

The National Laboratory Medicine Catalogue

Professor Peter Furness

President, RCPATH

It is surprising that the UK has not previously had a definitive list of the laboratory investigations that can be requested for the benefit of patient care. In respect of drugs, we have had the British National Formulary for many years. There are mechanisms to decide what drugs should be included in the list; whether they are available only on prescription, whether they are 'controlled'; the precise spelling of the single, unambiguous generic name; and basic advice on how each drug should (and should not) be used.

In contrast, in laboratory medicine tests do not even have an 'official' name. Different names in different settings may mean the same thing, or (worse) the same name may mean different things. There is no national mechanism to agree whether or not a test is worth using. The result, when considered across the country, is dangerous, wasteful and generates confusion.

This is about to change with the development of the National Laboratory Medicine Catalogue. It is being established by the Department of Health (England) and the main driver is Connecting for Health and the electronic patient record; computers are even less tolerant of variation in the way things are named than humans are. The result should have far-reaching benefits (Box 1). At the request of the Department of Health (DH), the RCPATH has established a Governance Board to oversee the development and maintenance of the catalogue.

History

Attempts have been made over several years to generate a national catalogue in laboratory medicine. Several local catalogues were merged, but every time a new local catalogue was added the size of the problem was highlighted; on every occasion a large number of new terms were added. Many of these were synonyms. Some were needed to satisfy the idiosyncrasies of local computer systems or ways of working; some were clearly obsolete. But the result was a huge, unwieldy list.

Part of the problem was that this list was 'pre-coordinated', which means that each item actually represented several separate elements. Even a

Box 1. Some potential benefits of the new National Laboratory Medicine Catalogue.

- It will define a common terminology so that doctors across the country will use the same words when ordering laboratory tests or receiving results.
- Results on a single named test delivered anywhere will be amenable to combination without risk of misinterpretation, whether by computer or by human intervention. This is crucial in the age of the electronic patient record.
- A process to guide whether or not a test should be included in the catalogue will represent a national decision process on the clinical utility of a test, minimising the work needed for local evaluation and providing a focal point for research input and manufacturers who wish to see a new test adopted throughout the country.
- The same test evaluation process will highlight gaps in our knowledge on test use, thereby guiding well-focussed translational research.
- Codes associated with each test (SNOMED-CT) will facilitate seamless, reliable electronic linkage to and between other relevant databases (such as Labtests Online, Map of Medicine and others).
- The process of evaluating tests for inclusion in the catalogue will, over time, generate a database of professional guidance on test use that will be made available to guide clinical use and interpretation – and avoid over-use.

simple entry such as 'plasma sodium level' is a concatenation of three elements; the substance to be evaluated (sodium), the sample type (plasma) and the type of measurement (the concentration). In 2008 it was decided that this 'single list' approach was unwieldy and would not work. The catalogue is now being converted to a 'post-coordinated' form, akin to a relational database rather than a flat-file database. 'Post-coordinated' means that the full definition of each test can be produced as and when needed, from the separate lists of attributes within the catalogue.

The Plan

The core dataset in the catalogue will include a list under each of the following headings:

- The test name. This will usually be a concatenation of the name of analyte or organism to be measured (e.g. 'sodium') and the type of measurement (e.g. 'level') An associated short display name and approved alternative test request display names will also be stored. A single 'test' may also be an order set or a profile (e.g. 'urea and electrolytes' or 'full blood count').
- The SNOMED CT code for that test
- The specimen type (e.g. 'plasma').

There will also be lists of terms to allow the definition of topography, morphology, laterality, test-specific specimen handling instructions and preferred units of measurement, as required. The full definition of a request will then be generated by concatenation of relevant items from each list, using appropriate rules. When deployed within a local system each organisation can choose which NLMC test requests to make visible to requesting clinicians as part of the local pathology services provided.

The core principles of the catalogue will apply across all disciplines of laboratory medicine, but the consequences will vary considerably in different disciplines. For example, clinical chemistry will involve a large number of tests and a small number of specimen types; topography, morphology and laterality will rarely be important. In histopathology there will be few tests, perhaps only 'histology' and 'cytology'; but the range of topology will cover the whole human anatomy.

Initially the catalogue will be constructed to permit the development of order communications systems for clinicians to use, but the next steps will include 'intra-laboratory orderables' (such as immunohistochemistry requests in histopathology or sub-typing of organisms in microbiology) and 'reportable' items.

The Methods

At the request of (and funded by) the Department of Health, the RCPATH has established a Governance Board to oversee the development of the Catalogue. A National Clinical Lead has been appointed (Paul Collinson), together with five Specialty Leads covering the main disciplines of laboratory medicine. These individuals are being funded part-time by DH to work on this project, but they will need to recruit specialists to assist and advise them. The existing unwieldy pre-coordinated list of tests has not been completely abandoned, because it represents a valuable check-list of the concepts that the new catalogue will need to cover. Compatibility with 'legacy' computer systems will be maintained as far as possible. But the flat-file list has been converted to a post-coordinated set of lists, as explained above, and an online software tool has been created to facilitate its editing. The work of eliminating duplicates and improving consistency has begun. Protocols for editing the database are being developed and ultimately approval of changes will be the responsibility of the Governance Board.

The Future

Milestones for the development of the catalogue will include the initial release date, implementation by users and approval by the Information Standards Board. The NLMC Governance Board is working closely with

the UK Terminology Centre to ensure coding meets the necessary standards. . These milestones apply only to the initial list of 'clinician orderable' items. The incorporation of intra-laboratory orderables and reportable items will come next. Once the catalogue has documented the tests we use now, the major challenge for the future will be keeping the catalogue up to date.

Decisions on whether the health service uses a new development should be based on the benefit it brings to patients; on its clinical utility. This is much harder to measure than parameters such as the sensitivity and specificity of a test. Demonstrating patient benefit from a new drug is notoriously difficult and expensive, but demonstrating patient benefit from a new diagnostic test can be even harder. For example, clinical trials of drugs are usually restricted to patients who have a specific disease. How do you define entry criteria for a diagnostic test, in a way that will allow meaningful evaluation of its clinical utility? If a test has utility in hospital, what does that mean in primary care? The National Institute for Healthcare and Regulatory Excellence has always had a remit to cover diagnostics in addition to therapeutics, but so far it has had little impact in that field. This is set to change, with expansion of the work of NICE in diagnostics and a new set of methods more suited to the difficulties of working in this area. But it seems inevitable that NICE will still be unable to answer every question that arises. It will address the issues that are important, in terms of patient numbers, patient impact and cost to the NHS. But at the other extreme, it is unlikely that NICE will wish to consider whether or not a new antibody is helpful in the characterisation of a rare tumour. It is uncertain what other mechanisms will be required for the evaluation of diagnostic tests not undertaken by NICE; but it seems inevitable that the Governance Board will have to take some decisions on the content and the structure of the catalogue in relation to issues that NICE cannot handle. A 'triage' mechanism to decide how each new development should best be handled has yet to be agreed.

Making these decisions will demand the accumulation of evidence on the use of tests. That information must not be wasted, but should be made available to users, much as the British National Formulary provides advice on drug use. This evidenced based route to the inclusion of new tests or new uses for established tests will be supplemented by work currently commissioned by DH on creating a decision support system for laboratory tests. This work includes a trawl of available information from a wide range of resources, creation of an editorial process to review the information acquired, transforming information in order that it answers users' questions and determining what electronic format is required to link to NLMC.. Although not the initial priority of the catalogue team, a longer-term aim is to have a very open approach to the generation of advice, potentially inspired by the success of the online encyclopaedia 'Wikipedia', where anyone can offer a contribution. We hope to involve trainees in this process. Being able to search the published literature, evaluate the evidence and synthesise logical conclusions are skills that any consultant needs. So it is hoped that pathology trainees will be invited to take an investigation, evaluate the evidence and produce (or improve upon) advice on its use. Submissions judged worthy of publication will no doubt be worthy of inclusion in the author's *curriculum vitae*.

The Stakeholders

If you have read this far, you clearly have an interest in this process, so you (or, more probably, an organisation that you represent) may wish to become a National Laboratory Medicine Catalogue Stakeholder. This is the method by which we aim to ensure that the catalogue remains relevant and responsive to its users and the wider healthcare community. NLMC Stakeholders will:

- Obtain regular updates about the catalogue by email
- Have online access to all NLMC documents, including minutes of meetings, operating procedures, Editorial Principles etc.
- Be invited to express opinions and advice to the Governance Board at any time.

- Be invited to an annual Stakeholder Meeting to exchange views on how the catalogue is developing

Stakeholders can propose themselves for acceptance by email to anne.boxill@rcpath.org ; the Governance Board will decide on admission to the list, but we do not intend to be unduly restrictive. We hope to hold the first Stakeholder's Meeting in December 2009.