The work plan for the national pathology clinical network group includes:

- Establishing, leading and facilitating the regional networks;
- Establishing, leading and facilitating the specialist sub-groups for histopathology, haematology, microbiology, and biochemistry clinical value added services;
- Developing, with the Health Service Executive's proposed national standards group for clinical standards and clinical governance, and with the Health and Information Quality Authority, proposals for comprehensive accreditation covering clinical and administrative governance of all laboratories, including point-of-care testing. This should include:

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- Facilitating the accreditation process, for example maintaining a central, but easily customisable, repository of relevant information and operating procedures;
 - Setting the timetable for achieving accreditation;
 - Defining the costs of achieving this.
- Developing a comprehensive strategy for point-of-care testing covering services at home, in the community and in hospital. For health service point-of-care testing establish plans for training, quality, management, distribution logistics and communications including integration into the pathology networks and electronic patient records;
 - Developing a strategy to provide all patients with local access to phlebotomy and specimen collection services;
 - Working with the relevant regulatory bodies and training bodies to develop proposals which integrate future workforce skills and numbers with training needs;
 - Integrate specific national reference laboratories with the larger hospital laboratories;
 - Developing a programme for pathology research and development focused around both new and emergent technologies which support the delivery of patient focused pathology services; and
 - Fiscal plans including regional and national procurement, service level agreements, payment mechanisms, private practice and incentives to encourage appropriate referrals.

The work plan for the regional clinical networks includes:

- Network plans for integrating laboratory medicine into newly emerging patient focused emergency care, planned care, maternity and children's clinical networks and detailed care pathway mapping;
- Workforce proposals including education, training, and forward planning;
- Technical proposals including websites, information management systems, telemedicine, equipment, facilities and logistics; and
- Public Health plans including statutory provisions, communications, referrals to national and international reference laboratories, infection control, and scoping research and development requirements.

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Work programme for the 'Cold' Laboratory Procurement Group

The initial work plan for the 'Cold' Laboratory Procurement Group to report back on within 3 months includes:

- Review the procurement options for how an engagement process with the public and private sectors could be undertaken. For example reviewing options for public sector delivery, joint venture management arrangements and full service transfer;
- Review the impact of different regulations and taxes on the private sector in the procurement of chemicals, diagnostic kits, and reagents. Consider the potential impact on value for money;
- Review options for securing logistics expertise and/or capability to ensure that the revised care pathways and sample processing and reporting pathways are viable, sustainable and deliverable;
- Prepare an output based specification for a 'cold' laboratory and the supporting end-to-end service provision including sample collection, handling and sorting, analysis, post analytical and delivery of results; and
- Prepare a business case for investing in up to 3 'cold' laboratories.

Medium term plans for years 1 to 5

The pace at which the wider health service ambition for clinicians to drive best practice into their service delivery will in part be dependent on the speed at which laboratory medicine drives forward. With the pivotal role of laboratory medicine, there is an opportunity in the short to medium term to lead this agenda forward.

Medium term plans and objectives include the following:

- Delivering the initial regional networks plans;
- Pathology networks acting as a catalyst to frontline health professional at critical stages of individual patient pathways such as at home monitoring, initial diagnosis, routine testing in long term conditions, enhanced cancer diagnosis, key stages of critically ill patients, and hospital discharge;
- Revised education and training schemes preparing new staff for new roles;

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- Enhance the clinical role of laboratory medicine in emerging clinical technologies;
- Implementing regional network plans for laboratory medicine facilities alongside the evolution of regional hospitals;
- Decisions about whether to procure more 'cold' laboratories; and
- Rollout of a standardised end-to-end laboratory information management systems (LIMS) across the new networks.

In the next section, we look at the benefits to patients from the new system.

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The benefits for patients from the new system

The results of implementing the new system will be profound: much better laboratory medicine services for patients and clinicians; far fewer laboratories, a smaller technical and support workforce; and a more cost effective service.

Almost all patients accessing the health service require pathology tests of one type or another. In addition, many require the input of clinical pathology into their specialist care.

While the changes proposed to the organisation and delivery of laboratory medicine services are fundamental, patients should be assured by the Health Service Executive that:

- Current services will be maintained until the new system and services are in place and tried and tested; and
- The changes proposed are geared towards the delivery of a high quality, safe, sustainable, locally accessible and financially sound service.

Benefits which patients are entitled to expect the Health Service Executive to deliver from the new system include the following:

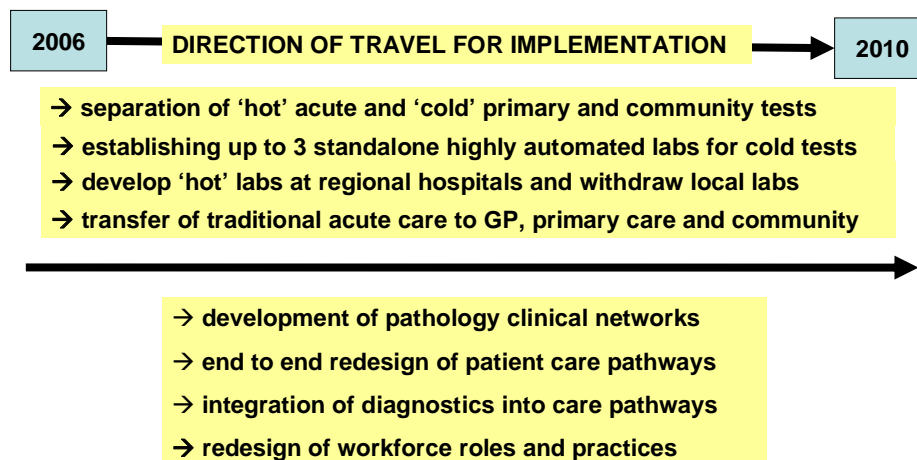
- Guaranteed and shortened turnaround times between a patient providing a sample and receiving test results;
- Confidence in the system with guaranteed quality of processing of every patient sample through full accreditation of all laboratories;
- Easier access for patients to provide samples locally, reflecting the often ignored financial overhead for the patient in providing a sample;
- A reduction in the inconvenience and discomfort which patients bear through fewer repeat tests;
- Through the patient's GP better access to specialist advice, when required;
- Simplicity, convenience and immediate decision making from access to comprehensive point-of-care testing;

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- Much more local sample provision and point of care testing in primary care and local hospitals rather than through current patterns of attendance for tests in A&E departments and outpatients at acute hospitals;
- For patients with long term conditions, better co-ordination and provision of samples for routine testing as part of self-management programmes;
- Easier access to expert clinical laboratory medicine specialist advice for patients with complex conditions; and
- For critically ill patients, immediate sample provision and testing available together with expert clinical pathology advice.

“The 2010 vision is to enable people to have easy access to high quality care and services”



This is a major programme of change for a key clinical service which straddles all six of the Health Service Executive’s priority transformation priorities for the period to 2010⁹⁵. We commend this report to the Health Service Executive and urge for its prompt consideration and establishment of a robust implementation programme to ensure the benefits are realised.

⁹⁵ Health Service Executive, Transformation Programme 2007-2010, December 2006.

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Appendix 1 – Terms of reference and Steering Group members

Terms of reference

The terms of reference of this review as determined by the Health Service Executive Steering Group are included below.

Statement of Requirements

Health Service Executive wishes to invite nominated firms to submit tenders to provide a written report recommending the most appropriate structure and arrangements for the delivery of laboratory medicine services required by the Health Service Executive across the full continuum of care including primary, community, secondary, and tertiary care.

Scope and Requirements of the Assignment

The Review will be all encompassing to determine the most appropriate structure and arrangements for the delivery of laboratory medicine services required by the Health Service Executive across the full continuum of care including primary, community, secondary, and tertiary care. The Review will provide recommendations in the context of current resource constraints, on:

- The timeliness, reliability, capacity and efficiency of current laboratory medicine services provided by or for the Health Service Executive, benchmarked against leading international practice and standards.
- The feasibility of and benefits to be gained from
 - service reconfiguration, innovation and modernisation,
 - involvement of the private sector.

The review will also provide a framework for the implementation of the proposed model or models of service delivery. In the event that reconfiguration entails a move to regionalisation of certain services, or for certain services to be provided in only a small number of locations, recommendations will be required on the criteria to use in determining size and location of the relevant services.

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Specifically, the Review will cover the following:

1. Review of current laboratory medicine services configuration in Ireland, identifying benefits and risks of the present system.
2. Review of leading local and international practice, including new and emerging technologies.
3. Review of developments in clinical services and the impact on pathology services.
4. Application nationally of evidence based, leading practice, having due regard to population projections and legislative requirements, to determine:
 - i. Optimum model for the provision of laboratory medicine services for acute hospitals with a focus on quality, operational efficiency, and patient convenience, to include capacity and size of laboratories.
 - ii. Optimum model for the provision of laboratory medicine services for primary, community and continuing care, including capacity of laboratory services required.
 - iii. Appropriate use of protocols in relation to utilisation of services at i) and ii) above and of clinical/laboratory audit to ensure optimal effectiveness of investigations and protocols.
 - iv. Appropriate level of access to diagnostics for primary, community, continuing, secondary and tertiary care within the context of the protocols referred to at iii) above.
 - v. Appropriate level of laboratory services for specialised services such as screening services (e.g. cervical), public health and public analyst services.
 - vi. Appropriate skill mix/staffing levels of laboratory personnel.
 - vii. Information system requirements including decision support, ordering, specimen tracking, reporting of results and audit.
 - viii. The role of Research and development in the context of the Health Service Executive requirements to develop and deliver optimum laboratory medicine services.
 - ix. Primary, postgraduate and continuing education requirements.
 - x. Clinical and administrative governance arrangements.

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Steering group members

Membership of the Health Service Executive Steering Group for the National Review of Laboratory Medicine Services is included in Table 13.

The steering group is responsible for agreeing the terms of reference for the review and for the overall direction of the review'. Teamwork was commissioned to produce a report on an independent basis.

Table 13: Steering Group membership as at 3rd October 2006

Name	Role on Steering Group	Designation
Tom Finn	Chairman	Assistant National Director, NHO
Donal Kelly	Project Manager	Contracts and Utilisation Manager, NHO
Dr. Sean Cunningham	Group Member	Consultant Biochemist, St. Vincent's Hospital
Dr. Julie Heslin	Group Member	Consultant in Public Health Medicine
Bernadette Kiberd and Orla Treacy	Group Member	Local Health Office Manager, North West Dublin and Primary Care Unit, PCCC, and Director of Primary Care PCCC Dublin/North East
Dr. Rob Landers	Group Member	Consultant Histopathologist, Waterford Regional Hospital
Chris Lyons	Group Member	Network Manager, North Eastern Hospital Group, Acute Hospital Services
Moss McCormack	Group Member	Manager, Strategic Planning and Performance Management, Dublin Midlands Hospital Group
Dr. Sean McGuire	Group Member	Advisor to Chief Executive Officer, Health Service Executive
Louise McMahon	Group Member	Network Manger, Dublin South Hospital Group, NHO
Dr. Eleanor McNamara	Group Member	Consultant Microbiologist, Cherry Orchard Hospital and St. James' Hospital
Tony McNamara	Group Member	General Manager, Cork University Hospital
Gerard O'Toole	Group Member	Immunology Laboratory, Mater Hospital
Pauric Reilly	Group Member	Laboratory Manager, Beaumont Hospital
Simonetta Ryan and Maeve O'Brien	Group Member	Principal Officer and Assistant Principal Officer, National HR and Workforce Planning Division, Department of Health and Children
Dr. Barry White	Group Member	Consultant Haematologist, St. James' Hospital

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Appendix 2 – Fact finding interviews

The following fact finding interviews (FFIs) were undertaken following review and agreement with the Health Service Executive Steering Group for the National Review of Laboratory Medicine Services.

Table 14: Schedule of FFIs

FFI No.	Date	Name	Designation
1	15 th August 2006	Gerard Boran and Miriam Griffin	Faculty of Pathology, Royal College of Physicians
2	15 th August 2006	Fran Thompson	Director of Information Systems, Health Service Executive North East
3	16 th August 2006	Don Mulahey	Head of Processing and Hospital Services, IBTS
4	16 th August 2006	Dr John O'Mullane	President, Association of Clinical Biochemists in Ireland
5	16 th August 2006	Dr Mary Hynes	Assistant National Director, Quality, Risk and Customer Care, National Hospitals Office, Health Service Executive.
6	16 th August 2006	Jacqui Barry O'Crowley and John Gibbons	Academy of Medical Laboratory Scientists (AMLS)
7	16 th August 2006	Dr Kevin Kelleher	Assistant National Director of Population Health
8	20 th September 2006	Prof John O'Leary	Professor of Pathology, Trinity College, Dublin.
9	20 th September 2006	Dr Eamonn Shanahan	Chairman, ICGP
10	20 th September 2006	Simonetta Ryan, Bernie McNally and Bernard Carey	Principal Officer, National HR and Workforce Planning Division, DoHC Chief Therapist Advisor, National HR and Workforce Planning Division, DoHC Assistant Secretary, National HR and Workforce Planning Division, DoHC
11	20 th September 2006	Jane Carolan and Dave Molloy	Acting Assistant National Director, Planning Monitoring and Evaluation, PCCC Environmental Health Advisor to the PCCC
12	4 th October 2006	Dr Sean McGuire and Bernadette Kiberd	Primary Care Advisor to the CEO, Health Service Executive Local Health Office Manager, PCCC
13	16 th October 2006	Seamus Dooley	Laboratory Manager, NVRL

PCCC – Primary Community and Continuing Care

DoHC – Department of Health and Children

ICGP – Irish College of General Practitioners

NVRL – National Virus Reference Laboratory

IBTS – Irish Blood Transfusion Service

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Appendix 3 – Laboratory site visits

The following fact finding visits were arranged for a sample of existing laboratories following discussion and agreement with the Health Service Executive Steering Group. It was never the intention to visit all laboratories.

The laboratory sites visited were divided into four main types:

- Large university hospital labs;
- Large general hospital labs;
- Medium sized labs; and
- Small multi-discipline labs (<8 wtes).

Table 15: Laboratory site visit schedule

Site Visit No.	Date	Hospital	HSE Laboratory Category
1	28 th August 2006	Our Lady of Lourdes, Drogheda	Medium
2	28 th August 2006	Letterkenny General Hospital	Medium
3	29 th August 2006	Roscommon County Hospital	Small
4	29 th August 2006	University College Hospital, Galway	Large University
5	30 th August 2006	Mid Western Regional Hospital, Dooradoyle, Limerick	Large
6	30 th August 2006	Mallow General Hospital	Small
7	30 th August 2006	Cork University Hospital	Large University
8	31 st August 2006	Mercy University Hospital, Cork	Medium
9	31 st August 2006	Our Lady's Surgical Hospital, Cashel	Small
10	31 st August 2006	South Tipperary General Hospital, Clonmel	Small
11	31 st August 2006	Waterford Regional Hospital	Large
12	1 st September 2006	St James' University Hospital, Dublin	Large University
13	1 st September 2006	Beaumont University Hospital, Dublin	Large University
14	4 th September 2006	Rotunda Hospital, Dublin	Medium
15	4 th September 2006	Our Lady's Hospital for Sick Children, Crumlin, Dublin	Medium
16	4 th September 2006	Midlands Regional Hospital, Tullamore	Medium

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Site Visit No.	Date	Hospital	HSE Laboratory Category
17	5 th September 2006	St Vincent's University Hospital, Elm Park, Dublin	Large University
18	6 th September 2006	Mater Misericordiae University Hospital, Dublin	Large University
19	6 th September 2006	Adelaide & Meath & National Children's Hospital (AMNCH), Tallaght, Dublin	Large

Note: Definition of laboratory size is based on the Report of the Medical Laboratory Service Group, October 2001 chaired by Liam Dunbar as by the Health Service Executive and provided to Teamwork.

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Appendix 4 – Document review

The following is a list of the documents provided by the Health Service Executive and reviewed as part of the context and background information for the National Review of Laboratory Medicine Services.

Table 16: Documents reviewed

Doc No.	Title	Author	Date
1	Development of Microbiological Reference Laboratory Services in Ireland	Draft 3 – Report of the Microbiological Reference Laboratory Group, Health Service Executive	2006
2	Comments re Job Plans for Consultants in Pathology and Royal College of Pathologists (UK) Documents	Sean Cunningham	2006, Sept
3	Distribution Register of Consultant Posts, Distribution of Pathologists by Former HB area	Comhairle na n-Ospidéal	2006, Sept
4	Distribution Register of Consultant Posts, Infectious Disease Posts by former HB area	Comhairle na n-Ospidéal	2006, Sept
5	Emergency Attendances(excluding return attendances at ED) January - August 2006	NHO	2006, Sept
6	Register of Permanent Consultant Posts, Pathology by former HB area	Comhairle na n-Ospidéal	2006, Sept
7	Register of Permanent Consultant Posts, Infectious Disease Posts by former HB area	Comhairle na n-Ospidéal	2006, Sept
8	Laboratory Services Review: Letter to Tom Finn; Haematology & Transfusion; General; Microbiology; Immunology & H and I; and Histopathology	Beaumont Hospital	2006, Sept
9	Rotunda Laboratory Services Review	Rotunda Hospital	2006, Sept
10	Nett issues to hospitals and Returns to IBTS, Jan-July 2006	IBTS	2006, Aug
11	Letter to Prof. Drumm re: Outsourcing of cytopathology backlog smears in the Republic of Ireland	The Irish Consultant Gynae-Cytopathologist Group (ICGCG)	2006, July
12	Comparison Of Red Cell Issues, Jan - May 2006 v Jan - May 2005	IBTS	2006, June
13	Implementation Plan for National Extension of Irish Cervical Screening Programme 2007-2010	Irish Cervical Screening Programme	2006, May
14	Division of Pathology, Cork University Hospital, Management Review 2006	Division of Pathology	2006, Feb
15	Report of the Review of NHS Pathology Services in England	Independent Review for the Department of Health	2006
16	Mater Hospital Work Outline for Pathology Service Improvement	Mater Hospital	2006
17	Hospital Blood Banks and Sites Supplied by the Authorisation Holder	IBTS	2006

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Doc No.	Title	Author	Date
18	Consultant Chemical Pathology/ Top Grade Biochemist Services	Comhairle na n-Ospidéal	2005, Dec
19	Draft POCT Terms of Reference, Interim/Standing Committee for Point-of-care Testing (POCT)	Cork University Hospital, Division of Pathology	2005, Nov 18th
20	Telemedicine and Telecare Strategy	The Telemedicine & Telecare Project Team (Commissioned by the Department of Health and Children and the Health Service Executive)	2005, Oct
21	A report on the Appraisal and Risk Assessment of the Pathology Laboratory Information Management Systems of the Cavan/Monaghan Hospital Group of the North Eastern Region, Health Service Executive	Sector Healthcare	2005, Aug
22	Cost/Benefit Analysis Report on Flexible Delivery of Pathology Services at Mater Misericordiae Hospital	Graine Connolly	2005, July
23	Servicing GP Needs Presentation	Tom Moloney, MMUH	2005
24	National Laboratory Information Systems (LIS): Procurement Project Update	NEHB	2005
25	Hazard Control Sheets Laboratory Risk Assessment		2005
26	Application for Accreditation	Clinical Pathology Accreditation Ltd	2004, Sept
27	Report on the Irish Cervical Screening Programme	Dr. Euphemia McGoogan	2004, July
28	Summary of Consensus Positions emerging from Meetings of the Roundtable Group, consisting of Biochemist, Medical Scientists, Health Service Executive and Department of Health and Children Representatives	Roundtable Group	2004, July
29	Strategic Developmental Review of Health Board Food Control Laboratories	Safe Food, DoHC	2004, July
30	Report on the National Laboratory Pilot Projects	Ursula Fox on behalf of the Joint Implementation Group	2004, Dec
31	Plan for the Strategic Development of Pathology Services	Southern Health Board	2004, Feb
32	Strategic Plan for the Development of Acute Hospital Services in Cork City: A Single Service for Multiple sites	Acute Hospitals' Planning Forum (AHPF)	2002, Nov
33	NHS Clinical Biochemistry: 'A Profession Under Siege', A Report on Consultant Staffing in NHS Clinical Biochemistry	Task Force established by the Association of Clinical Biochemists (ACB) and the Royal College of Pathologists (RCPATH)	2002, May
34	Irish Cervical Screening Programme: Cytology Laboratory Survey 2002	Irish Cervical Screening Programme Team (O'Reilly, M., Thornhill, M., Gallagher, J., Kelleher, K., & Cotter, S.)	2002
35	Report of the Medical Laboratory Service Review Group	Medical Laboratory Service Review Group	2001, Oct
36	Report of the Expert Group on Medical Laboratory Technician/ Technologist Grades	Expert Group on Medical Laboratory Technician/ Technologist Grades	2001, Feb

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Doc No.	Title	Author	Date
37	Analytical Review of Laboratory Services in the South Eastern Health Board Region (Staffing, Equipment and Accommodation Requirements)	Regional Department of Laboratory Medicine (prepared by Waterford Regional Hospital)	2000, Oct
38	Report of the Review on the Pathology and Laboratory Services within the North Eastern Health Board	A Review Group within the North Eastern Health Board, led by Dr. G. Day and Dr. R. Corcoran	2000, June
39	Towards a Regional Pathology Service: Report of Working Group	Working Group, Western Health Board	2000, May
40	A Strategy for the Control of Antimicrobial Resistance in Ireland	The Scientific Advisory Committee of the National Disease Surveillance Centre	2001, Apr
41	South-Eastern Health Board, Draft Report: Review of Laboratory Services (Version 1.1)	First Consulting Group	1999, July
42	Medical and Scientific Staffing of National Health Service Pathology Departments	The Royal College of Pathologists	1999, June
43	Pathology Services in the Midland Health Board Region	Committee on Pathology Services (Midland Health Board)	1998
44	Pathology Services in the Mid-West Region	The Mid-Western Health Board	1996, Mar



TEAMWORK

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