

Evidence, safety and quality - an information strategy for NHS Pathology

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Foreword

Now is a critical time for pathology to mark its role in the overall delivery of health care. Pathology can be rightly proud of its achievements to date especially with regard to the current emphasis on quality and safety. With the NHS rapidly entering an era of expanded clinical IT systems, pathology needs to re-evaluate how it maintains and improves quality and safety within the new context.

The driving force of the workshop from which this strategy document is derived was outward-looking with an emphasis on the development of instant access within an episode of patient care to authoritative guidance on the use and interpretation of diagnostic investigations.

The direction set out in this document will inform a Pathology IT Summit to be held in November 2008 during which elements feeding into the strategy will be discussed in depth.

We are delighted for the endorsement given to this publication by the Royal College of Pathologists, the Institute of Biomedical Science and The Association for Clinical Biochemistry.

In addition, we wish to thank David Laszlo of Medical Mosaic for joining the workshop and synthesising this strategy document from the proceedings.

We hope the strategy will generate debate not only for service providers and users but also organisations and industrial partners developing IT support to laboratory processes.

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Introduction

This document sets out an information strategy for NHS Pathology in England. It invites debate about the future of pathology IT; but it seeks to frame that debate in its social, organisational and cultural context. What is offered here is a *sociotechnical* strategy, encompassing not only the use of computers, but the governance procedures, the changes to clinical processes, and the cultural shifts that need to take place if NHS pathology is to play its full role as the “essential service.”

The document begins with the service imperatives – what in another kind of document would be called the business drivers. There is a clear vision for pathology, and demand is rising. The need is for pathology to play its part in raising the quality of patient outcomes, and to do so by forming flexible networks of service provision.

The second section deals with the management of knowledge – the intricate process by which new research and emerging best practice is moved from the laboratory into day-to-day clinical care. Here too new processes are evolving.

The third section looks at the use of patient-specific information and at the process of requesting and using pathology services. The emphasis here is on safety and on the quality of communication between pathologists and requesting clinicians.

The final section draws these threads together by considering how the whole information strategy will impact the quality of the patient experience. It also draws attention to the challenges that lie ahead in implementing such a far-reaching set of changes.

In taking this approach the focus is overtly on the external relationships of laboratory services, and on the connections that can be established between co-operating clinicians and between the IT systems that support their work. Important developments are also taking place “inside” pathology, in the systems used for production, and these should also be the focus of debate and strategic engagement. Here, however, we seek to consider the impact of pathology in the context of wider developments in healthcare and healthcare IT.

Service imperatives

NHS Pathology has been on the brink of major change for a decade. Now, the components of that change are falling into place.

- There is a clear vision for pathology, as an essential diagnostic service at the heart of the NHS's pursuit of higher quality.
- The demand for pathology services is rising sharply.
- The technology that will support change is becoming available.
- There is a growing consensus about what needs to be done.

Pathology seems to be at a tipping point. Yet now more than ever there is a need for clear-sighted clinical leadership to ensure that the change, when it comes, produces real benefits for patients. This paper seeks to inform and energise that clinical leadership by setting out a strategy for pathology information.

The NHS in general, and pathology in particular, is an information business. Pathologists provide useful answers to good questions. This is a strategy to make the questions even better, and the answers more helpful.

Quality

Lord Carter's review of pathology services, like Lord Darzi's NHS Next Stage Review, makes quality the major focus. The patient experience is the primary component of quality. The NHS is to focus on creating a partnership with patients to ensure that patients get appropriate, timely and accessible care. In pathology, this implies a shift of power. Increasingly, it is the patient, and not the requesting clinician, who will own the test result. Arguably, the patient should be responsible for ensuring it is followed up. Yet they will continue to need the advice of clinicians to help them interpret results, and clinicians will continue to be held accountable for their use of test results. Our information strategy needs to help to resolve this tension between patient responsibility and clinical accountability.

Networks

Lord Carter places great emphasis on the power of networks to improve both efficiency and quality in pathology services. By networking, the service can adjust its capacity to meet the demand both for increasing volumes of routine tests, and for increasing numbers of unusual tests. Networks, by definition, require co-operation and interoperability: of people, of processes, of systems. Our information strategy needs to improve interoperability.

Transparency

As pathology laboratories co-operate increasingly, and the results of their work are made ever more accessible through improving information systems, so the nature of their work becomes increasingly visible. Variations in working practices and quality are less and less acceptable.

Results from one laboratory will be compared with those from another in a longitudinal patient record. Variations in reference ranges may obscure the picture; variations in the naming of tests may cause confusion. The answers will become less helpful; the questions may be lost. Our information strategy needs to support standardisation and be supported through standardised coding and messaging.

Evidence: using knowledge

Standardisation is helpful, but we need to choose the right standards. Our standards need to be based on the best available evidence.

This is not an easy process. The explosive availability of evidence and pseudo-evidence is a feature of the modern world. If all this information is to be turned into useful standards and is to improve the quality of the pathology “conversation,” it has to be harnessed: it has to be evaluated, to be disseminated, and to be governed.

Evaluating knowledge

Within the NHS, the task of evaluating the information provided by a wealth of sources falls to a range of bodies: the Department of Health, NICE, the NPSA, and so on. Following the Darzi Review, the role of NICE will be expanded and will absorb some of the functions of other agencies. Within this new structure, pathology needs to create its own capacity to evaluate the evidence base for its clinical practice.

It needs to be able to recommend the use of new tests, while advising against the use of outdated tests or those whose utility is questionable. It is proposed to create for this purpose a **National Pathology Catalogue Governing Board**, one of whose purposes will be to recommend the correct use of pathology tests based on evidence of utility.

Spreading knowledge

The NHS has created its own official channel for the dissemination of clinical knowledge: the National Library for Health. Following Lord Darzi’s NHS Next Stage Review, this will be integrated with the National Institute for Clinical Excellence (NICE) as NHS Evidence. Alongside this there are a very large number of other channels: traditional scientific and medical journals, informal networks of clinicians, the internet. Within pathology, there are a number of websites aimed at professional audiences. **BetterTests** and **LabTestsOnline Pro** (the “professional” pages of LabTestsOnline) contain stable, edited content designed to improve the use of tests. **Pathopedia** uses the “wiki” model allowing users to edit, add to and comment on the pages that are provided. The wiki model gives room for the growth of virtually-linked networks of clinicians who want to collaborate and take part in the definition, as well as the dissemination, of good practice.

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Governing knowledge

Once knowledge has been disseminated, we also need to be sure that it is being used and implemented correctly. The NHS Next Stage Review creates a new role in NHS organisations: the Chief Knowledge Officer, who has the responsibility to ensure that knowledge is both spread and implemented in their organisation.

Within pathology, the development of a **National Pathology Catalogue** will be a key tool in the governance of knowledge. The catalogue will be:

- Evidence-based and regularly updated.
- Clinically led and hosted by the Royal College of Pathologists.
- Owned by the NHS.

It will contain a current list of all tests for which there is clear evidence of utility. Each test description contains additional information or web links to ensure that the tests are used and interpreted correctly.

The day-to-day responsibility for the catalogue will fall to the National Pathology Catalogue Governing Board, which will have the power to accept novel assays and deprecate outdated ones. Local laboratories will be able to select subsets of the catalogue for their own use and to vary some attributes, for example sample tube specifications. Technical governance of the catalogue and its dissemination to IT systems will fall to NHS Connecting for Health (NHS CFH).

The catalogue is currently being created through the merger of existing regional catalogues drawn up under the National Programme for IT (NPfIT). These were themselves based on laboratory handbooks contributed by trusts in each region. The current effort is editorial: towards improving the data quality of the catalogue by removing obvious duplicates and ensuring that all tests have the full set of attributes. Only when the Board is set up will non-duplicate tests be added or removed.

The merger of the regional catalogues, and their underlying lab handbooks, has once again thrown a spotlight on the variation in working practices between labs. The **Harmony** project has been set up to address this variation.

It seeks to reduce variation in such things as reference ranges and test nomenclature through consensus, and by challenging idiosyncratic practice to justify itself. In the absence of a complete evidence base, this pragmatic approach is enabling the pathology community to move forward towards greater standardisation. This standardisation is essential if pathology services are to have credibility among other clinicians, and if the results of pathology tests are to be useful nationwide.

The **Primary Care Benchmarking Project** provides a complementary tool for comparison of requesting patterns.

The Harmony project improves communication between humans by standardising the names of tests and the definitions of “normal” for each one. Communication between machines requires a different sort of standard.

The NHS has adopted three key standards for IT interoperability:

- **SNOMED CT** for the unambiguous identification of clinical concepts such as diseases, findings, and procedures.
- **HL7** for the exchange of messages between systems from different manufacturers.
- The **NHS Number** for the unambiguous identification of patients.

These three technologies will, in the near future, work together to ensure that human networks of communicating clinicians and patients will be supported by computer networks of interoperable applications.

In pathology, we have created:

- Subsets of SNOMED concepts that are particularly useful to NHS pathology.
- A set of HL7 messages that can support the safe transmission of test requests and results between different systems.
- A National Catalogue where each test is identified by its associated SNOMED concepts.

The **Primary Care Pathology Requesting and Reporting Project**, already in its early stages, will implement a full requesting and reporting service between primary care and laboratories using these national standards. This will form the starting point for an eventual end-to-end IT infrastructure for pathology, as called for by Lord Carter.

This technology will not, on its own, achieve much. But the safe, efficient clinical practice which it enables will make a major contribution to the quality of the patient experience. The next section describes the features of that clinical practice.

Safety: using information

This section describes how patient information will be used and managed within the pathology service to improve patient safety and the quality of outcomes. In the terms we have been using, it describes how the conversation will be improved: good questions made even better, useful answers made more so.

Through the Primary Care Requesting and Reporting Project, and through Order Communications systems implemented in secondary care under the NPfIT, requesting and reporting pathology tests will become an electronic process.

Early systems will ensure that all the basic information is safely and unambiguously transmitted: NHS Number, SNOMED test request, and any other essential data to guide the test process.

Future systems will support the decision making of the requesting clinician, helping them to identify the right test, prompting them to offer useful additional information, helping them to request supplementary tests that may complete the picture. Not only will the name of the test, but also its purpose – the clinical context – be communicated. Sample taking will also be supported, and the reception of the sample at the lab will be swift and safe through the use of barcode ID.

Since the groundbreaking PMIP project, it has been possible to enter results into the GP-held patient record automatically. But the evidence shows that results are not always accessed by requesting clinicians. This gives rise to significant clinical risk. Further, in primary care, the patient record is often not available out of hours. Future systems will include processes for ensuring that abnormal or worrying results are acted upon regardless of the time of day, through the use of alerts and acknowledgement messages that confirm to the lab that the requester has taken responsibility for follow up.

The patient needs to be empowered to take on some of that responsibility. Future systems will send test results direct to patients, together with helpful interpretative information, and perhaps links to websites with more.

Because test results are standardised, they can be trended over time. The longitudinal patient record will become an increasingly powerful tool for the management of chronic disease as the quality of pathology data rises. And as patients begin to access their record regularly, they can learn to become expert in their own condition, and take their share of responsibility for keeping well.

Accurate and unambiguous data will make a major contribution to the care of the individual patient. But it will also provide a rich and growing corpus of data for other purposes. It may be used for benchmarking and service level reporting, and in turn for shaping future service provision. It will support research into trends in diagnosis such as staging of cancers at presentation, into the prevalence of microbial infections and changing antibiotic sensitivity. It will also allow processes to be developed for direct public health research and interventions.

Quality: Improving outcomes

Improved clinical decision-making and the safe transmission of results: these will create reductions in adverse incidents, in the time to diagnosis, and in the incidence of exacerbations of long term conditions. The cross linking of pathology results and interpretive comments will increasingly be a key element of care pathways and will assist in their creation and deployment.

The opportunities for significant, measurable improvement in patient outcomes are certainly there. Yet there are some significant challenges ahead as these new systems are implemented.

New measures of quality, specific to diagnostics, will need to be devised and there will need to be sustained effort and clinical leadership to ensure that:

- The evidence base for pathology continues to improve.
- The research is evaluated and disseminated.
- Governance procedures will take time to set up.
- They will need to build legitimacy through excellent leadership and through the transparency of their processes.
- Investment in IT will need to be matched by investment in process change, to ensure that the benefits of new technology are realised in practice.
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- Evidence informs the governance procedures, and through them, the catalogue
- Decision support still presents considerable technical challenges to system designers.

The partnership with patients implied by giving them direct access to test results involves a major cultural change for both patients and clinicians.

The path that this document sets out is not an easy one. But there are huge opportunities to be grasped for a safer, more efficient, more nimble pathology service. If we do not take them, our position will become harder and harder to defend.

This strategy summarises how the whole information flow, from new research findings to the most routine test request, will be managed and harnessed to enhance quality, reduce risk, and increase efficiency. This will rest on the twin foundations of sound clinical evidence and of excellent information technology.