

Arise Sir Bio-informatician

A proposal for a new Advanced Practitioner in Laboratory Medicine

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Introduction

This article will attempt to make a strong case for pathology to manage its own informatics resources, by demonstrating the magnitude of activities that are involved across all pathology disciplines. It can be argued that we do not have sufficient number of trained personnel in order to effectively achieve this. In the UK, it is common for those responsible for managing IT systems have been recruited from those biomedical scientists who have shown a strong interest in the field. Our IT professionals working within NHS trusts often perceive such staff as gifted amateurs. This would be an unfair criticism and the efficiency and robustness of Pathology Informatics programmes is a tribute to the hard work and energy of these dedicated staff. The GP connect project success is further evidence of the ability of such staff to get national projects implemented. The job they do needs to be formally recognised and I propose that there should be an Advanced Practitioner in Laboratory Medicine (AP) with an Advanced Specialist Diploma; which demonstrates expertise within the field, closely associated to the Professional Doctorates. This article could be viewed as an embryonic syllabus for such a course. I will discuss the logistics of how such practitioners could be deployed in the summary.

The challenging/changing world of IT in the NHS

Connecting for Health (CfH), with all its flaws is intended to deliver the Electronic Healthcare Record (EHR) in the UK and revolutionise information flows within the NHS. Central to the project is improved electronic communication of patient data. Pathology is the largest single source of electronic data and are critical to diagnostic decision-making and the planning of patient journeys. Pathology has moved on from being a data generation facility to an information generation resource with all the information management challenges that are faced by much larger organisations in the corporate world

There is a need to understand the processes involved and the information technology solutions available to meet those requirements [1]

A range of technologies both hardware and software will be required. The development of informatics proficiencies for laboratory staff is crucial to support this. Radically one could argue for the reclassification of Laboratory Medicine as an information science.

Why ? Because informatics is central to everything we do.

We need trained bioinformaticians in our laboratories involved in the research, development and application of computational and statistical tools and approaches facilitating, expanding and accelerating the use of laboratory information including those to acquire, store organise, analyse, visualise, interpret and present such information.

Integration of Informatics into routine laboratory life.

Informatics is so closely entwined into all the activities performed in the medical laboratory, it is easy to become indifferent to its presence. The scope of such support can be considered on two levels.

Level 1 Those Informatics resources that support the management and operation of the medical laboratory

Level 2 Those Informatics resources that support the requesting / analysis / reporting cycle

A Supporting the management and operation of the medical laboratory

Generic Management in Laboratory Medicine

- AP will be adept in the use of information technology to manage pathology resources including:
Advanced spreadsheet skills
- Knowledge of data repositories,
- Relational, object-relational database and knowledge base systems

Supporting Generic Professional Practice Roles of the Pathologist

Communication Skill sets: AP will be proficient in the following areas:

- Use of email
- Use of software to create visual materials that effectively support oral presentations
- Use of electronic communications appropriately in specific situations
- Effectively employ written, electronic, and oral communication
- Use of available technologies to share information and to network with colleagues
- Collaborate across multiple sites using electronic mail, discussion lists, news groups, teleconferencing, and related communication technologies
- Comply with institutional policies relating to the appropriate use electronic communications

Quality Control and Quality Assurance

The proposed AP will advise on informatics techniques that can be applied to laboratory quality control and quality assurance. The most notable examples of this are the deployment of rule based acceptance systems embodied into analysers and laboratory Information Systems (LIMS). The skill sets required extend beyond the manipulation of character based information. The AP will also need skills in pathology image management including:

- Telepathology
- Digital Microscopy
- Digital archiving of anatomic pathology imagery (DICOM)
- Electrophoresis data
- Flow cytometric, DNA sequencing and Cytogenetic data

Such skills will enable continuous quality improvement (integrating evidence based medicine)

Finance and Budget

AP will advise on the use of appropriate data sources (including laboratory information systems, PAS, claims and reimbursement information, and on-line data). The goal being improved management of patient care. Specific skill sets will include

- Knowledge of coding and clinical term semantics in order to understand complex hierarchies of categories e.g. SNOMED
- Data Mining skills, data cube manipulation, business objects
- On-line analytical processing tools to support queries that involve laboratory, pharmacy, clinical and financial data
- Laboratory tests by particular test, clinical category, panel, test instrument
- Use hierarchies to formulate queries
- Screening for hospital acquired infections and using software packages that target antibiotic use to optimise efficacy, reduce development of resistant organism strains and reduce costs

Supporting Near Patient Testing (NPT)

This is an increasingly important area in laboratory medicine. The information flows that need to be considered as a consequence of this are challenging .

The AP will need to have skill sets that appreciate capture of patient laboratory data from systems remote to the laboratory, combine with clinical data and intervene when clinically indicated. Proactively AP will devise strategies to identify patients who would be appropriate candidates for new medical services.

AP will provide coordinated IT support for distributed laboratories utilising software

to coordinate operation of laboratory and point of care laboratory testing devices

AP will be able to advise on:

- Data capture and management from point of care diagnostic devices remote from the central laboratory
- ongoing assessment of quality of test results and of operator competence
- Proactive real time intervention to prevent errors and to flag critical values
- The appropriateness of the NPT programme, by continuous monitoring of the use of diagnostic equipment remote to the central laboratory

Acquisition of Pathology IT Equipment

The AP will require skill sets that will enable:

- Needs assessment for new systems
- Producing output based specifications / functional specifications
- Undertake contract specification and negotiation for software and hardware provision (project management skills)
- Work with other IT professionals to evaluate integration with existing IT systems
- Manage systems implementation
- Use appropriate software packages (project management, spreadsheet and statistical) to plan for change
- Undertake project management of new systems implementation

Specific Communication skill sets for imaging

AP will advise on the use of photomicrography, digital microscopy, telepathology effectively for education and MDT's. He/she will have an understanding of dynamic digital telemicroscopy and be familiar with software that allows local and remote users to capture, view, annotate and manipulate microscopy datasets. AP will be familiar with imaging standards e.g. DICOM and be planning for the incorporation of these into the EPR. AP will also be able to manipulate image databases that allow comparison with other specimen images from the same and other patients.

AP will advise on, teleconferencing that involves multiple sites, certification, platform to run algorithms that grade tumours using morphometry, platforms for pattern recognition algorithms. AP will be sensitive to other pathologists who wish to view microscopy data and servers for storing and managing such data. Pathologists may also need world wide access to global collections of fully digitized cases, there should be no need to rely on slides available at local institution. This includes links to relevant portions of digitized cases from medical information systems, electronic publications and textbooks.

Accessing Sources of Information for Self- and Continuing Education

AP will be able to advise on:

- Available information resources and tools to support lifelong learning
- Effective use various computer-based instructional tools, including electronic tutorials and patient simulations
- Effective use of a variety of computer-based self assessment tools

Promoting best practice for the incorporation of developments in medical informatics into the laboratory domain

P will need good critical appraisal skills to critically review medical informatics literature. They will need to be able to discriminate between types of information sources in terms of their currency, format (e.g. a review vs an original article), authority, relevance, and availability (Use of Internet, understanding authenticity), filter, evaluate, and reconcile this information.

The AP will be trained to exhibit good "information habits" that support the effective use of information technology, using a variety of information sources for problem solving they should maintain a healthy scepticism about the quality and validity of all information. When promoting the use of new technology they should caution as to the potential to introduce new sources of error

Developing New Knowledge through Research

AP will have skills to support research within the network they serve. They will be called upon to identify and locate existing data sets maintained at his / her own institution or extraneous to it (eg, national registry data) that might be used to address a specific clinical question. This will require knowledge of database format and design, more importantly be aware of data mining tools for interrogating and organising such data. A thorough understanding of clinical terms and concepts and how the relationships between them in coding systems will be required as a pre requisite. They will in all likelihood be the first point of contact to advise on representation of study data that supports computer-based analysis. They will select the appropriate computer software to perform statistical analysis. They will evaluate information technology's impact on basic biomedical research, with reference to genomics, proteomics and bioinformatics and advise their networks accordingly.

Ethics and Confidentiality

AP will advise on compliance with the data protection act and ethical issues that surround the manipulation and use of patient data, including:

- Compliance with legal, ethical, and medical requirements relating to patient documentation in the practice of pathology, including confidentiality and data security
- Comply with copyright and intellectual property rules, especially with regard to materials that are retrieved electronically
- Comply with government initiatives in medico-legal issues related to technology
- Protect confidentiality of private information obtained from patients, colleagues, and others

- Advocate for, and protect, patient rights

Health Service Planning

The AP would be expected to advise on strategic issues in the wider sense through the use of clinical information in the aggregate to determine health care service planning for populations, eg pathology laboratory reporting to registries

Use on-line resources for legislation, for political advocacy, and for setting local health care policy

Explain the costs and benefits of pathology informatics for individuals and society.

These activities include surveillance of new or emerging technologies that are relevant to pathology e.g. Use of PDAs (for pathology result "push" technologies)

B Those Informatics resources that support the requesting / analysis / reporting cycle

AP will need to support the "core" activity of the medical laboratory. I have noted the skill sets required in each section of the analytical cycle. Reflecting on the laboratories interaction with other clinical disciplines will equip our practitioners with the abilities to be an information diplomat.

Informatics support for the Pre analytical phase

Reliance on diagnostic services to support the patient journey through a hospital episode has never been greater. The workload demand and test repertoire offered has expanded at an exponential rate over the last decade. There are increasing concerns that the expansion has outpaced the clinical requirement; neither numbers of patients treated nor the incidence and prevalence of disease has grown at the same pace. The systematic review of laboratory audits [2] performed by Naylor and Carl van Walraven in 1998 demonstrated that inappropriate testing is very common (4.5% to 95%) and they point out that this is not only causing unnecessary patient discomfort but it also increases the likelihood of increasing the number of false positive results, causing unnecessary worry and further investigation

Concern that expensive diagnostic services are not being used effectively, are thus well founded.

The key to controlling demand is the effective use of informatics in the pre laboratory phase of the analytical cycle; the AP will have a crucial role to play in securing better use of the pathology service.

They will undergo training in workflow analysis to gain an appreciation of routes used to access Pathology services. They will be aware of decision support systems to maximise the efficient use of the pathology service. This will necessitate knowledge of process mapping techniques to formally represent the pathways of access. An appreciation of human cognition issues in the use of computer interface design, as well as design of computer instructional materials for point of request systems. This is particularly relevant in respect of knowledge based support in the ordering process through the use of algorithmic systems (e.g Map of Medicine) and other rubrics that support evidence

based medicine and use of these during the ordering process.

An awareness of coding, classification, lexicons and other systems to represent the pathology requests will be required to achieve this. At a technological level, our resident will have an appreciation of character recognition systems for acquiring the request from paper based orders as well as bar coding technologies to embody request information. They will promote compliance with positive patient identification through the use of minimum data sets and the interface with EPR, extending these best practice models for the use of PDA's and wireless technologies to support mobile requesting behaviours.

They will have a central role in embedding rule based technologies and decision support in operational systems remote from the central laboratory, to influence requesting activities and reflect departmental / nationally agreed policies and procedures. The logistics of remote order requesting requires additional knowledge of the capabilities of systems in primary care, and a variety of configurations may be needed from a complete electronic order to a hybrid of using 2 dimensional barcoded (PDF) printed labels. Whatever means is used to communicate the request, supporting data protection remains important, including the application of basic cryptographic techniques to reduce the threat of message interception and tampering. Requesting will be facilitated by through process and workflow analysis tools to model logistics of pathology specimen transport from multiple sources to the laboratory.

Sample reception and pre analytical processing

Improving the workflow within the specimen reception through the use of advanced messaging systems (e.g. Buddyscape) for enhanced communications between the reception team is essential to dealing with the increasing laboratory workload. Medical laboratory aides (MLA) and technical officers (MTO) are increasingly required to be familiar with OCR form scanning. There are training and staff support needs in this context. Robotic systems for pre analytical sample processing are now common in laboratories and their integration in the specimen reception workflow will require thorough understanding of the way they interact with LIMS systems, particularly where rule based sample processing is required.

Analytical Phase

The majority of UK laboratories utilise instrument management systems that are positioned between the analysers and LIMS system. The AP will need knowledge of analyser interface design, and coding systems such as HL7. They would be expected to work with IT system suppliers to influence analyser-human interface design. It is envisaged that constraints on budgets and scarcity of trained staff will increase the dependence on robotics and there are major interface design challenges to ensure the technology supports the process rather than hindering it.

Post analytical phase

Input into this phase centres around the archiving and reporting of pathology data. This requires an awareness of regulatory requirements for data retention and organisation

of the laboratory databases to meet those needs. The datasets will be multimedia, including images, video, and increasingly audio as voice recognition technology is used for histopathology reporting. Archiving and organizing digital information of clinical importance will remain the domain of IT departments but the AP would be expected to be involved with the procedures that apply to this.

Communication of results to systems remote to the laboratory will be the responsibility of the AP. In the UK the requirements for this are stated in the Good Practice Guidelines CFH. This requires continuous monitoring of the transmission process and familiarity with middleware systems. Of relevance here are the mapping of test codes to ensure they are compliant with national coding systems (in the UK, Read and Snomed). The AP will be aware of the need to use the National Messaging Assurance Service (NMAS) and will have had their own organisation message accredited by this service. The policing of compliance with standards is a crucial requirement for the AP, they will also monitor the cryptographic procedures for public and private key management. A detailed description of what is required in this context is beyond the scope of this paper but can be referenced here. Inevitably patient misidentification problems will occur. The AP will ensure that staff utilise the national patient tracking service for conflict resolution.

Data Retrieval

The AP will have an understanding of the strategies required to retrieve specific information from laboratory information systems and other health records in order to display selected subsets of the information available about a given patient. For clinicians wishing to review their patients pathology results, the AP will need to ensure that systems (remote from the laboratory) can accurately identify and locate patients pathology data in their systems. The pathology dept has a responsibility to ensure that their data is displayed accurately on remote systems and that all the data elements that are needed to intelligently communicate the result are displayed on end user systems.

Data Analysis and Synthesis for Diagnostic reporting

This will be a strategic role for the AP who will have the skills to synthesise knowledge from the patterns that lie within pathology datasets. The goal is to improve decision support within pathology networks. The AP will be familiar with advanced informatics tools to achieve these high level aims. This will include knowledge of neural networks for data analysis and other pattern matching tools. Use of data mining tools to capture and deploy knowledge in laboratory and clinical decision support systems to ensure relevance and currency. The AP will use information technology to develop, implement, and monitor compliance with clinical pathways or guidelines and other forms of patient care protocols

Summary

This article is lengthy and deliberately so. The activities described will require a team supporting an advanced practitioner in pathology informatics with a status equal to that of a medical consultant. The most desirable configuration would be an AP serving a

pathology network encompassing up to 5 acute hospital units, each with their own pathology informatics support manager. The professional bodies that govern pathology will need to consider how best to put in place a training programme that will deliver the necessary skills and award a Diploma in Pathology Informatics that will be the seal of competence for such an individual.

References

[1] Jones RG & O'Connor JO. Information management and informatics: need for a modern pathology service. *Ann Clin Biochem*: 2004; 41: 183-191. This paper originated from the Pathology Modernisation Programme.

[2] A Systematic Review of Laboratory Clinical Audits Carl van Walraven, MD, MSc, FRCPC; C. David Naylor, MD, DPhil, FRCPC *JAMA*. 1998;280:550-558.)