

## **Modernising Pathology: Building a Service Responsive to Patients**

**Submission from the Association for Clinical Biochemistry to**

**The Pathology Service Review Panel**

**January 2006**

### **Executive Summary**

- Clinical Biochemistry as a dynamic specialty recognises the need to continue to evolve new approaches to service delivery.
- Clinical Biochemistry is a paradigm for Laboratory Medicine
- The current service is demonstrably cost-effective.
- The current service provides significant added-value within these costs.
- The interfaces between primary/secondary/tertiary care are currently facilitated.
- Provision of access to laboratory services in the community should not be at the expense of the above points.
- Partnership arrangements will enable interchange of information and services.
- The preferred service model is a Disseminated Laboratory i.e. the community based testing is linked to its local hub laboratory for reasons of Clinical Governance and Risk Management. Laboratory Medicine should no longer be located in the secondary care sector. It should straddle primary/secondary/tertiary care services.
- Patient safety is paramount.
- Laboratory Medicine impacts on acute and chronic disease diagnosis, management and treatment. From this arises the ability to effectively deliver service and to develop meaningful policies and guidelines.
- Networking as required by Pathology Modernisation will enable effective implementation of a quality, safe, effective disseminated laboratory able to meet the needs of 21<sup>st</sup> century patients.

## **Introduction**

The Association for Clinical Biochemistry (ACB) is the professional association of practising medical and scientific Clinical Biochemists in the UK and also has an international membership. The ACB promotes the specialty of Clinical Biochemistry in the UK and internationally through scientific meetings, congresses, scientific publications and training. It also co-operates with the Royal College of Pathologists on issues concerning laboratory medicine including, examinations and continuing professional development. Investigation and use of diagnostic systems and the role of the profession in clinical care are promoted, informing appropriate health agencies in the UK e.g. Departments of Health in policy making.

### **1. Overall Vision**

Clinical Biochemistry needs to continue to develop to encompass new technology, a changing workforce and the increasing emphasis on access and patient choice, while remaining a patient-centred, knowledge-managed, context-specific service, that complies with quality standards that are fit for purpose, and that is provided by a multi-professional team, each of whom can demonstrate competence appropriate to his or her role. In addition as a Science based speciality we subscribe to the values of the scientist: to innovate, improve practice, increase knowledge and challenge established concepts and processes.

It should be noted that this document primarily addresses the provision of clinical biochemistry services, but the principles involved are equally applicable to other areas of laboratory medicine, and developments in clinical biochemistry need to be integrated and co-ordinated across the whole of laboratory medicine to provide the scientific support to inform diagnosis and patient management.

“With 60-70% of diagnoses based on pathology, NHS pathology services are vital for patients to get the services they need at the time and in the place they need them” (Pathology – the Essential Service: Dept of Health consultation document 2002). With this statistic in mind, the vision we propose is of high quality laboratory services delivered by networking existing clinical laboratories within a geographical area, linking community based laboratory testing through the Pathology Network to ensure clinical and fiscal governance and that patients receive comparable high quality services wherever they access them.

### **2. Developments Required to Deliver the Vision**

#### **2.1 Patient Centred: - equable, quality, ready access**

- Provision of clinical biochemistry services closer to the patient and/or faster turnaround of test results in appropriate clinical situations:
  - Effective use of point of care testing (volume and repertoire) in acute hospital settings, primary care, the community pharmacy, the workplace and the home.
  - Improved access to services by improving the availability of phlebotomy provision. In many cases (especially in chronic disease

management) a test is not required at the point of care, although the result is and the patient's overall experience is improved by being able to provide a specimen in advance of a clinic appointment at a place and time convenient to them, such that the result of the test is available for the clinic appointment [vignette 1]

- Matching of the availability (timeliness and repertoire) of clinical biochemistry services to optimal patient pathways e.g. provision of HbA1c monitoring of diabetes in the community enhances the control of blood sugar, giving better control of complications and avoiding the need to refer patients to hospital [vignette 1].
  - Greater involvement of clinical biochemistry staff in extra-laboratory activities and services e.g. provision of natriuretic peptide analyses in a central laboratory to rule-out patients suspected of having heart failure is much more cost-effective than sending them for echo-cardiography.
- Greater involvement of clinical biochemists in direct patient care, both through outpatient clinics in metabolic medicine and other clinical specialties and through proactive involvement in ward rounds, multidisciplinary meetings, and managed clinical networks. For non-medically qualified clinical biochemists adoption of Physician Assistant roles would enable unique expertise to be made more readily available at locations more convenient to the patient and their carers.
  - Provision of better information to patients through the further development and promotion of the 'Lab Tests Online' website (A web-site produced by the ACB and supported by the Dept of Health to give patients basic information about laboratory tests. In January 2006, the website had 100,000 visitors), and through the use of appropriate media for the preparation and distribution of patient-centred fact sheets on chronic disease management. It should be possible to create a mechanism for patients to directly access advice on their results and further investigations from appropriately qualified clinical laboratory staff.
  - Networking of Specialist services ensures best provision of expertise for clinicians and their patients.

## 2.2 Knowledge-Managed: - developing better services

- Increasing involvement of clinical biochemists in the formulation, adoption and implementation of evidence-based clinical guidelines and investigation protocols. Such protocols enable best-practice and aid resource management [vignette 2]. The laboratory can use IT to block requests which do not comply with evidence-based guidelines. In the University Hospital of Coventry and Warwickshire such an initiative has significantly reduced unnecessary requests for thyroid function tests.
- The contribution of "added-value" by clinical biochemists to reports, through clarifying interpretations, adding further investigations, etc. can result in better patient care [vignette 3] or enable intervention in acute life-threatening events [vignette 4].

- Contribution of clinical biochemists to national initiatives such as the Map of Medicine, Electronic Laboratory Handbook and National Guidelines on Investigation [vignette 5].
- Expansion and improved co-ordination of clinical audit activity on the effectiveness of clinical biochemistry investigations and services in defined clinical situations [vignette 1].
- Laboratory Medicine can effectively inform the development of clinical practice through research and development [vignette 6].

### 2.3 Context Specific: - laboratory investigations where and when they are needed

- Consideration needs to be given to the service requirements and quality standards for clinical biochemistry in a number of different clinical settings including acute medical care, scheduled medical care, chronic disease management, screening and case finding and self-monitoring. To ensure consistency of approach and access there needs to be improved agreement on issues such as reference ranges, analytical platforms, choice of methodologies and investigation protocols.
- In this context it may be possible/desirable to separate the generation of data (analytical phase) from the interpretation and management of the knowledge that arises from that data (post-analytical phase). The generation of data may be undertaken in the laboratory, the clinic, the workplace or the home and may be undertaken by NHS staff, the independent sector, a carer or the patient. However, connectivity of the generated data to a specialist knowledge management service and to the patient record is essential if the benefits of context-specific clinical biochemistry are to be realised.
- It is important to stress that current services in laboratory medicine span primary, secondary and tertiary care, and this linkage has considerable advantages. It means that hospital consultants and general practitioners have access to the same service and can share and discuss results as patients move between the three settings. It also means that laboratory consultants can assist primary care workers with information about patient referrals and can facilitate transfers between primary and secondary care in urgent cases [vignette 7]
- Co-operation between clinical services can be tailored to be patient-centred, the expertise of each contributing specialty being brought together to provide a high quality 'one-stop' service [vignette 8].
- Improved, flexible and responsive information technology and information management is an essential pre-requisite for the development of modern clinical biochemistry services. Making order-communications available improves a clinician's access to service and concomitant provision of disease orientated intelligent interfaces can minimise inappropriate and costly repeat testing. Hyperlinking to knowledge bases could aid clinicians' result interpretation.

- Inherent in these concepts is the benefit to patients in terms of safety, quality, risk management, clinical governance and resource management of a disseminated laboratory servicing the Health Community.

#### 2.4 Quality Standards: - best practice provision for patients

- “The NHS will work continuously to improve quality services and reduce errors.

The NHS will ensure that services are driven by a cycle of continuous quality improvement. Quality will not just be restricted to the clinical aspects of care, but include quality of life and the entire patient experience. Healthcare organisations and professions will establish ways to identify procedures that should be modified or abandoned, and new practices that will lead to improved patient care. All those providing care will work to make it ever safer, and support a culture where we can learn from and effectively reduce mistakes. The NHS will continually improve its efficiency, productivity and performance” [NHS Plan (2000) – NHS Core Principles].

- UK Clinical Biochemistry and Laboratory Medicine have led the world in the development of External Quality Assessment Schemes, which are fundamental to quality assurance in the clinical laboratory. The United Kingdom National Quality Assessment Service (UKNEQAS) has had a key role in improving and maintaining the quality of laboratory performance and participants in its schemes are based in all parts of the world. It is vital that any new arrangements for service provision incorporate such safeguards to maintain quality standards for the benefit of patient care.
- Existing quality standards need to be adapted and applied to clinical biochemistry services in the different contexts and settings described in the previous paragraph. Such standards should include minimum performance criteria and turnaround times and the adoption of uniform units of measurement, reference intervals and action limits. These standards should adopt a common template but with the detail agreed and accountable in the local context.
- Any site that provides a range of clinical biochemistry services is acting as a laboratory and should be accredited to internationally defined standards for the medical laboratory [ISO 15189] – such as those used by Clinical Pathology Accreditation (UK) Ltd.
- Any hospital or GP-based point of care testing [POCT] service should comply with the guidelines of the Medicines and Healthcare Products Regulatory Agency (MHRA) with oversight and training of staff under the direction of an appropriately registered expert healthcare professional from an accredited laboratory (i.e. the disseminated laboratory).

- Statutory guidance is required to define the quality standards required to perform POCT in the community, workplace and home. Some form of licensing system would seem to be appropriate, to cover operator training, quality control, trouble shooting and the arrangements for data interpretation and knowledge management. We suggest that these requirements could be a function of an Accredited laboratory servicing its sector.
- Competence assessment and an appropriate level of regulation is required for all healthcare professionals involved in the design, delivery and evaluation of laboratory medicine services. Adoption of 'A Career Framework for Healthcare Scientists in the NHS' is recommended with equivalent competence assessment for healthcare workers in the independent sector.
- It is essential that all professional staff, whether NHS or in the Independent Sector, should be regulated; a condition of remaining on the relevant professional register (GMC or HPC) is satisfactory participation in continuing professional development (CPD)

## 2.5 Pattern of Service: - reconfiguring service delivery

All clinical biochemistry laboratories have seen sharp rises in workload over many years. The table below shows the year-on-year increase in workload for the Clinical Biochemistry service in Shropshire. Workflow analysis, adoption of new technologies and changes to working practice have led to increased productivity yet the cost per request has remained stable.

### DGH Clinical Biochemistry Workload, Productivity and Costings 1999-2005

	1999-2000	2000-2001	2001-2002	2002-2003	2003-2004	2004-2005
<b>Workload (sets)</b>	749,141	833,632	917,227	1,036,800	1,192,405	1,192,405
<b>Change (%) compared with previous year</b>	10.4%	11.3%	10.0%	13.0%	15.0%	20.2%
<b>Productivity (sets/WTE)</b>	23,722	25,026	24,951	26,530	29,885	34,712
<b>Change (%) compared with previous year</b>	8.7%	5.5%	0.0%	6.3%	12.6%	16.1%
<b>Total budget (£ M)</b>	1.27	1.28	1.62	1.80	1.91	2.15
<b>Change (%) compared with previous year</b>	11.4%	1.0%	26.6%	11.3%	6.1%	12.6%
<b>Cost/request (£)</b>	3.73	3.44	4.03	4.06	3.85	3.99

Most recently, the most rapid rise in workload has originated from the primary care sector, to the extent that for many laboratories primary care represents the source of more than 50% of the workload. For example, in 2003/04 there was an average 18% increase in workload from primary care, with the greatest increases occurring in those tests linked to the targets in the General Medical Services contract. Whilst this changing pattern of work reinforces the role of clinical

biochemistry as the linchpin of chronic disease management it also brings challenges for there has been limited success for laboratories in obtaining reimbursement from Primary Care Trusts for this additional work, so contributing to marked pressure on most laboratory budgets. (2)

- To ensure consistency of quality, clinical governance and management of risk, consideration should be given to the inter-relationships of providers. Within a Health Community consistency and accountability would be best delivered by adopting an expert 'hub' with linked distributed 'spokes', resulting in a disseminated laboratory within the Health Community.
- Retaining the current staff expertise is essential for continuity of current secondary and tertiary care. Some re-location and re-training of current staff to work between or within the primary care sector is possible. Development of new roles consistent with the Health Care Scientist Framework will facilitate dissemination. Care must be exercised to ensure the critical mass of competent staff is maintained in the expert hub to permit provision of an appropriate 24/7 service for acute medical, surgical and trauma admissions and patients being cared for in intensive care and high dependency units.
- The proposed disseminated laboratory should be responsible for laboratory medicine provision within a geographical area across primary, secondary and tertiary care. To be effective the laboratory medicine service should no longer be confined, as currently, to the secondary care sector, but should straddle all sectors.
- Other staff groups: nursing, PAMs, pharmacists etc could be used to deliver analytical/interpretive aspects, but for reasons of patient safety, should be accountable for these elements to an appropriately registered and qualified member of the laboratory network staff.
- To achieve new models of service, staff must be appropriately trained and re-trained. Independent Sector providers should contribute to the trained staff pool
- There is currently sufficient capacity in NHS laboratories, but at evenings and week-ends this capacity is under-utilised. Changes in patient access to services outside their working hours could harness this with minimal extra cost.
- Efficiency is readily demonstrable against absorption of the increased workloads in laboratories, currently ~10% pa, without increased capital or staff revenue costs. However this efficiency rewards poor requesting practice, lack of access to previous work and protocol driven investigation. Effectiveness of the service would be enhanced by the adoption of disease investigation linked order-communications. These offer the opportunity to challenge atypical requesting and offer educational feedback. Such systems are currently under-developed and unevaluated.

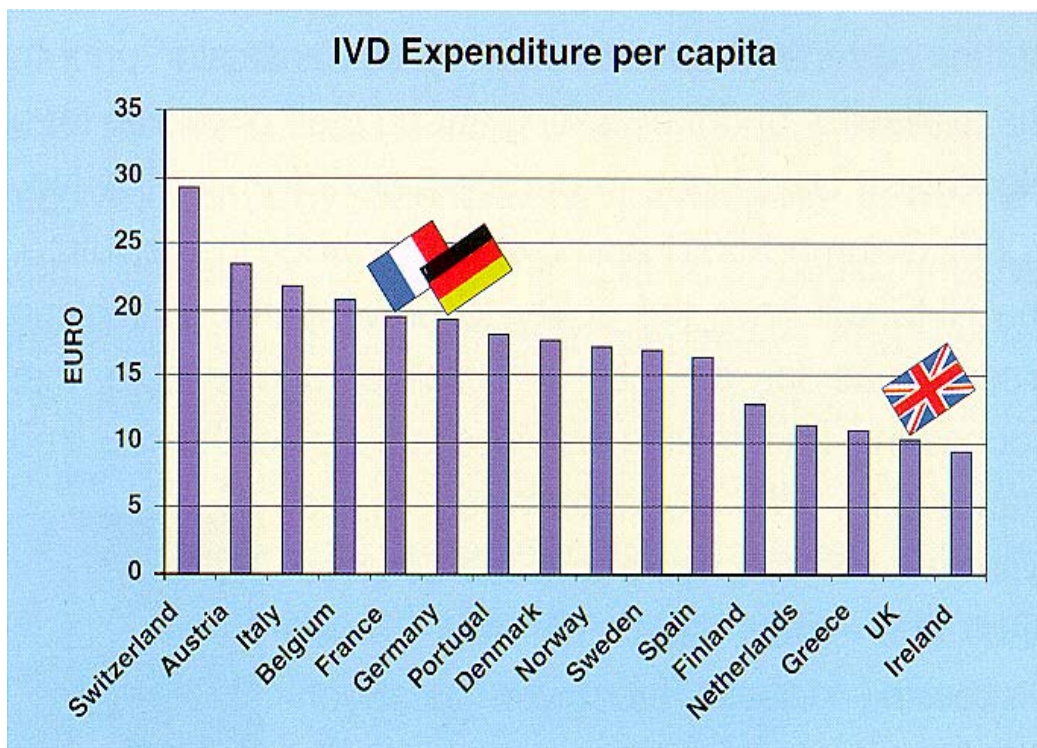
## 2.6 Economics: - value for money

- The Association has also worked on international benchmarking, and organised a symposium at a recent international conference to look at aspects of service in the UK, Australia and the USA. One of the most powerful lessons from that exercise was the difficulty of international benchmarking, as it is extremely difficult to ensure like-for-like comparisons between different health systems, different case mixes, different staffing structures and approaches to laboratory organisation. However, a striking finding was the close similarity in basic test costs across the three systems, implying that the UK is at least as efficient as other health economies in provision of testing:

	UK	USA	Aust
Cost per core chemistry test (USD)	0.89	0.87	0.88
Cost per full blood count (USD)	0.79	0.87	1.18

The UK service costs incorporate a full interpretative service across primary, secondary and tertiary care.

**That the UK provides highly cost-efficient Laboratory Medicine services is illustrated by the EDMA data from 2004 below. It is important to realise that this incorporates full clinical advisory/intervention as an integral part of the service.**



- Review of the claimed and actual economic benefits/disbenefits of existing Pathology Networks should be considered to determine how best to proceed.
- The collection of systematic reviews on Point of Care Laboratory Testing by the US National Academy of Clinical Biochemistry [www.nacb.com] found little evidence for impact of POCT on outcomes. As such devices have high revenue consequences there is a need for a critical economic assessment of the effect of options around patient choice for such testing on the NHS budget.
- The Independent Sector should be viewed as providing additional resources: staffing as well as capital. It should not be a drain on NHS resources.

## 2.7 Partnerships: - new service delivery approaches

Perhaps the greatest strength of the provision of Laboratory Medicine in the UK compared to almost any other country in the world is that it is ‘joined up’. NHS laboratory services, which comprise analysis and full interpretive reporting and clinical liaison, are provided in an identical fashion to patients and the public from primary (including community care), secondary, tertiary and sectors. This allows for consistency of quality and for connectivity of laboratory information for the individual patient as he/she moves between the different care sectors.

There is clearly scope for involving more stakeholders in the provision of Laboratory Medicine services to take advantage of their individual strengths in the quest for greater quality and value for money. The Association recognises that a ‘one size fits all’ model of Laboratory Medicine is not appropriate to modern healthcare. However, the Association believes that it is essential that any moves towards greater diversity of stakeholder involvement must be done in partnership with the NHS in order to preserve and enhance the current ‘joined-up’ nature of laboratory services. Breaking up the current system by allowing new stakeholders to ‘cherry pick’ sections of the service for independent provision may result in efficiency gains in parts of the service but it also risks a loss of overall quality through deterioration in integrated laboratory service provision.

There will be many ways in which stakeholders can work in partnership to improve quality and/or value for money. Four examples are given below:

- Partnership within the NHS. The creation of Laboratory Medicine networks between existing NHS service providers allows for economies of scale in purchasing, harmonisation of reference ranges and communication systems and the rationalisation of specialised services and expert knowledge. The Association strongly supports the ongoing development of Laboratory Medicine networks across the UK, including the disseminated laboratory model referred to elsewhere in this document.
- Partnership with the diagnostics industry. The diagnostics industry has considerable international experience of Laboratory Medicine from the perspective of equipment, consumables and logistics. This managerial and organisational experience is increasingly being used in partnership with the

NHS to bring about imaginative solutions, including the Managed Service Provision described in Vignette 9. The Association strongly supports increased partnership working with the diagnostics industry, and wishes to see implementation of the recommendations arising out of the Health Industry Task Force. Such models are being adopted through Pathology Modernisation strategies and are being shown to be effective [vignette 9].

- Partnership with Community Pharmacies. The Association recognizes that the quality of POCT devices has improved to the point at which their use may increasingly be devolved to a variety of settings including the community pharmacy. However, three major areas of concern remain for the Association, which may be resolved by partnership working with the NHS laboratory service. Firstly, the training and accreditation of staff who use the POCT devices and the quality assurance of the POCT service provided must be improved in the interests of patient safety. Secondly, the consistency of the POCT result with the corresponding laboratory result must be established and the POCT result should then find its way into the patient record. Thirdly, the interpretation and follow-up of abnormal POCT results would benefit considerably from close working between the community pharmacy and the NHS laboratory including the joint use of evidence-based protocols and guidelines. A model of community access through Boots pharmacies and subsequent central laboratory confirmation for Chlamydia screening in the North-West is a model of the hub and spoke type arrangements referred to in section 2.5 [vignette 10].
- Partnership with the independent sector. In the UK the independent sector currently has a relatively small percentage of the Laboratory Medicine workload. This is in contrast with the situation in many other countries where the independent sector has developed expertise in logistics and the management of laboratory services including customising services to meet the needs of individual users. The Association can see clear benefit in harnessing the skills and experience of the independent sector to improve the management and delivery of laboratory services through partnership working. For example, the independent sector could take a lead role in Managed Service Provision (see Vignette 9) in an NHS Trust or laboratory network.
- Development of a situation where the management of the complete (joined-up) Laboratory Medicine service is no longer located in secondary care sector but services all health care sectors and thus managed as a stand alone NHS service is a logical progression of networked laboratories providing a disseminated service.

We would submit that from these considerations that the following points require consideration:

- Co-operation between public and private sector, whether the Diagnostics industry, the Independent sector, or both, in delivering analytical service models within a Health Community will yield best quality for patient care.

- Analytical information, wherever generated, should be of sufficient quality that the results may be safely interpreted by an appropriately registered, competent practitioner.
- It is essential that there is consistency of data information across providers as it is inevitable that patients will move between providers. Consistency in the use of tests and the interpretation of results will lead to consistency of outcome. Without it, the incidence of repeat testing will escalate and there will be the potential for misinterpretation and consequent harm to patients. International guidance on the calibration and reporting of haemoglobin A<sub>1c</sub> results (used to monitor diabetes) from expert bodies has stopped the confusing scenario of GPs served by more than one laboratory receiving different values dependent on which laboratory processed the specimens. The test now has standardised values which simplifies monitoring.
- Public sector partnerships should be established with equipment suppliers across a Health Community. This will have the benefit of enabling significant cost-efficiency, standardised measurement of laboratory medicine parameters, future-proofing and potential for added value.
- Independent sector providers must operate to the same accreditation, training and liability standards as the NHS, these frameworks are required of the NHS as safeguards for patient safety.
- Accountability for the components of service delivery needs to be clearly established and adhered to.
- Costs, savings, liabilities, strategies between partners should be clearly defined.

## 2.8 SWOT analysis of current Clinical Biochemistry services in the UK

### Strengths

- Cost-effective service as currently configured.
- High value-added knowledge based advisory/intervention.
- Quality services independently accredited.
- Integral part of delivered medical services.
- Effective acute interventions in metabolic disorders.
- Effective policy, protocol and guideline development locally and nationally.
- Highly qualified staff enabling delivery of effective services.

- Effective delivery of clinical biochemistry services for long-term, chronic disease management

### Weaknesses

- Inadequate IT structure.
- Service efficiency limited by inadequate specimen logistic systems
- Insufficient trained staff to enable dissemination of analysis into the community.
- Lack of agreed quality and governance structures.
- Payment by Results tariffs are untested.
- Lack of enforceable guidance for Point of Care Testing
- Unclear how provider inter-relationships will operate.
- Under-developed and untested order-communications

### Opportunities

- More patient accessible services.
- Effective disseminated laboratory providing equivalent standards to current service.
- Greater involvement within the community.
- Development of greater multi-tasking roles for all staff
- New partnerships delivering new service provision models.
- Creation of geographical area-wide managerial structures for managing risk and Clinical Governance.
- Engage the under-utilisation of current equipment provision by changing patient access.

### Threats

- Service fragmentation resulting in loss of current integrated service delivery.
- ‘Cherry-picking’ by the Independent Sector undermining the less attractive, to them, but necessary elements of the service.
- Risk of different/inadequate skills being applied to analysis resulting in errors.

- Inadequate knowledge base resulting in inappropriate/wrong interpretations and consequent incorrect/dangerous intervention or lack of it.
- Increased costs for service provision through inappropriate testing with point of care devices, or duplication.
- Loss of skilled workforce in the face of perceived threatening change.
- Fragmentation leading to inaccessibility of samples for subsequent testing e.g. rubella testing in patients' samples in early pregnancy and a rash.
- Inappropriate or inadequate funding models.
- Poorly informed Commissioning.
- Inappropriate implementations could lead to financial settlements to patients for failure to deliver 'best practice'.

We believe that there is an opportunity for radically changing patient access to Laboratory Medicine services that can build on the current highly professional, cost-effective service. We support the creation of a framework that can harness these attributes, though they are a significant challenge. We advocate the current structural barriers being overcome to enable equitable service provision, wherever and however it is delivered.

## Vignette 1. Primary Care: Improving Diabetes Services

Diabetes causes a huge burden on the NHS. While Type 1 insulin dependant diabetes presents acutely, maturity onset Diabetes (Type 2) is insidious, damaging many body organ systems irreparably before diagnosis. Further once detected Diabetes requires tight control of plasma glucose (blood sugar) levels. In addition there are many people unaware they have Diabetes: 'The Missing Million'.

**Detection:** Patients may present with symptoms to their doctor. These can be vague and unless a blood sample is taken to check their glucose they may be missed. One initiative between Southport and Ormskirk Hospital Biochemistry Laboratory and Southport and Formby PCT found that enquiring of the laboratory computer database for abnormal plasma glucoses from hospital, out-patient and primary care requests enabled GP Diabetes leads to check whether their patients had been further investigated. Following piloting it was determined that as many as 100 additional new patients per annum would be identified across the PCT utilising this approach.

Currently diagnosis requires a fasting plasma glucose to be above 7.0mmol/L, with those with a value of 6.1-6.9mmol/L inclusively requiring an Oral Glucose Tolerance Test (OGTT). Across Primary and Secondary Care, an agreed protocol requiring a fasting venous plasma glucose before an OGTT is performed has ensured those already with Diabetes are not delayed in having their condition dealt with, that those with clinical symptoms, but are in fact normal are reassured and that only those requiring further investigation receive it.

**Monitoring:** Many patients are fortunate enough not to require frequent plasma glucose monitoring. However for those that do a large variety of glucose meters are on the market. Review of patient meters shows a variety of meters of different vintages used by in a variety of ways to yield numerical values for the glucose, which are used for day to day management. Drop-in clinics with laboratory staff supporting Diabetic Nurses to review techniques and provide quality control checks has helped ensure patients achieve the goal of effective day-to-day glucose control by ensuring correct use and meaningful values. In Bradford initiatives have shown that ready availability of HbA1c (a marker of long-term glucose control) in the community further reinforces control. The laboratory has supported the network to ensure comparability of results across the Health Community.

**Access:** A general approach to improving services for patients with chronic diseases where key laboratory tests are needed at every clinic visit to assess the state of the disease and response to treatment is to enable patients to have blood specimens taken a week in advance of the appointment, so results are immediately available at the clinic visit. This requires improving access to phlebotomy, so patients can have samples taken at a time convenient to their schedules. In Shropshire, this is being achieved through primary care centres, and also by the provision of a phlebotomy location in the centre of town, so office workers and shoppers can drop in without needing to attend hospital or primary care surgery. In one Birmingham acute Trust, patients attending Diabetes clinics arrive 30 minutes before their appointment with the doctor. A blood specimen is collected from a finger prick and a series of biochemical markers of glucose control and cellular damage which leads to the development of

complications are measured by laboratory staff in a satellite laboratory in the clinic. 'Real time' values are then available to the diabetes specialist at the time of consultation

Points: Cross care sector co-operation identifies patients, agreed protocols maximise effort on required patients

## Vignette 2. Policy: Clinical Investigation

Sub-arachnoid haemorrhage (SAH) is a bleed in the brain due to a weakness in the walls of the blood vessels (aneurysm). It is rapidly fatal in about 35% of patients or causes them to be severely damaged. Of the remainder around 40% will suffer a re-bleed, resulting in death or severe debility. However early detection and intervention can mitigate these dire outcomes, indeed some patients can literally be saved.

In expert hands with state-of-the-art Computed Tomography (CT) scans up to 98% of SAH can be detected. However patients do not present to such centres, they go to their local hospital which will not have the calibre of CT equipment nor the expertise to detect the minor bleeds; patients can present several days post-event when the blood can no longer be seen on CT, or be in the minority of cases where CT, no matter how good, cannot detect the bleed.

Classically a lumbar puncture of an SAH patient will yield cerebro-spinal fluid (CSF) that is yellow in colour due to blood breakdown, instead of its usual clear colour. Advice from the Royal College of Radiologists is that in clinically suspicious patients with negative CT, this procedure should be performed. This inspection until recently was done visually.

Investigation by a group of Clinical Biochemists demonstrated that this procedure was insensitive and operator dependant with the result that false-negative reports were frequent. This disadvantaged those very patients most likely to benefit from early intervention as they would have the lowest amount of the yellow colouration.

A co-operative review from six UK centres gave nearly 800 well-documented cases with known outcomes. This resulted in the production of clear criteria for instrumental spectrophotometric measurement of the yellow colour minimising the risk of false-negatives and also false-positives as there is a low, but definite risk of stroke associated with the further interventionist investigation.

This instrumental technique was reinforced by the simultaneous development of a Quality Assessment Scheme to enable laboratories to determine their performance. From this work has come evidence to show that spectrophotometry, not visual inspection, is the reliable method for detecting CT-negative SAH. This advice has been promulgated through the Association for Clinical Biochemistry, The Royal College of Pathologists and is on-going through the UK National External Quality Assessment Scheme. The review group continue to present data in the scientific literature to ensure as many professionals as possible are aware of the evidence.

The consequence is that the patients most likely to benefit from intervention can be identified at their local hospital and those appropriate for further investigation and intervention identified and transferred to their tertiary referral centre, enabling saving of life and debility.

Points: knowledge-base, co-operation, patients lives saved, decrease NHS resources used in suspect patient group

### Vignette 3. Primary Care: Laboratory Generated Clinical Advice

General Practitioners (GP) are making increasing use of laboratory services due to the GMS2 contract. Even so this still only accounts for around 5% of their activity. Consequently while there are some conditions in which the changes to be expected in laboratory parameters are familiar, they do not have such awareness of what to them are rare and unusual presentations, though these are familiar to specialists in Laboratory Medicine who encounter them more frequently. The result is that every laboratory Consultant frequently receives calls from GPs seeking advice on result interpretation, further investigation, referrals and treatment. It is no surprise therefore that laboratory surveys of GP service satisfaction typically receive strong support for their interpretative services, this is reinforced by CPA (Accreditation) surveys, which are an integral component of the laboratory inspection process.

Knowledgeable clinical laboratory staff who are appropriately registered and qualified are ideally placed to add additional tests to the original request based on GP provided clinical information and results of requested tests. This can more rapidly identify serious disease e.g. myeloma.

To aid GPs in their clinical decision making Clinical Biochemists are expected to add clinically meaningful comments, advice and interpretation to their reports. This aspect is assessed by CPA. Work conducted in Hull on advice given by the laboratory Consultant regarding thyroxine replacement therapy showed that there were 22% fewer patients under-replaced with thyroxine, improving patient well-being and indicating that GPs do respond to the interpretative/advisory component of the Laboratory Medicine service.

Points: added tests help patients get earlier interventions improving the opportunities for diagnosis and improved prognosis; Advice/interpretation assists GPs to make the best decisions for their patients whether it be for diagnosis, further investigation or part of on-going treatment.

#### Vignette 4. Acute Medicine

A 79 year old man, Mr H, with known Chronic Obstructive Pulmonary Disease was admitted to hospital due to breathing difficulties. His admission bloods showed a low serum sodium. He had a chest infection, which was assumed to be the cause of the low sodium. However despite successful treatment of the chest infection his sodium got worse. The laboratory Consultant was asked to review and advised further investigations and a review of his medication. It was agreed that his proton pump inhibitor medication be changed and his serum sodium checked 48 hours later.

4 days later still no sample, the laboratory Consultant checked up and found that her advice had not been followed, indeed none of the investigations or medication changes had happened due to staff changes on the ward and poor record-keeping. By this time Mr H had a dangerously low sodium. The laboratory Consultant contacted the patient's Consultant as a result of which the medication was changed, the other laboratory investigations to identify the cause of the problem were done and the advised treatment instituted.

Mr H improved and with his chest infection cleared and his changed medication he recovered to his previous level of health and discharged home.

There are many examples of this kind of interaction occurring daily across the length and breadth of the country. Many more can be supplied if desired.

Points: Continuity, co-operation, saving on bed-stay, symbiotic relationships

## Vignette 5. Policy: Service Availability

Some 5% of patients presenting to Accident and Emergency Departments (AED) of hospitals are poisonings and many of these patients require supportive treatment. To aid this they need routine Laboratory Medicine parameters measured as these can be a guide to prognosis and diagnosis. In other patients specific measurements of the presence and concentration of a poison need to be made, again for diagnosis and prognosis. The huge number of potential drugs and poisons and their clinical presentation, investigation and treatment is a serious challenge to AED clinicians. Clinicians get advice in these situations from the National Poisons Information Service (NPIS), from this they decide on further investigations and treatments.

It became clear there was disparity between the advice AED clinicians received and what was necessary medically and was possible in Laboratory Medicine. This was causing difficulties in relationships within hospitals between AED and laboratory staff. The situation was addressed by forming a joint working party between the Medical Directors of the NPIS and nominees of the Association for Clinical Biochemistry (ACB).

Guidelines were agreed on Laboratory Medicine analyses to be available 24 hours per day and the turnaround times for more unusual poisoning investigations. These were adopted as UK guidelines and are in current use by the NPIS.

This has resulted in 'best practice' investigations for patients presenting with poisoning episodes to AED. This means that patients do not unnecessarily undergo investigations and that patients requiring early diagnosis and intervention have this. Such interventions can be life-saving as outlined below.

A 27 year old car mechanic presented to his AED confused and apparently inebriated. His preliminary laboratory investigations showed a marked accumulation of acid in his blood. The NPIS using the Guidelines indicated further investigations. The laboratory could not do these in house, but could access a service regionally as recommended by the Guidelines. The results indicated a potentially lethal poisoning with anti-freeze which the AED physicians were able to treat to stabilise him while they found a centre able to haemodialyse him. He made an uneventful recovery; if undiagnosed he would have died.

Points: Pooling of knowledge to ensure best practice, ensure clinically appropriate intervention for poisoned patients, appropriate direction of resources, minimising unnecessary admissions, helps to achieve 4-hour wait target

## Vignette 6. Research: Laboratory Research Informs Medical Practice

There is a National shortage of organ donors for transplantation. Therefore preservation of transplanted organ function without rejection is vital to ensure optimal utilisation of this precious resource. The advent of effective immunosuppressant therapy has enabled these goals.

Cyclosporine was one of the first such drugs. Introduced in the early 1980s it soon became apparent that 'clinical judgement' of its efficacy was unsuccessful in avoiding toxicity to the kidney or preventing organ rejection. Combined laboratory and clinical studies by Profs Holt and Johnson at St Georges and Barts in London amongst others, showed that a knowledge of the drug concentration and the duration of exposure to critical concentrations was important.

From the laboratory this required expertise in method development, the ability to identify how true a value was to the real value without a source of guaranteed pure material was vital (a problem still being struggled with), the ability to model how the drug is handled by the body and relating this to observed outcomes in scientifically rigorous studies. With the obtained data this was analysed to determine how different individuals handled the drug to find if there were any toxic metabolites and how many of these were therapeutically or toxically active. There are now over 30 known metabolites.

From the data obtained the laboratory had to determine concentrations that would avoid organ rejection yet also avoid organ damage, thus avoiding significant morbidity and mortality. The upper and lower ranges were initially determined for kidney transplants, other organs needed different ranges.

However it was found that a single sample point following a dose did not adequately characterise a patient's concentration profile and that some combination of multiple sampling points was required to achieve the twin goals of neither rejection, nor toxicity. Some 20 years later this is still being refined.

In the meantime more immunosuppressant drugs needing similar investigations have been introduced. Not only that, but these drugs are used in combination; how do they interact?

Points: laboratory skills in R&D are necessary to enable meaningful clinical research end-points to ensure effective therapies for patients, effective therapies enable best use of resources.

## Vignette 7. The Primary/Secondary Care Interface

Clinical biochemists are often uniquely placed to provide the interface between primary and secondary care. They work closely with hospital clinicians, particularly in the areas of general medicine, diabetes and endocrinology, and also have good relationships with primary care physicians. In many cases, these links can be used effectively to provide rapid and effective patient care. Two examples (from very many which could be cited) illustrate this

In Lincolnshire, on Christmas Eve 2004, the laboratory received a request for thyroid function tests from a general practitioner. The initial results of the tests suggested that the patient might have the rare condition of hypothyroidism secondary to hypopituitarism. The clinical biochemist arranged emergency confirmation tests, confirmed the diagnosis (which is potentially life-threatening) contacted the consultant endocrinologist (whom he knew well) and arranged follow-up with the GP. The patient was on treatment by the end of that day.

In Shropshire, the duty biochemist discovered a very high testosterone result on a sample sent from a GP from a middle-aged woman. Such results may suggest the presence of a tumour which secretes the male hormone testosterone. The biochemist immediately telephoned the consultant endocrinologist, who agreed to see the patient in his clinic two days later. The biochemist contacted the GP, explained the situation and the GP arranged for the patient to attend the clinic. The GP and the patient were very grateful for prompt and effective action.

Both these cases illustrate the key role laboratory medicine can play in improving the links between primary and secondary care, and delivering effective treatment quickly. Handling GP and hospital work by different mechanisms and in different settings would destroy these extremely efficient and effective links, which benefit patients every day.

Points: Expertise, linkage of primary and secondary care, facilitation of rapid intervention, improved patient care

## Vignette 8. Clinical Biochemistry beyond the Laboratory Setting

### One Stop Clinic for Assessment of Risk (OSCAR) for Trisomy 21 (Down's syndrome)

The Harris Birthright Research Centre for Fetal Medicine at Kings College Hospital established OSCAR to screen for Down's syndrome in women who are 11-14 weeks pregnant. Results from a prospective study of 15,030 pregnancies have been reported.

In a single one hour visit the woman has the following clinical, radiological and biochemical parameters determined:

- Maternal age
- Crown-rump length (CRL)
- Fetal nuchal translucency thickness (NT)
- Serum free  $\beta$ -human chorionic gonadotrophin (HCG)
- Serum pregnancy-associated plasma protein-A (PAPP-A)

From these investigations it was possible to derive the risk of the women carrying a baby with Downs Syndrome and to discuss that risk with the woman during her single visit.

In order to run the OSCAR it was necessary for the Clinical Biochemistry department to be present with equipment and staff to perform the HCG and PAPP-A analyses and to oversee the derivation of the individual risk factor.

The reported study showed that ~90% of Down's syndrome pregnancies were detected for a false-positive rate of 5%. These figures compare well with outcomes from conventional methods of risk assessment.

From the perspective of the woman the OSCAR was an outstanding success because she was only required to make a single one hour visit and she left knowing the risk of her carrying a Down's syndrome baby. This compares with at least two visits to the antenatal clinic and/or GP to determine the risk by conventional means.

From the perspective of the clinicians OSCAR offered earlier diagnosis of Down's syndrome than conventional investigation leaving more time for counselling the patient and determining the most appropriate course of action.

Points: Inter-discipline co-operation, on-site expertise, patient satisfaction

## Vignette 9. Partnership Working between NHS Laboratory Medicine and the Diagnostics Industry

### Managed Service Provision for the City of Glasgow

During 2004/05 NHS Greater Glasgow tendered for a single contract to provide equipment and consumables for all the high volume Clinical Biochemistry, Haematology, Blood Transfusion, Virology and Immunology across the seven NHS laboratories in the city. The tender complied with European Union law and after 6 months of intensive work a 7-year contract was awarded in May 2005 to Abbott Diagnostics. The new equipment began to be installed in September 2005 and the process will be completed in June 2006.

Under the terms of the contract Abbott Diagnostics offer a Managed Service Provision. A full-time project manager has been appointed to look after all ordering, stock control, customer care and working relationships with the third-party suppliers who are also managed by Abbott. An engineer is also permanently based in Glasgow. This is the largest contract ever awarded in Europe to a single diagnostics company, being worth several millions of pounds per annum.

One positive outcome from the project is that all NHS hospital laboratories have identical equipment, reference ranges and standard operating procedures. This means that the same result with the same interpretation will be available to the whole population of Glasgow. It also means that there is fully integrated back-up so that there are never any delays in delivering results.

From the perspective of laboratory management the project allows for single point contact and rapid response from the service provider. It also facilitates movement of staff between sites and has allowed for the gradual introduction of a single reporting and out-of-hours advisory service for Clinical Biochemistry for the whole of the city. In the near future the project will allow for rationalisation of the working day and the number of sites offering 24/7 services

For NHS Greater Glasgow there is an added benefit achieving a financial saving of ~£1Mpa whilst equipping all of its laboratories with state of the art equipment and technological support for the next seven years.

The project is an excellent example of NHS Laboratory Medicine and the diagnostics industry working in partnership in a large network environment to deliver improved quality, harmonization and improved value for money for the NHS.

Points: Public-private sector collaboration, clinical & cost efficiency, new model of service delivery.

## Vignette 10. Partnership working: Accessing Chlamydia testing through pharmacies

Chlamydia infections can result in male and female infertility yet there may not be any symptoms. Detection and treatment can cure the infection and avoid loss of fertility.

John, a 21 year old sexually active student at a University in Liverpool, has had unprotected sex and knows from literature on the campus that he is at risk from an STD. However he is uncomfortable with the idea of attending the University medical service. He visits his local National chain pharmacy and notes that they are offering screening tests for STD. John provided a specimen.

The pharmacy acted as a gateway providing convenience and anonymity to patients, the sample were collected that day and transported to the central Health Protection Agency laboratory for specific molecular testing. He was positive for Chlamydia and was advised to attend the local GUM clinic for treatment, which he did. He was successfully treated.

Not only did this approach enable a 'reluctant patient to receive a diagnosis', but enables epidemiological tracking of infection spread and prevalence, vital to Public Health Medicine in tailoring the National Chlamydia programme with a view to reducing the population at-risk.

Points: Convenient access, linkage with expert centre through private sector gateway

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