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# Standardisation of test requesting and reporting for the electronic health record☆,☆☆

Michael Legg

*School of Medical Sciences, University of New South Wales, High St, Kensington, NSW 2052, Australia*
*Pathology Informatics Advisory Committee, Royal College of Pathologists of Australasia, 207 Albion Street, Surry Hills, NSW 2010, Australia*
*Michael Legg & Associates, 12 Dianella Street, Caringbah, NSW 2229, Australia*

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ABSTRACT

This paper is a review of the standardisation required to achieve interoperability for pathology test requesting and reporting. Interoperability is the ability of two parties, either human or machine, to exchange data or information in a manner that preserves shared meaning. This is needed to make healthcare safer, more efficient and more effective. Interoperability requires standardisation around: transmission of data; identification policies; information structures; common terminology; common understanding; and behavioural agreement. It is dependent on consensus. Each of these aspects is considered from the perspective of pathology requesting and reporting concluding that while much has been done, much remains to be done.



## 1. Introduction

All countries with advanced economies are facing increased demand from ageing populations with chronic diseases. Many also have shortages of skilled workers and evidence of avoidable errors causing serious harm in their health systems. Indeed it seems optimal care only occurs about half the time in even the best performing health systems [1]. Doing more of what we do now just a little better, even if that is continuous, will not be enough to address the looming crisis in sustainable healthcare.

Laboratory medicine and informatics have important roles to play in transforming healthcare so that it is much safer, more effective and more efficient. Core to this is being able to bring science, technology and people together. In particular, we need the help of machines to cope with the ever more complex knowledge domain and the greater demands put upon the people working to care for the sick, but importantly for all the stakeholders, in moving from reactive medicine to more proactive healthcare [2,3].

Conveying meaning from the head of one person to that of another while engaging the power of informatics and its machines to help with decisions and freeing humans up to do what they do best, requires the standardisation of knowledge, language and communication. Laboratory medicine has been at the vanguard of this.

### 1.1. Standardisation

Standardisation is the reduction of variation in a process with the intent of improving compatibility, interoperability, repeatability, safety and other elements of quality. It often involves developing and implementing technical standards but it starts with policy and premier, the policy on what should be standardised.

Standards have been around in healthcare for a very long time. The Code of Hammurabi inscribed on a stone pillar before 1750 BC included laws relating to the practice of medicine in Babylon.

Standards are given a lot of different names in health. Titles like policy, procedure, protocol, work instructions, guideline, handbook, rules, statement, code of conduct, regulation, benchmarks and law may be used to describe a standard. The different words that are used

*Abbreviations:* CDA, Clinical Document Architecture; CIS, Clinical Information System; EHR, Electronic Health Record; HL7, Health Level 7; HUGO, Human Genome Organisation; IHTSDO, International Health Terminology Standards Development Organisation; ICD, International Classification of Diseases; ICDO, International Classification of Diseases for Oncology; IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; IUPAC, International Union of Pure and Applied Chemistry; LOINC, Logical Observation Identifiers Names and Codes; C-NPU, IFCC Committee on Nomenclature, Properties and Units; SNOMED CT, Systematized Nomenclature of Medicine-Clinical Terms.

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sometimes indicate the level of consensus or authority with which they are made and/or are intended to be used but not always.

In the end, implementing standards or standardisation should save money, save time and/or improve health outcomes.

Standards can come about by:

1. Consensus — amongst competent authorities which is usually achieved through strategic stakeholder representation in committees.
2. Defacto — where standards just exist by custom and general consent without ever being formalised and have come to be accepted because they make sense.
3. Legislation — where a particular standard is mandated by law. Usually, the legal process is preceded by a process such as one of the above.
4. Hijacking — where standards are produced by a major player, either a vendor or a purchaser, which sets a trend that others follow.

For the most part, the standards relevant to requesting and reporting pathology are being developed by consensus. It is too hard to do it otherwise. They gain authority through approval by recognised bodies through documents that provide for common and repeated use rules and guidelines aimed at the achievement of the optimum degree of order.

### *1.2. Policies*

The process of standardisation requires agreeing on what is trying to be achieved and the principals around how that is to be done. In management and informatics these are often called business rules. These may themselves begin with policy statements from learned bodies such as medical colleges or from governments and their agencies. At the more detailed level, business rules are recorded in structured documents such as what the Prince II project management methodology calls a 'Concept of Operations'. Much of what needs to be done for standardisation happens, or at least should happen, at this policy level.

Consider what the role of laboratory medicine is in healthcare at the highest level. Whether it is initiated as the referral of a patient to a specialist in laboratory medicine (where a clinical question is often asked) or ordered from a laboratory as a catalogued test, will and does have significant bearing on how the laboratory is used and so, on how and what is standardised especially when it comes to requesting and reporting.

The answer to questions like this is not straight forward and depends on timing and discipline. Furthermore with the current rapid advances in our understanding of biology, the prevailing answer may well change in the near future.

By contrast standardisation at the lowest levels is fundamental and so somewhat less controversial. Regardless of the high level considerations, most agree that standardisation of what a 'test' is called, what units are used to measure it, and how you communicate it so you get most value is both desirable and achievable. It is sometimes described as having the right information, in the right place, at the right time, for the right person and in a form that the right people and their machines can make use of it. The right people here are consumers, patients, clinicians, managers and researchers.

Prevailing policy has bearing on standardisation. For the requesting and reporting of pathology in a digital world this includes policies relating to:

1. Ethics and privacy
2. Security and authentication
3. Evidence based medicine and guidelines
4. Taxonomy and health concept representation
5. Quality systems, audit and assessment
6. Records management, retention and business continuity
7. Chain of information custody and handover
8. Communications
9. Funding and payments

The remainder of this paper focuses on standardisation to achieve interoperability in the requesting and reporting of pathology at the fundamental level.

## 2. Interoperability

Interoperability is the ability of two parties, either human or machine, to exchange data or information in a manner that preserves shared meaning[4].

Work towards this standardisation in pathology has been going on as long as pathology has been a recognised discipline. For electronic communications it has been underway for some 40 years and so it is not even new here [5]. This does not mean that it is all done and there is no more to do however.

In terms of the pathology process, we know that most errors occur not in the analysis phase, but in the pre-analytical and post-analytical phases [6] and so interoperability for requesting and reporting pathology offers the most opportunities for improvement. Imai would say it provides a mountain of treasure [7].

Because of this, and because many of its practitioners are systems-thinkers, pathology has been always been at the vanguard of the expanding electronic communications of health information. National repositories and information exchanges nearly always include pathology. Reports are being distributed more widely and the reports from different laboratories (and their component results) are being mixed and matched more often than ever before. All of this adds to the risk of error where there is variation.

Analysing a common, although as it develops not so simple scenario involving the requesting and reporting of pathology is a useful exercise in understanding what standardisation is required and why.

In this scenario or use-case a patient visits the family doctor and has pathology tests requested (a in Fig. 1). The request includes an identifier for the patient that must be unambiguous wherever the request goes and be linked to the resulting report wherever that goes. The request also contains either the question being asked of the laboratory or the tests being ordered from it. In either case this has to be fully understood by the receiving laboratory.

There will often be associated information needed by the requestor around the test to aid in the selection of the tests (or how to ask the clinical question) and for specimen collection. Conveyed with the request is the clinical information required by the laboratory to undertake the testing and to provide its professional advice. This clinical information derives from the electronic health record of the requestor and is conveyed from one system to another electronically so that it has the same meaning at the laboratory as at the family practice. In addition a level of urgency and preferred mode of communication is conveyed along with other demographic, timing and billing information related to the transaction.

In this scenario the laboratory is not able to do all of the tests requested of it (which is not unusual) and some tests are referred to another laboratory (b the request and c the report for this in Fig. 1).

All of the relevant information related to the subject is conveyed to the second laboratory in the request, and the report from Laboratory 2 is matched to the patient episode and incorporated into the electronic health record at Laboratory 1. The electronic health record here is generally referred to as being a Laboratory Information System LIS or similar.

A report that includes the results of the referred testing is then returned to the requesting doctor (d in Fig. 2) with a copy sent to the specialist that has also been looking after the patient (e in Fig. 2). An address is required to send the pathology report.

On receipt, the pathology report is linked to the patient in the electronic health record of the family doctor (often called a clinical information system (CIS) or office system). The pathology laboratory needs to know that the report has been received in the manner it was sent and the receiver needs to know that the request has been fulfilled in the