Information management and informatics: need for a modern pathology service

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Abstract

Requirements for information technology in pathology now extend well beyond the provision of purely analytical data. With the aim of achieving seamless integration of laboratory data into the total clinical pathway, 'informatics' – the art and science of turning data into useful information – is becoming increasingly important in laboratory medicine.

Informatics is a powerful tool in pathology – whether in implementing processes for pathology modernization, introducing new diagnostic modalities (e.g. proteomics, genomics), providing timely and evidence-based disease management, or enabling best use of limited and often costly resources. Providing appropriate information to empowered and interested patients – which requires critical assessment of the ever-increasing volume of information available – can also benefit greatly from appropriate use of informatics.

General trends in medical informatics are reflected in current priorities for laboratory medicine, including the need for unified electronic records, computerized order entry, data security and recovery, and audit.

The increasing demands placed on pathology information systems in the context of wider developmental change in healthcare delivery are explored in this paper.

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Introduction

Fully integrated laboratory information technology (IT) systems are pre-requisites for efficient clinical service delivery and laboratory management. For the past three decades, hospital laboratory computing systems have often provided the most sophisticated information systems within hospital settings,[1–3] but new approaches to managing information are now required, in order to implement major tenets of the National Health Service (NHS) modernization agenda,[4] including the following:

(a) The consolidation of pathology services into larger units of organization, e.g. managed clinical networks of laboratories
(b) The increased role for primary care within the broader health service
(c) Introduction of new approaches to service delivery, e.g. point-of-care testing (POCT)
(d) More open access to the knowledge base supporting evidence-based medicine
(e) Integrated management of all aspects of clinical services.

This paper reviews the current status of pathology IT systems and wider pathology informatics issues, describes requirements for future IT systems, and considers how best to meet the information demands of the NHS modernization agenda.

Current IT requirements

The data processing requirements of modern pathology laboratories are highly complex. Data from the Performance Monitoring for Pathology Messaging (PMIP)[5] and related benchmarking exercises suggest that an average multidisciplinary pathology service for a population of 0.5 million receives about 1 million specimens per year from around 200 000 patients. The service typically generates approximately 5 million reportable test results, and serves approximately 500 consultant clinicians and 300–400 general practitioners (GPs) in 100 practices.

Optimal system organization

The informatics requirements for an integrated pathology service can usefully be considered, from a business perspective, in terms of four layers of operation, each having a different role in service delivery (Table 1). These four layers (*see* Table 1) must function in an integrated manner so that all services are fully supported. Seemingly trivial incompatibilities (e.g. in test code definitions) can have major adverse impacts on data transfer, whether for clinical purposes or for analysis of data for managerial purposes. This model is analogous to the planned role of the electronic patient record, which supports clinical activity as a core pre-requisite (*see* Fig. 1), while also supporting audit and knowledge generation, and thus contributing to service delivery (*see* Fig. 2).

Current IT provision

Although, as a result of under-investment in recent years, IT provision across the NHS (as in many other countries) is somewhat fragmented, the best laboratory information management systems (LIMS) currently available enable the following:

- Recording of all requests for all tests
- Online, real-time linking of the LIMS to automated analytical instruments

Table 1. *Informatics requirements for an integrated pathology service*

Layer	Description	Clinical functions	Management functions	Information content
4	Executive systems	Clinical decision support	Performance monitoring Planning quality Management	Knowledge
3	Intermediate systems	Ward requesting Clinical reporting R&D support	Workload statistics Contracting Supplies Quality assurance statistics Department of Health returns	Aggregate information
2	Operational systems (e.g. traditional LIMS and workstations)	Analytical control Reporting POCT networks	E-mail Word processing Web browsing	Operational data
1	Network/infrastructure	Servers/PCs Network/printers/voice and image management		Operational

R&D = research and development; LIMS = laboratory information management system; POCT = point-of-care testing, PC = personal computer.

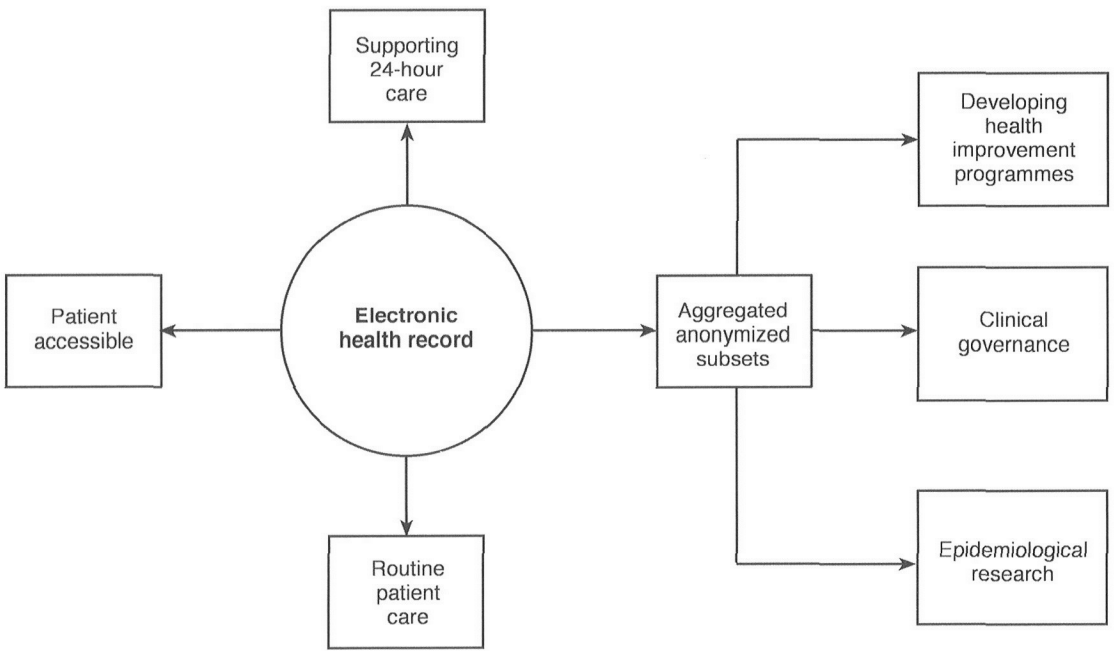

Figure 1. *Diagram of electronic record interrelations in clinical activity.*

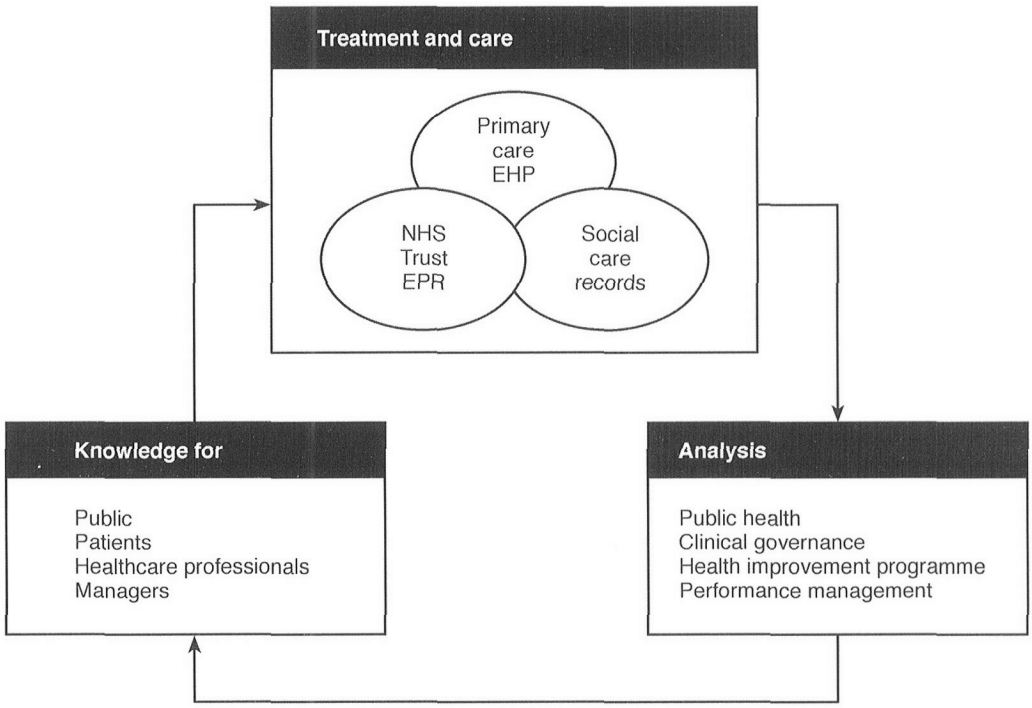

Figure 2. *Diagram of electronic record uses in audit and knowledge generation. EPR = electronic patient record; EHR = electronic health record.*

- Automated validation of test results
- Real-time recording of quality control data
- Electronic delivery of results to clinical users
- Implementation of decision support systems to enhance clinical outputs
- Support of data analysis for audit, clinical risk management, disease surveillance and epidemiology (e.g. cancer registration, screening programmes, communicable disease reporting and external quality assessment data management)

Key issues for modern pathology information systems

Identification of pathology service needs

Ideally, information system functionality for pathology IT systems should be determined by service needs rather than drive these. The NHS modernization agenda provides a major challenge for pathology informatics, requiring a significant shift in focus, away from traditional internal laboratory issues (e.g. instrument interfacing, data reduction technologies, robotics) towards broader external service issues (e.g. clinical system integration, test requesting and reporting of results, clinical audit and management).[6] Knowledge management and performance management (reflected in value-added clinical output) are now key drivers, superseding earlier preoccupations with workload and cost.[7] Specifically, the trend towards managed clinical networks requires the development of new information systems integrated across different hospital Trusts, multiple clinical laboratories and component disciplines. Expansion of primary care services also requires greater linking of requests and reports from multiple sites, together with expanded user access, while ensuring appropriate security and confidentiality.[8]

Larger test repertoires and greater use of new technologies, including POCT, will almost certainly lead to increased service demand. Containing this demand within finite resources requires careful management, to which effective IT can make a major contribution. For example, providing fully integrated electronic patient records and links to clinical decision mechanisms can support evidence-based clinical care.[9,10]

Availability of IT systems meeting pathology service needs

Systems required to meet fully the objectives outlined above are not yet available, as current systems were not designed to fulfil these requirements. Planning new IT systems therefore requires a medium- to long-term approach, and in the interim pragmatic procurement decisions may be necessary to facilitate service reconfiguration. However, it is essential that these decisions do not conflict with strategic requirements.[10]

Factors likely to influence the future choice of IT systems in the UK are discussed below:

- *The global nature of the diagnostics business.* IT systems produced elsewhere may offer better technological features but may not fulfil requirements specific to the UK market (e.g. central reporting, clinical coding systems). The cost of introducing these systems may also be prohibitive.
- *NHS procurement policy.* Future IT systems may be selected as part of a wider strategy (e.g. relating to uniform electronic records). This will inevitably reduce the scope for purchasing customized pathology systems from specialist suppliers, as has already occurred in several UK procurements in which choice of LIMS has been determined by the hospital system.[10]
- *Increased availability of highly specialist IT subsystems.* Integration of specialized systems (e.g. in clinical genetics, where a system able to retain family pedigree data would be highly desirable) may become more cost-effective than purchase of a traditional monolithic system.
- *Availability of more sophisticated systems covering a wide range of applications.* The functionality required in a LIMS (ordering, equipment interfacing, scheduling etc) is common to other hospital information systems currently in development. In the future, procurement of integrated analytical and information systems may supersede separate purchase of LIMS. The cost of developing such systems is likely to disadvantage small suppliers, while also discouraging innovation in the public sector.

Infrastructure requirements for pathology service IT systems

Network infrastructure

Robust and reliable information and IT are required to support the following:

- Communication between geographically distant laboratories
- Rapid communication of both test requests and test results, e.g. between GPs, hospital clinicians and pathology laboratories
- Convenient access to advice from specialist staff and specialist testing facilities located elsewhere
- Appropriate access to patient information, test protocols, and supporting evidence-based information and references.

Substantial progress has already been made on implementing a national IT infrastructure for the NHS.[11] All Health Authorities and Trusts now have connections to the NHS network (NHSnet). By March 2002, 98% of GP practices and 97% of pathology laboratories had connections to NHSnet. High-speed broadband connections are expected to be in place throughout the NHS by the end of 2004.[5]

In order to maximize the benefit of these developments, local arrangements must be made to ensure that (a) appropriate and accessible infrastructure is in place, (b) all relevant systems and devices are fully connected via the local network onto NHSnet, (c) staff have convenient access at work to e-mail, the Internet, and NHSnet, and (d) where telepathology applications are required, the NHSnet connection and other local equipment are of appropriate capacity.

Implementation of existing and future standards

Secure and efficient exchange of data is fundamental to delivery of the NHS modernization plans. This can best be achieved by adopting appropriate standards at all levels, including technical (e.g. networking, hardware, software), communications, managerial (e.g. benchmarking and performance monitoring) and clinical [e.g. National Service Framework (NSF) minimum data sets for cancer or coronary heart disease] standards.

Key to successful implementation is a common and consistent set of patient identifiers, most conveniently the individual's NHS number. Working to ensure that this number is used as a common patient identifier is a key objective of the newly established NHS Information Standards Board. Many of the technical standards are already agreed as part of e-government. Considerable effort throughout the NHS will be required to ensure that these standards are adopted and implemented locally.[11–15]

Ensuring security and confidentiality

Current initiatives will lead to more sharing of patient-related information, thereby increasing the responsibility of professionals to ensure the confidentiality of the data held and accessed. In a joint project entitled *Information Governance*, the NHS Information Policy Unit and Information Authority are developing national standards relating to confidentiality, security and data quality. Requirements particularly relevant to pathology laboratories include the need for the following:

- *Adherence to provisions of the Data Protection Act 1998.* This came into force in March 2003 and now covers all manual and electronic records.
- *Awareness of the role of local Caldicott Guardians.* Any local activity relating to patient information must be cleared with the Caldicott Guardians who are appointed by every Trust to safeguard the confidentiality and security of both manually and electronically held personal information.
- *Implementation of the ISO 17799 standard for security of information.* This standard has been adopted and

requires that encryption arrangements are in place for pathology data exchange.[15]

- *Digital signatures, where required.* This is essential in some areas for electronic requesting (e.g. ordering of blood products) and reporting (e.g. histopathology).

Knowledge management

The principal driver for IT in pathology is to ensure that pathology services are used to best effect for patient care and to improve the health of the population at large.[7] Pathology IT systems can support and promote best practice, both within laboratories and by external users.

Clinical governance: supporting best practice

Clinical governance is 'a framework through which NHS organizations are continuously accountable for improving the quality of their services and safeguarding high standards of care'.[16] IT provides a powerful means of promoting and integrating high standards of laboratory practice within the wider clinical environment.

Widespread implementation of electronic patient records should significantly improve the way in which pathology services are used, through better demand management, targeted requesting and more effective use of results.

It is anticipated that there will be increased electronic pathology order requesting from locations away from the central laboratory, mainly from hospital wards, but also from primary care. The normal checks performed in the laboratory to monitor requests will not necessarily be available in this context. The following should therefore be taken into account when specifying interfaces into electronic record systems, in order to encourage appropriate test requesting:

- The requester should have access to the appropriate evidence base at the time tests are requested, including agreed local protocols and guidelines, and should also have access to external resources, e.g. the National Electronic Library of Health (NELH).[17]
- Clinical systems will need to 'share' information. For example, a pharmacy system might have rules which require access to the pathology system to check a potassium concentration if digoxin is ordered. Agreement between pathology and other clinical specialities regarding clinical alerts, prescribing, etc. will also be required.
- The decision to request a test needs to be made in the full knowledge of tests previously performed. Data should be displayed so as to highlight trends, eliminate unnecessary repeat requests and draw attention to alert values.
- Pro-active requesting. The pathology IT system should be cross-referenced to clinical care pathways and should prompt requesting of additional appropriate tests if not ordered.

Evidence-based medicine: use of protocols and guidelines

Clinical guidelines or protocols have been in limited use for many years, but the current emphasis on evidence-based medical practice strongly encourages increased involvement of all staff in their design, maintenance and use. Local dissemination and maintenance of protocols and guidelines is essential, together with training in guideline development and deployment.[17,18]

Phlebotomists and junior doctors require information about specimen type, sample timings, etc. in order to ensure the quality of the pathology service offered and optimize its use. Hospital intranets are increasingly being used for this purpose, and there have been some marked successes, particularly in microbiology and infection control.[19]

Epidemiological analysis of the results of tests performed in clinical laboratories is essential to improving patient care and enhancing our understanding of disease-related processes. Pathology IT systems should provide support for these activities.

Exploiting decision support systems in pathology

Increasingly sophisticated, rules-based systems are being used in pathology, particularly in the areas of test selection, result validation, image analysis, clinical reporting and risk calculation (e.g. Down syndrome screening). It is essential that such systems are appropriately quality-assured, with particular attention to liability and risk management.[18]

The potential risks of inappropriate decision-making using such systems require the development of robust processes for their selection, implementation and management. These must take account of the developing legal regulations for software used in medical devices (e.g. the European Union *In Vitro* Diagnostics Directive).[20]

Ensuring that staff appreciate the implications of inappropriate and unregulated use of these systems is also essential.

Research and development

In some cases, laboratory data may contribute to development of new database resources of regional, national or international interest (e.g. the UK Association of Clinical Biochemists' AssayFinder[21]). Specialist services have access to large databases of information linked to the specific analytical services they offer. They are in a unique position to contribute national and international data repositories

supporting the practice of evidence-based pathology. The availability of such information could be made available for online publication through a pathology branch library of the NELH.[17]

Supporting communications

Current trends in technology are blurring the boundaries between computers and communication systems. Networked, handheld devices and services such as text messaging provide major opportunities for rethinking how information is communicated within the pathology service and between the pathology service and its users.

Telepathology

Telepathology is a subspecialty of telemedicine, which promises to be of particular use in situations where expertise is located in centres of excellence geographically distant from the site of clinical service delivery. Remote support is not limited to imaging modalities, and the definition can be broadened to include any circumstance in which remote access enables transfer of expertise, including remotely accessible POCT.[22]

Storage of images

The introduction of digital medical image sources in the 1970s and the use of computers in processing these images after their acquisition led the American College of Radiology and the National Electrical Manufacturers Association to form a joint committee in order to create a standard method for the transmission of medical images and their associated information. This standard is referred to as Digital Imaging and Communication in Medicine (DICOM Standard Version 3). A major concern for pathology, where image data is of increasing interest, is that no equivalent data standards exist. Images are being captured and transmitted in many different formats (e.g. bitmap, JPEG, TIFF) with little regard as to how they might be stored, exchanged or analysed in a collaborative manner in future networked systems. Consideration is being given in some centres to whether images from whatever source (e.g. scanned images, histopathological images, photographs of gels, cytogenetic smears, etc.) could and should be stored in DICOM Version 3. However, it is still debatable whether this is an appropriate format, e.g. for histopathological images.

An example of the use of DICOM is the Picture Archiving and Communication Systems (PACS) now in common use in radiology departments throughout the world. Rather than store images in the host pathology system, it would be feasible to include them in the local PACS. The adoption of non-standardized image storage systems in pathology raises concern, as incompatibilities in data formats will limit the potential for future exchange of data.

Implementation of call centre technology

Use of call centre technology and sharing of access to centralized expert-system technologies may prove more cost-effective than expensive, high-bandwidth imaging applications. Modern telephone-enabled computer systems allow integration of such activities with information stored electronically on intranets, the best healthcare example being the coupling between NHS Direct and NHS Direct Online[23] and their integration into the emergency services network.

Such call handling technologies are already well established and widely used in the private service sector (e.g. in banking). They offer many opportunities to link information systems, e.g. by providing a single point of telephone enquiry with call filtering, queuing and internal routing to appropriate services. Potential applications of this technology in pathology include provision and/or coordination of results 'hot lines', multidisciplinary advice enquiry points, messaging services, specimen transport, handbook and protocol supplies, and other activities related to 'customer service'.

Specifications for laboratory information systems

The framework determining the future clinical requirements for pathology IT systems will be the integrated care pathway (ICP), which 'determines locally agreed multidisciplinary practice based on guidelines and evidence where available for a specific patient/client group. It forms all or part of the clinical record, documents the care given and facilitates the evaluation of outcomes for continuous quality improvement'.[24] An ICP essentially maps the process of care from first clinical encounter to discharge, for each clinical episode.

Laboratory Information Management Systems

The next generation of LIMS should therefore have powerful multidisciplinary clinical facilities, well beyond those required for simple automated processing of 'normal' results and rapid access to results requiring review. The improvements required include the following:

- Expansion of rule-based clinical authorization
- Provision of dynamic, multidisciplinary views of patient results
- Improved recording of clinical information
- Facilitation of computerized queries supporting multidisciplinary audit.

Issues arising from interactions of LIMS with hospital systems

Ward order communication systems

Ward order systems essentially automate the requesting of pathology tests. Their potential role in encouraging clinicians to select the most appropriate tests, thereby helping to control the demands on pathology services, is of major importance. It is essential that pathology staff play an active role in the procurement and deployment of ward order communication systems.

Results reporting systems

As electronic reporting of data increases, pathologists should contribute actively to the design of the systems used (e.g. formatting, display, downstream processing of data). Where standards exist [e.g. from other professional bodies such as the Royal College of Pathologists or the NHS Information Authority (NHSIA)] these should be adopted.[11]

Impact of increasing use of point-of-care testing

To achieve a quality of service meeting the demands of the Medicines and Healthcare products Regulatory Agency, appropriate training, equipment monitoring, audit trails and result storage need to be considered.[25]

IT requirements for POCT include the following:

- Network access to allow performance monitoring and intervention from the parent laboratory
- Retrieval and storage of reports in the parent laboratory LIMS
- Access to computer-assisted learning technologies supporting end-users
- Adherence to the existing connectivity standards.[22,26,27]
- Supporting the requirements of the Data Protection Act, by ensuring suitable safeguards and control of patient information access.

Impact of increased specialization of services

Local specialist service systems

Specialist services may require specialist subsystems to support their activity. Ideally, these should fall within the framework of the main pathology system, to avoid fragmentation of information and to ensure resource efficiency. Particular attention should be paid to standards development in these areas, since specialist services may require rapid development to meet new demands.

Introduction of new testing strategies often requires new codes, specialized datasets and databases, as is already the case in clinical genetics, neonatal screening and cancer. Availability of pedigree information, for example, is desirable when interpreting genetic tests, but may necessitate new IT systems or radical redesign of current systems, which cannot record family linkages. Similarly, application of proteomic testing to clinical practice will require new methods of data analysis, manipulation and storage.

Regional and national specialist service access

The current Supra-Regional Assay Service is likely to be enhanced for specialist assay referral at the tertiary level. Plans for a pilot national network, supporting lab-to-lab communications and facilitating communication with specialist centres, are already in place. Such a network could store and forward requests to specialist centres, provide electronic reports and ultimately encourage standardization (e.g. of test codes). An aim of the pilot project, in association with the NHSIA, will be to advise on the best topology for any network, as well as considering coding and standardization.[28]

Impact of requirements of primary care

A significant proportion of the pathology workload (>40% in some laboratories) is from GPs who generally appreciate advice on test selection and interpretation. Aspects of IT of particular relevance include the following:

- Online requesting from and reporting to primary care
- Development of disease registers in support of NSFs and other services, e.g. thyroid and lithium registers
- Remote support of POCT, e.g. HbA_{1c} in diabetes
- Community services, e.g. anticoagulation control.

Facilitating GP access to computerized pathology resources, perhaps through extended district hospital extranets, would also be desirable.

Online reporting to GPs

The NHSIA Pathology Messaging Implementation Project, which is working towards electronic transmission of all pathology results, is already at an advanced stage.[5] By the end of January 2003, 88% of GP practice systems were able to receive results and 75% of UK laboratories had already installed and were testing the new transmission systems. By the end of December 2003, most laboratories were able to send most reports electronically.

Issues of direct patient access

There is increasing interest both in self-testing and in patient access to health records. In some specialist areas of practice in which shared records are used, patients already have access to pathology results, e.g. in obstetrics.

While there are currently no plans to increase patient access to pathology data, potential growth in this area could have a significant impact on future requirements for electronic data.

Public access to the knowledge base is also being encouraged and will most likely be through a health portal such as NELH, for which limited access is already available over the Internet.[17]

Managing laboratories using information systems

Pathology information systems will play an increasingly important role in service management, particularly with the expanded scope of pathology networks. Existing systems (e.g. for finance, personnel and resource management) will have to evolve to meet these needs.

Modelling of workload and logistics, production of financial forecasts, and detailed cost analysis will be required to maximize efficient delivery of services. As pathology expenditure accounts for around 6% (£500m per annum) of the NHS consumables budget there is scope for major savings if ordering procedures can be automated. Effectively, this has already been piloted on some diagnostic instruments, which place automatic orders for reagents on the basis of workload.

Supporting and exploiting research and development in informatics

The increasing integration of clinical data in the future will raise many new problems of data classification and standardization, and greater understanding of the syntax and semantics of information content will be required to solve them. These skills will relate more to linguistics and logic than to electronics, and early investment in training and development of suitable individuals will be highly advantageous. A national programme of multidisciplinary research is already addressing the following topics:

- Decision support
- System usability
- Long-term storage and retrieval
- Data 'mining' – clinical knowledge engineering
- Data and information standards.

Resources, staffing and skills

The ability to update information systems will depend critically on the availability of resources, both staff time and financial.

Information system management

Ideally, all pathology laboratories should have a Systems Information Strategy Group, which has the remit of defining IT requirements to meet the internal and external needs of the service, both current and projected. These groups should be formally represented at the highest levels of management.

Expertise and qualifications for IT staff

There is a need to develop a cohort of suitably qualified IT staff to support the full range of information systems. Ideally, a laboratory systems manager should hold professional qualifications in both laboratory sciences and IT, with some members of the IT team being computer science graduates with expertise in database administration, networking and desktop support.

General IT education and training needs

Implementing the *NHS Plan* and *Working Together with Health Information* will require many changes in staff education and training, and a multiprofessional standard for clinical education has already been adopted by all the major professional and regulatory bodies.[29]

An internationally recognized qualification, which assesses computer literacy and is known as the European Computer Driving Licence (ECDL), has already been adopted as the basic standard for the NHS, and will in future be used to improve computer skills of NHS staff.[30] All pathology staff will be expected to hold this basic qualification. Achievement of additional competencies, at an appropriate level

Table 2. *Future informatics skill profiles for pathology staff*

Skill level	Required competencies	Staff to which these apply
Basic	European computer driving licence, including data access and entry	Administrative and clerical Technical
Intermediate	General applications, including word processing, spreadsheets, databases	Administrative and clerical Supervisory technical Scientific
Advanced	More advanced applications, including statistical analysis, modelling, website design	Scientific Research and development Management
Specialist	Information system development and other specialist applications, including design of customized management or decision support systems	System managers IT support

IT = information technology.

depending on job function (*see* Table 2), would be anticipated.

Conclusion

The core of any pathology department is its information system. In the past three decades, these systems have developed from supporting core pathology services to delivering services throughout the hospital network. The integration of pathology systems and the processes required to support this are becoming ever more complex, reflecting modern requirements for healthcare delivery, including electronic healthcare records. Pathology data contribute significantly to these records, which will determine the design of the next generation of IT systems.

Optimal use of pathology services will depend on greater involvement of IT in the pre- and post-analytical phases, both to manage demand and to encourage appropriate test requesting. This necessitates more sharing of information between different clinical systems, and hence improvements both in standardization and in communicability. Clinical governance requires adherence to protocols and guidelines, which can be facilitated by pathology systems. Clinicians are likely to become increasingly dependent on direct access to pathology data. The challenge for laboratory scientists is to ensure the timely and effective introduction of IT systems that can meet the needs of 21st century medicine.

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