

FINAL REPORT

The Pathology Units and Terminology Standardisation Project

A Report by
The Royal College of Pathologists of Australasia

to the
Australian Department of Health and Ageing

Diagnostic Services Branch



Australian Government

Department of Health and Ageing

Pathology Section

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ABBREVIATIONS

APUTS	Australian Pathology Units and Terminology Standardisation (Standards and Guidelines)
HL7	Health Level Seven
IAC	(RCPA) Informatics Advisory Committee
LOINC	Logical Observation Identifiers Names and Codes
MSIA	Medical Software Industry Association
NEHTA	National E-Health Transition Authority
PAC	Pathology Associations Council
PITUS	Pathology Information, Terminology and Units Standardisation (Project)
PUTS	Pathology Units and Terminology Standardisation (Project)
RACGP	The Royal Australian College of General Practitioners
RACP	The Royal Australasian College of Physicians
RCPA	The Royal College of Pathologists of Australasia
SA-IT-14-6-5	The sub-committee at Standards Australia responsible for diagnostics
SNOMED	Systematized Nomenclature of Medicine
UCUM	Unified Code for Units of Measure

Definitions and references by URL are provided for many of these terms in Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines

EXECUTIVE SUMMARY

Introduction

Pathology reports have evolved from being department-specific to covering the whole patient episode. Now they are often synthesised from the results and records of multiple, sometimes-unrelated, organisations. Pathology reports are also now distributed more widely. It is current routine practice for clinicians to receive reports from multiple laboratories and in some cases for these to be further aggregated into regional health records. The PCEHR promises to do this at the national level.

Despite electronic reporting of pathology since 1993 and an Australian Standard for messaging since 1998, there remains significant variation in the form and content of electronic pathology reports. This is especially true of the way that tests are named and coded but also in the units that are used for reporting. This variation arises from different laboratories having different policies but also from the same laboratory providing different outputs to different customers. Reports go to widely different healthcare settings including hospitals, community medical practices, indigenous health services, aged care institutions, allied health practices and homes.

Components of reports are frequently used in comparative displays and in decision support. There is a risk of misinterpretation if terminology and units differ, but even when these are the same, there are circumstances where differences in test methods and/or reference intervals make comparison inappropriate. All this has led to serious concerns for clinical safety. This, combined with the growing desire to make more use of pathology for decision support in other information systems, drives the requirement for standardisation of units and terminology.

To address this, a National Pathology Terminology and Information Standardisation Plan was developed and endorsed by NEHTA, Standards Australia IT-14-6-5, and the Pathology Associations Council. The plan has the following vision, aims and principles:

- Vision
 - Australia has access to and uses standardised pathology information structures and terminologies to optimise systems for recording, decision support, communication and analysis so as to improve healthcare for the individual, population health and the healthcare system for its practitioners and payers.
- Aims
 - Set-up a system to develop, maintain and distribute pathology health concept representation (terminology and information structures) for Australia
 - Develop specific guidance for the binding of terminology in messaging
 - Undertake content development by discipline
 - Develop a standard for the representation of units in Australian pathology reporting
 - Establish a one-stop shop for all pathology terminology
 - Drive adoption
 - Establish a workable compliance conformance and accreditation environment relating to pathology terminology
- Principles
 - That terminology for pathology reporting and requesting should be standardised
 - That no single terminology can do it all - indeed many will be needed for different purposes (including but not limited to SNOMED, LOINC, HL7 tables, ICD-O, MeSH)
 - That terminology development, maintenance and distribution is a specialised activity that would best be done in a dedicated unit with the same tools – The NCCTI (NEHTA) has indicated its capability and willingness to work with industry and the profession on this

- That the 'traditional knowledge owners' who know and care should be in charge of developing that knowledge in terminology

The PUTS Project

A national project for the Standardisation of Pathology Units and Terminology (PUTS) was initiated by the RCPA in July 2011 with support from DoHA. The RCPA-led Pathology Units and Terminology Standardisation Project addresses four of the nine sub-projects in the 2011 National Pathology Terminology and Information Standardisation Plan¹. These four projects were the projects that the profession had undertaken to lead. They were:

- Standard for units of measure which aims to develop a revised standard for the use of units in pathology indicating preferred units for display and a mechanism for their representation in electronic messaging.
- Australian pathology terminology sets which aims to develop sub-sets (or reference sets) of pathology terminology for requesting and reporting pathology by discipline
- Standardisation of report terminology for common biochemistry items which aims to develop fully specified terminology for the reporting of common chemistry items used in decision support
- Terminology for structured cancer reporting which aims to review the protocols for structured cancer reporting and ensure terminology is available, consistent and ultimately able to be used in electronic decision support.

Around 80 pathologists, scientists, informaticians and other clinicians worked in 8 working groups to establish guidelines for the use of terminology and standardised units covering each of the pathology disciplines.

Project Outcomes

The project produced:

- Constrained sets of the most common terms and their corresponding codes and units have been developed for requesting and reporting pathology using consensus-based standards development and good clinical governance. The Project Steering Group decided on the adoption of: SNOMED for requesting; LOINC for the reporting question (HL7v2 OBX-3); and UCUM for the representation of units.
- A Standard that describes the rules and records knowledge work done by the PUTS project teams.

The Standard, information models, terminology and recommended units have been endorsed by the College at its meeting of February 25, 2013 as policy following internal and public review and endorsement from all of the main stakeholders.

A summary of project outcomes against its objectives is provided in the Table below:

¹ The full plan is provided in the Introduction to the Standards and Guidelines at Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines

From the Agreement	Achievements of the PUTS project
<p>To develop and approve a revised set of standards for units of measure that are able to be represented electronically.</p>	<p>The APUTS Standards and Guidelines document describes the principles for selection of units (applied by the PUTS working groups), provides guidelines on the use of units in reports and provides a table of preferred units. Each of the reporting test terms for which a code was chosen had a preferred unit assigned. These appear in the reference set with the code and Australian preferred term.</p>
<p>To develop and approve standard terminology sets (SNOMED CT, LOINC, etc) including advice for their use.</p>	<p>After diligent review and consideration of the options, SNOMED CT AU was selected as the preferred terminology for requesting pathology tests and LOINC for the test name (or heading) to report it. This is now policy of the RCPA through the APUTS Standards and Guidelines. A code was selected from the appropriate terminology for common tests in requesting and reporting. For each of these the Australian preferred term and preferred units were determined along with synonyms. These form reference sets grouped by requesting and reporting disciplines. In a small number of cases preferred units could not be chosen and more work is needed. In order to select the appropriate terms an information model was required in a number of cases. These were developed for the common instances. Where terms were not available an application has been made to NEHTA/IHTSDO or Regenstrief/LOINC for these terms to be added. An additional piece of work was done by the Microbiology working group and that was to develop an Australian reference set for pathogenic organisms from SNOMED-CT-AU</p>

<p>To develop a fully specified terminology for the reporting of 'common' biochemistry items used in clinical decision support including advice for their use.</p>	<p>To address the safety concerns around the dangerously inappropriate combination of tests in cumulative reports, graphs and decision support software, a traffic light system of indicators was developed and applied to the reference set of reported biochemistry tests. Green indicates that the tests may be combined providing specified but general criteria are met; Orange means that there may be danger in doing this but where there is detailed knowledge about the laboratory and how the results are to be used that it may be acceptable; and Red means that results from these tests should never be combined. In addition to these indicators different LOINC codes were chosen for most of the 'red' tests and a rule developed for the APUTS Standard that says test with different codes should never be combined. A back up system of an indicator in one of the fields in the electronic message will also be needed and development of this and its inclusion in the messaging standard forms one of the important future tasks.</p>
<p>To review the protocols for cancer reporting and ensure terminology is available, consistent and able to be used in electronic decision support including advice for their use.</p>	<p>Two cancer reporting protocols were analysed in detail. Because it was found that LOINC did not have terms with the level of granularity required by the structured cancer reports, the RCPA SPR project in conjunction with the Anatomical Pathology working group undertook development of terms using temporary codes with OID (unique) identifiers that can be added to terminologies as appropriate. The College has taken an OID trunk from HL7 Australia in order to undertake this work.</p>

All project milestones were met and in many cases exceeded. This, however, did require an extension of time.

Conclusion and Next Steps

Work toward the standardisation of pathology requesting and reporting has been underway for more than 20 years. While significant and valuable further progress has been made with the PUTS Project there remain a number of opportunities for improvement. This is especially so in the uptake of standards and standardisation.

It is critical to provide all the artefacts necessary before compliance and conformance can be put in place to achieve full semantic interoperability. While close, there remain barriers to interoperability between systems which will be further addressed by the projects proposed under the Pathology Information Terminology and Units (PITUS) Project.

The deliverables from the PITUS project will also support increased consumer involvement and provide the infrastructure and tools to make the provision and consumption of pathology services safer and easier.

In the end however it is facilitating and supporting uptake and implementation of standards that will break down the existing barriers. A number of aspects of this project directly address this most difficult of areas of standardisation. The group of organisations assembled for this project and led by the College is most likely to influence and effect those changes seen as beneficial.

The PUTS Project Steering Committee, as part of its work, considered the next steps that should be undertaken. They subsequently developed a plan which itself forms a component of the broader plan of the Informatics Advisory Committee (IAC) of the College. The plan of the RCPA IAC showing the context of the PUTS and PITUS projects, what has been achieved so far and what is being proposed with PITUS can be found at Appendix K – RCPA Informatics Project Plan.

The RCPA will work with members of the Pathology Associations Council, NEHTA and the Department to build on and extend the work of the Pathology Units and Terminology Standardisation (PUTS) project in the Pathology Information Terminology and Units (PITUS) Project. It will make use of the established and successful clinical governance structure and project team of PUTS and is supported by the PUTS Steering Committee. In particular the PITUS project will review and improve on implementation of the Standards developed for requesting and reporting pathology by PUTS and extend the policies and standards in those areas considered of clinical value where this can be achieved in the time-frame proposed.

The aim of the PITUS Project is to continue the development of standards for information in pathology requests and reports and to facilitate their uptake by pathology practices and their customers to allow safer and better quality use of pathology.

The purpose of the project is aligned to that of the Department's Quality Use of Pathology and E-Health Programs and the PITUS Project is a necessary requirement for the broader E-Health Program's success and the Pathology MoU Agreement.

The challenge in standardising as opposed to standards-development alone is to get uptake. An important strategy is to make it easy for implementers to conform and comply. Development of the RCPA knowledge management systems for sharing the output of these information based projects is a critical element of that process. This will also provide NEHTA with guidance as to how this function might be done more generally for their artefacts. The project as proposed is not intended to duplicate any existing functionality.

1 BACKGROUND

Pathology reports have evolved from being department-specific to covering the whole patient episode. Now they are often synthesised from the results and records of multiple, sometimes-unrelated, organisations. Pathology reports are also now distributed more widely. It is current routine practice for clinicians to receive reports from multiple laboratories and in some cases for these to be further aggregated into regional health records. The PCEHR promises this to be done at the national level.

Despite electronic reporting of pathology since 1993 and an Australian Standard for messaging since 1998, there remains significant variation in the form and content of electronic pathology reports. This is especially true of the way that tests are named and coded but also in the units that are used for reporting. This variation arises from different laboratories having different policies but also from the same laboratory providing different outputs to different customers. Reports go to widely different healthcare settings including hospitals, community medical practices, indigenous health services, aged care institutions, allied health practices and homes.

Components of reports are frequently used in comparative displays and in decision support. There is a risk of misinterpretation if terminology and units differ, but even when these are the same, there are circumstances where differences in test methods and/or reference intervals make comparison inappropriate.

All this has led to serious concerns for clinical safety. Combined with the growing desire to make more use of pathology in other information systems there has been a drive to standardisation of units and terminology².

1.1 Context

To address this concern, a National Pathology Terminology and Information Standardisation Plan was developed and endorsed by NEHTA, Standards Australia IT-14-6-5 and the Pathology Associations Council. The plan has the following vision, aims and principles:

- Vision
 - Australia has access to and uses standardised pathology information structures and terminologies to optimise systems for recording, decision support, communication and analysis so as to improve healthcare for the individual, population health and the healthcare system for its practitioners and payers.
- Aims
 - Set-up a system to develop, maintain and distribute pathology health concept representation (terminology and information structures) for Australia
 - Develop specific guidance for the binding of terminology in messaging
 - Undertake content development by discipline
 - Develop a standard for the representation of units in Australian pathology reporting
 - Establish a one-stop shop for all pathology terminology
 - Drive adoption
 - Establish a workable compliance conformance and accreditation environment relating to pathology terminology

² A longer description of the background including what constitutes good practice in terminology and the selection of units is provided in the Introduction to the Standards and Guidelines provided at Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines.

- Principles
 - That terminology for pathology reporting and requesting should be standardised
 - That no single terminology can do it all - indeed many will be needed for different purposes (including but not limited to SNOMED, LOINC, HL7 tables, ICD-O, MeSH)
 - That terminology development, maintenance and distribution is a specialised activity that would best be done in a dedicated unit with the same tools – The NCCTI (NEHTA) has indicated its capability and willingness to work with industry and the profession on this
 - That the ‘traditional knowledge owners’ who know and care should be in charge of developing that knowledge in terminology

A national project for the Standardisation of Pathology Units and Terminology (PUTS) was initiated by the RCPA in July 2011 with support from DoHA. The RCPA led Pathology Units and Terminology Standardisation Project comprised four of the nine sub-projects in the 2011 National Pathology Terminology and Information Standardisation Plan³. These four projects were the projects that the profession undertook to lead. They were:

- Standard for units of measure which aims to develop a revised standard for the use of units in pathology indicating preferred units for display and a mechanism for their representation in electronic messaging.
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- Terminology for structured cancer reporting which aims to review the protocols for structured cancer reporting and ensure terminology is available, consistent and ultimately able to be used in electronic decision support.

The RCPA Informatics Advisory Committee was established in November 2012. This represented a major milestone toward professional recognition of Informatics as a domain in pathology. As part of its informatics project co-ordination role for the College, the Committee began the development of a plan at its first meeting. The plan covers:

- RCPA Policy Development
- Informatics Standards Development
- Standards and Policy Adoption
- Knowledge Management, Workforce and Research

The RCPA Informatics Project Plan in its current form is provided at Appendix K – RCPA Informatics Project Plan. Marked on this plan is what has been done in the PUTS Project to date and what is proposed; both as part of the subsequent PITUS project and in other projects led by the College and where the College is a key participant. This is further discussed in the ‘Next Steps’ section of this document.

1.2 Stakeholders and expected benefits

The key stakeholders identified and their expected benefits for the activities associated with standardisation of pathology units and terminology are:

³ The full plan is provided in the Introduction to the Standards and Guidelines at Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines

Health consumers (subjects of care)

Health consumers (subjects of care) are the ultimate beneficiaries of improving the quality of use of pathology services which this project was aimed at. Improved efficiency by optimising requesting and removing waste in follow-up and from error are both direct and indirect benefits to consumers. Standardised information also increases the opportunity to link knowledge resources and to provide consumer decision support.

Requesters and report recipients

Easier, more accurate requesting of pathology and by providing the foundations for decision support leading to improved use of pathology are direct benefits to requesters. Report recipients benefit from more comprehensive advice provided with more history and clinical notes. Reduced error caused by variation in report rendering such as with cumulative report formats, units, comparisons and flagging of results. This variation has been identified by the RACGP as a significant issue.

Pathology laboratories

Reduced maintenance and development costs associated with information systems development in particular reduced cost of variation caused by different requirements from registries and GP/Specialist clinical systems are benefits to laboratories. There is also some potential for improved efficiency with not having to chase additional information associated with incomplete requests but this is offset by additional knowledge work with more to consider in making comments, recommendations and providing advice.

Pathologists

Improved capacity to add value and reduce risk in reporting with better recommendations and advice because associated history and clinical notes are available are benefits for pathologists. Increasing opportunity for targeted linkage to knowledge resources and decision support tools is likely to increase the quality and ultimately the productivity of pathologists who are in short supply and face workload stress.

Medical Software Industry

Industry has consistently called for standards that they can use in their design and implementation of systems that interact with pathology to reduce the workload in developing and maintaining information structures and terminology. These standards however also offer opportunity for innovation to add value leveraging the knowledge of others.

NEHTA

The NEHTA work program has clinical information and terminology as a deliverable at the national level. This can only be done by harnessing the knowledge from subject matter experts. PUTS and subsequently PITUS offer the platform for getting that knowledge in pathology. The outputs from PUTS and PITUS will be made available to the Clinical Terminology and Information Service. The most significant benefit to the NEHTA Program is effective engagement.

Governments

The Pathology Funding Agreement has components relating to pathology reports in the National Electronic Health Record Service and Decision Support for Requesting. This follows identification of smart requesting, smart reporting and workforce as significant opportunities to improve the Quality Use of Pathology. This project continues to deliver on the elements needed to advance this policy area and is required to meet commitments under the Funding Agreement.

1.3 This document

This document is the final report of the Pathology Units and Terminology Standardisation Project, as specified in clause 11.3 of the Standard Funding Agreement between the Department of Health and Ageing and the Royal College of Pathologists of Australasia dated April 2011.

2 GOVERNANCE AND METHODOLOGY

The governance and consensus process used for the PUTs project was modelled on the successful Structured Cancer Reporting Project which itself drew on processes adopted by Standards Australia and NPAAC. The success of the project reinforces the importance of good governance and strong consensus building processes.

Detail on governance and methodology is provided in Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines. This includes an organisation chart, a list of members of the expert committees and a full description the development process including public commenting. Also touched on are the International liaisons that took place.

The relevant excerpt from that document is provided here for convenience:

Excerpt starts here -----

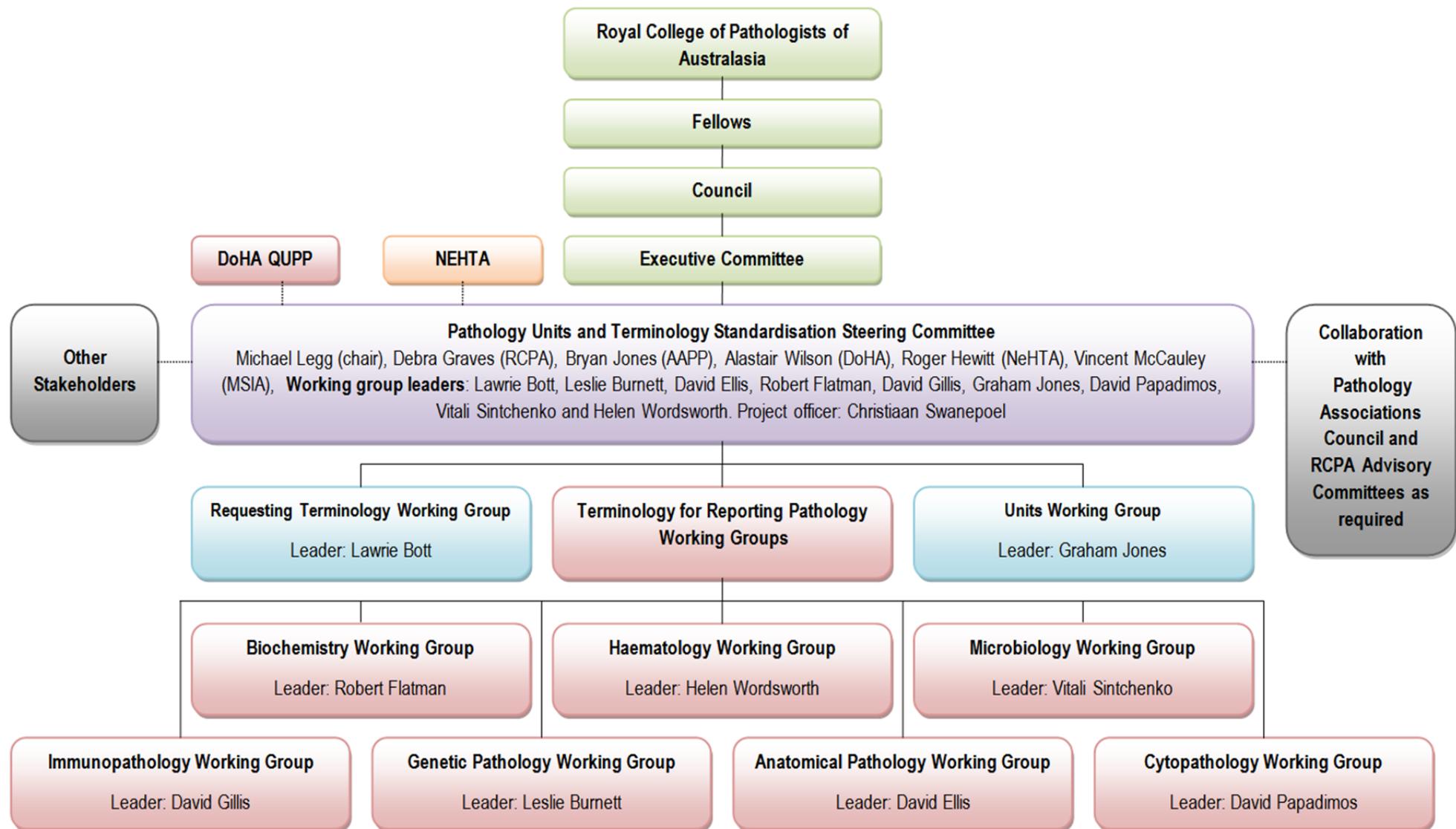
Authority and development

All of the authorised outputs from the APUTS project were subject to the governance described in the diagram below. This approach and governance structure is modelled on that used successfully by the RCPA for the development of protocols for reporting the laboratory findings associated with cancers.

While all member organisations of the Pathology Associations Council were stakeholders in developing consensus for these standards the ultimate authority for this document rests with the Council of the Royal College of Pathologists of Australasia.

The initial work for this standard and its associated documents was developed by some 80 pathologists, other clinicians, scientists and informaticians as part of the RCPA Pathology Units and Standardisation Project from April 2011 to November 2012. A similar process to that used by Standards Australia for the development of consensus standards was used here. More detail is provided in the 'Development process' section below.

Membership of the Steering Committee and the working groups is provided at **Error! Reference source not found..**



Standard developers

This standard was developed by expert committees, with assistance from relevant stakeholders. It draws on SNOMED owned by the International Health Terminology Standards Development Organisation and LOINC owned by Regenstrief Institute under their respective license terms. The license terms for SNOMED are provided at https://nehta.org.au/aht/index.php?option=com_content&task=view&id=5&Itemid=35; and for LOINC at <http://loinc.org/terms-of-use>.

Expert committee

The expert committee responsible for this document was the Pathology Units and Terminology Standardisation Steering Committee. Members of the Committee and its Working Groups are listed in **Error! Reference source not found.**

International liaison

Australia is an active participant in international activities toward the harmonisation of standards for pathology. In particular the UK National Health Service has for some years been working on a single national catalogue, the National Laboratory Medicine Catalogue (NLMC) for the electronic requesting, laboratory processing and report generation of pathology tests for use within the National Health Service. While the actual terminology used in England has not been adopted, in the interests of harmonisation we have attempted to align the rules here with those of the UK where this is practical. Similarly, this approach has been adopted with LOINC and SNOMED terminology rules.

Acknowledgements

The Pathology Units and Terminology Standardisation Steering Committee wishes to thank all the pathologists, other clinicians, scientists and informaticians who contributed to the discussion around this document. In particular, we acknowledge the active and diligent contributions of the Working Group Members.

The initial project had funding for its administration provided by the Australian Department of Health and Ageing. The time and effort of the members, however, was provided on a voluntary basis and this contribution by individuals and their employers is both recognised and appreciated.

Stakeholders

The pathology profession was represented through the Royal College of Pathologists of Australasia (RCPA) and other members of the Pathology Associations Council (PAC) www.pathology.med.pro.

The pathology profession defines and endorses the clinical terminology to be used for pathology in Australia with regard to the customers and colleagues of medical laboratories. The National Clinical Terminology and Information Service (NCTIS) within the National E-Health Transition Authority (NEHTA) is responsible for managing, developing and distributing SNOMED CT-AU in Australia and is expected to publish other terminologies for pathology in due course. The Standards Australia Committee IT-014, and in particular its

working group for diagnostics IT-14-6-5, provides the main link to Australian and international health informatics standards development, software developers and users. The Medical Software Industry Association provides a representative connection to the commercial developers of medical information systems.

Other relevant stakeholders are identified in the National Plan above.

Secretariat

Professor Michael Legg PhD FFSc(RCPA) FAICD FAIM FACHI acted as the Project Manager and Dr Christiaan Swanepoel MBChB MMedChemPath the Senior Project Officer for the APUTS project.

Development process

Where no reference is provided, the authority is the consensus of the expert group.

The initial work for this standard and its associated documents was developed by some 80 pathologists, other clinicians, scientists and informaticians as part of the RCPA Pathology Units and Standardisation Project from April 2011 to November 2012. There were 8 working groups covering each of the pathology disciplines. The working groups were:

- Units
- Terminology used for requesting pathology
- Terminology used for reporting pathology in reports:
 - Anatomical and cytopathology
 - Biochemistry
 - Genetic pathology
 - Haematology
 - Immunopathology
 - Microbiology

Working groups met fortnightly by phone and had a number of face-to-face meetings with the outcomes distributed to members between meetings for review.

Comment on committee drafts was sought from interested organisations identified by each of the working groups. In addition all other working group members were requested to review the material and a public notice was posted inviting comments.

All comments were considered and resolved by the respective working groups. The activity and process was promoted through conferences and membership activities of the stakeholder organisations with invitation for participation either as active members or corresponding members of the working group.

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3 PROJECT OUTCOMES

We are pleased to report that all project milestones were met and in many cases exceeded. This, however, did require an extension of time (the project team were grateful for the agreement of DoHA to this change). It is the experience of this and other projects that consensus building takes time but nevertheless is the fastest way to get an accepted position that will be implemented. Having consensus in turn is vital to the adoption of policy and standards. In addition, this complex and detailed work often requires levels of scientific and professional knowledge that very few in Australia can provide. PUTS was able to attract those that had this knowledge to participate either directly in the project or to comment on the outputs.

In terms of the deliverables from the PUTS sub-projects specified in Item A of the DoHA Contract Schedule, all have been produced. These were published on the RCPA website for public comment for six weeks to the end of January 2013. The comments that were received were addressed during the final Steering Committee meeting. The RCPA Board approved the documents as College Policy at their meeting on 25 February 2013. A comparison of the achievements of the project compared to the funding agreement is provided in the Table below.

From the Agreement	Achievements of the PUTS project
<p>To develop and approve a revised set of standards for units of measure that are able to be represented electronically.</p>	<p>The APUTS Standards and Guidelines document describes the principles for selection of units (applied by the PUTS working groups), provides guidelines on the use of units in reports and provides a table of preferred units.</p> <p>Each of the reporting test terms for which a code was chosen had a preferred unit assigned. These appear in the reference set with the code and Australian preferred term.</p>
<p>To develop and approve standard terminology sets (SNOMED CT, LOINC, etc) including advice for their use.</p>	<p>After diligent review and consideration of the options, SNOMED CT AU was selected as the preferred terminology for requesting pathology tests and LOINC for the test name (or heading) to report it. This is now policy of the RCPA through the APUTS Standards and Guidelines.</p> <p>A code was selected from the appropriate terminology for common tests in requesting and reporting. For each of these the Australian preferred term and preferred units were determined along with synonyms. These form reference sets grouped by requesting and reporting disciplines. In a small number of cases preferred units could not be chosen and more work is needed.</p> <p>In order to select the appropriate terms an information model was required in a number of cases. These were developed for the common instances.</p> <p>Where terms were not available an application has been made to NEHTA/IHTSDO or Regenstrief/LOINC for these terms to be added.</p> <p>An additional piece of work was done by the Microbiology working group and that was to develop an Australian reference set for pathogenic organisms from SNOMED-CT-AU</p>

<p>To develop a fully specified terminology for the reporting of 'common' biochemistry items used in clinical decision support including advice for their use.</p>	<p>To address the safety concerns around the dangerously inappropriate combination of tests in cumulative reports, graphs and decision support software, a traffic light system of indicators was developed and applied to the reference set of reported biochemistry tests. Green indicates that the tests may be combined providing specified but general criteria are met; Orange means that there may be danger in doing this but where there is detailed knowledge about the laboratory and how the results are to be used that it may be acceptable; and Red means that results from these tests should never be combined. In addition to these indicators different LOINC codes were chosen for most of the 'red' tests and a rule developed for the APUTS Standard that says test with different codes should never be combined. A back up system of an indicator in one of the fields in the electronic message will also be needed and development of this and its inclusion in the messaging standard forms one of the important future tasks.</p>
<p>To review the protocols for cancer reporting and ensure terminology is available, consistent and able to be used in electronic decision support including advice for their use.</p>	<p>Two cancer reporting protocols were analysed in detail. Because it was found that LOINC did not have terms with the level of granularity required by the structured cancer reports, the RCPA SPR project in conjunction with the Anatomical Pathology working group undertook development of terms using temporary codes with OID (unique) identifiers that can be added to terminologies as appropriate. The College has taken an OID trunk from HL7 Australia in order to undertake this work.</p>

3.1 RCPA policy development

A more detailed description of the work done by the Steering Committee and the working groups of the PUTS project follows. More detail still is provided in the Minutes of the Steering Group.

3.1.1 Steering committee

The PUTS Steering Committee acted as both the project governance authority and coordinating body for the project. In addition to this role, the Steering Committee was the drafting committee for the APUTS Standards and Guidelines.

The Steering committee held its final meeting by teleconference on 7th February 2013 to discuss the feedback received from the public commenting period. Minutes of all of the Steering committee meetings are provided at Appendix I – Minutes of the Steering Committee

3.1.2 Requesting

Standardised Department of Origin Codes

The PUTS project was requested by NEHTA and the Commonwealth to provide terminology for use as a component of metadata for the index entry of pathology reports in the PCEHR.

This index entry is to be used to identify the section of a laboratory where a report originated from. The current HL7 codes from Table 0074 (Diagnostic Service Section ID) required review for Australian use because they were often abbreviations of terms used in the US that the broader healthcare community would not relate to in the PCEHR.

The working group suggested a mnemonic 3 characters wide to allow multiple index entries on a single line pathology episode entry on the index screen of the PCEHR and drafted and approved a proposal for display mnemonics to be used for the pathology laboratory ID's in table 74.

The spreadsheet with the draft display mnemonics have been handed over to NEHTA and were incorporated into AS4700.2.

Choice of Terminology for Requesting Pathology

The working group selected SNOMED CT as the principle terminology for requesting pathology tests in Australia. However it was noted that SNOMED CT was not yet complete in its coverage of all domains.

SNOMED CT AU Requesting terminology reference set

The working group began by mapping the top 100 test request codes from 6 private and public based laboratories. In total 227 unique SNOMED CT terms have been mapped which cover more than 95% of the volume of pathology tests requested in Australia.

SNOMED CT terms were available for most of the request codes. In some instances the SNOMED CT terms were not as specific as required while for some concepts SNOMED CT terms were not available.

For each of the mapped request codes, a preferred term was chosen based on the rules documented in the APUTS Standard in line with contemporary Australian practice as well as synonyms where appropriate.

The subset has been reviewed by members of the Pathology Associations Council, NEHTA DSRG, the RCPA Advisory Committees and the other PUTS working groups.

3.1.3 Anatomical pathology

Cytopathology

The Cytopathology working group produced information models for cervical cytology; generic fluid cytopathology and generic fine needle aspirate reports and mapped LOINC terms for the high level headings.

The templates were reviewed by the RCPA Cytopathology and Anatomical pathology advisory committees, the Australian Cytology Society and the Health Group of the Australian Institute of Health and Welfare. No major issues were identified during the review period.

Histopathology

The Anatomical Pathology working group produced a generic surgical report information model which is a higher level version of the templates developed for the RCPA Structured Cancer Reporting project.

The structure and content of the template with LOINC terms were reviewed by the RCPA Anatomical Pathology advisory committee. A small number of new LOINC terms will be required for headings of ancillary reports. A request for new codes has been submitted to Regenstrief.

Structured Pathology Report (SPR) templates

The working group reviewed the Gastric Carcinoma and Melanoma structured reporting protocols as candidates for a prototype information model with LOINC terms. The Melanoma protocol was chosen because it is more pertinent to current international standardisation activity that Australia is involved in.

An information model was created. During the terminology binding of the synoptic elements, it became clear to the working group that LOINC does not provide adequate detail-level terms needed for cancer reporting.

The RCPA SPR project therefore developed their own temporary codes using an OID tree through HL7 Australia to ensure that the local codes generated are unique.

3.1.4 Chemical pathology

The biochemistry working group produced a reference set of 214 standardised LOINC codes to cover frequently requested biochemistry tests and therapeutic drugs.

The LOINC terms for the therapeutic drugs were selected based on the recommendations of the AACB, ASCEPT, RCPA & the RACP Common Units for Reporting Drug Concentrations Working Party.

The subsets were reviewed by the RCPA Chemical Pathology advisory committee and the AACB.

Methods to prevent inappropriate data combination

The working group had concerns about the limited knowledge of how LOINC encoded laboratory data will be used by vendors and end users. A mechanism to prevent inappropriate data combination in end user systems although modelled remains to be considered by the Standards Australia group prior to inclusion in the appropriate standard (AS4700.2).

In terms of identifying those tests that can be safely combined and those that cannot be, the group implemented a traffic light system to classify results into groups. Those allocated to the red group should never be combined. Only tests known to be well harmonized or with where there is no clinical risk will be placed in the green category. Orange was reserved for those where caution is required in any combination of results and indicates that the risk of doing this should be assessed on the receiving end of the result. Where green indicates that with attention to safety and subject to the notes below results from these tests can be combined.

The group notes that:

- There is clinical risk in combining data.
- The signed-off full formatted PDF version of a laboratory report with comments and cautions should always be available for reference in the receiving system and the reviewing clinician is encouraged to reference this in making any clinical decision.
- The Working Group believes that the least variation and safest approach for monitoring a chronic disease is to use the same laboratory.
- The pre-co-ordinated elements derived from a LOINC coded result does not contain all of the information needed to confidently group data from different laboratories for statistical purposes. If laboratory data is required for research the source laboratory should be contacted.

3.1.5 Genetic pathology

The working group produced an information model for the reporting of a genetic pathology report.

The decision for the generic genetic pathology report template was made because there are potentially 30,000 genes that could be analysed, LOINC will not be able to provide codes for all the variations that could be tested for.

Report elements were chosen in an attempt to satisfy the requirements of molecular genetic pathology and cytogenetic tests. LOINC terms were selected for headings where available.

This proposed format will lend itself to both the future growth of the field, as well as being compatible with the informatics requirements for both reporting and for later analysis and meta-analysis.

The draft documents were reviewed by the RCPA Genetics Advisory Committee, the HGSA Executive and the ASOC and the working group incorporated the recommendations the draft information model.

The information model is available in a mind map and spreadsheet form.

3.1.6 Haematology

The working group produced a standardised LOINC reference set with 116 terms. This subset includes the routine high volume haematology tests as well as more specialised tests such as the haemostasis and coagulation assays.

This subset was reviewed by the RCPA advisory committee as well as the Australasian Society of Thrombosis & Haemostasis and the Haematology Society of Australia and New Zealand.

The working group also produced a draft template for the high level headings in the Bone Marrow report mapped to LOINC where terms are available. The template and LOINC subset was submitted for review.

The RCPA Structured Pathology Reporting project is about to start with a new structured bone marrow report protocol. It was decided to delay publication of the PUTS bone marrow template in order to align the template with the new SPR protocol..

3.1.7 Immunopathology

The working group produced LOINC subsets for reporting of auto-antibodies, immunochemistry (including protein electrophoresis) and flow cytometry of T-cell subsets. In total 171 standardised LOINC terms were selected.

The RCPA Immunopathology advisory committee and the Laboratory practice committee of ASCIA reviewed the auto-antibody LOINC subset.

The flow cytometry T-cell LOINC subset was submitted to the RCPA Microbiology and Immunology advisory committees as well as Australasian Society for HIV Medicine (ASHM) for review.

The immunochemistry and protein electrophoresis subsets were reviewed by the Biochemistry working group, the RCPA Immunology and Chemical Pathology advisory committees, the Working Party on Standardised Reporting of Protein Electrophoresis and the Australian Leukaemia and Lymphoma Group.

The group decided to indefinitely postpone the mapping of flow cytometry of haematological malignancies due to the difficulty in standardisation of the tests required for diagnosis.

3.1.8 Microbiology

Mapping of organisms of SNOMED CT

Working group members contributed frequency ranked organism names from their Laboratory Information Systems. This list was edited to remove ambiguous entries and clinical concepts which did not belong in the list.

The organism names were mapped to SNOMED CT terms in the organism hierarchy and reviewed by the RCPA Microbiology advisory committee as well as the other PUTS working groups. The review identified a number of missing organisms and non-specific concepts frequently used as well as the presence of duplicate and out-dated terms. After resolution of feedback the final list contains 2964 SNOMED CT mapped organisms.

Microbiology serology and molecular LOINC subset

The working group started the mapping of LOINC terms for the serology and molecular tests that are used to establish laboratory diagnosis of notifiable conditions in Australia according to case definitions outlined by the Public Health Laboratory Network (PHLN).

The CDNA list overlapped with tests on the RCPA QAP Serology programs, which are more frequently requested. Therefore the working group decided to prioritise mapping of the high frequency serology and molecular tests in the QAP programs.

In total 383 LOINC terms were mapped for microbiology, serology and molecular assays.

Urine microscopy, culture and sensitivity report template with LOINC binding

The working group produced an information model with LOINC mapping for the urine microscopy, culture and sensitivity report.

3.1.9 Units

Standardisation of units for therapeutic drugs

The working group reflects the RCPA's recommendation that mass units be used routinely for the reporting of therapeutic drug concentrations with the exception of assays where there are current uniformity of reporting in molar units (eg lithium and Methotrexate) and drugs which are also present as endogenous substances where the units used routinely should be used.

Code for Units of Measure (UCUM)

The working group assisted with the section on Units of measure in the APUTS standard and produced a table with recommended units in their preferred display and UCUM format.

Unit Surveys

With the assistance of the RCPA QAP, surveys were sent to laboratories taking part in the following external quality assurance programs: Tumour markers, Haemostasis, Endocrine, IGF-1, Trace elements, Specific proteins, Rheumatoid, IgE, Lipids and Cerebrospinal fluid.

The surveys attempted to determine if there is a difference in the way laboratories report units in patient reports to clinicians compared to reporting to the QAP.

A large number of Australian laboratories enrolled in the programs responded and provided useful information. A preferred unit could be selected for most tests based on the feedback. For a small number of units there is significant variation present.

The working group corresponded with a number of clinical and laboratory advisory committees to select preferred units for each test based on a set of principles for unit selection (see APUTS standard).

Recommended units

The terminology for reporting working groups selected units for specific tests during the LOINC standardisation process. These units are listed in the terminology reference set spreadsheets of the Biochemistry, Haematology, Immunopathology and Microbiology working groups.

For most of the tests, the unit selected was also the recommended unit approved by the units working group. However there are tests where more than one assay format will have results of different unit types (e.g. titres and U/mL). Until the assays are standardised, there cannot be a preferred unit for these tests.

3.2 Informatics standards development

There was good linkage between the PUTS project and relevant standards development organisations (SDO). There was at least one participant in the PUTS project team that was also a participant in relevant activity of each SDO.

Standards Australia

The table required by NEHTA to provide indexing metadata for the PCEHR was developed by the PUTS project and incorporated into AS 4700.2.

A project was initiated for the Standards Australia work program (IT-14-6-5) to make use of the output from the PUTS project into both ages 4700.2 and HP 262 the standards for electronic messaging of requests and reports.

NEHTA

NEHTA personnel were significant contributors to the steering committee and most of the working groups. NEHTA acts as the Australian release centre for SNOMED CT AU and the application for new terms has gone to them.

IHTSDO-Regenstrief

Application has been made through NEHTA for additions to SNOMED and to Regenstrief for additions to LOINC. Michael Osborne who is a member of an IHTSDO Advisory Group and the Australian contact for Regenstrief was a member of the steering committee and has acted as the communication point for PUTS new terminology applications.

International Agency for Cancer research

The work of the structured pathology reporting in terminology development has been undertaken in conjunction with by the International agency for Cancer research through David Ellis and Meagan Judge.

Pathology Colleges and Scientific Societies

The work of biochemistry working group has been shared with other biochemical societies who are themselves involved in national and international harmonisation through Robert Flatman and Michael Legg.

The work in structured pathology reporting has been shared with pathology colleges in the US the UK and Canada by David Ellis and Meagan Judge.

HL7

The work of the PUTS Project was provided as a contribution to the January 2013 US Working Group Meeting by Michael Legg. This was of Special Interest to the Genomics Group. The first whole genome sequencing clinical report from an accredited pathology laboratory was in turn provided to us to aid our development of standards in this area.

3.3 Standards and policy adoption

3.3.1 Policy endorsement

The project deliverables were endorsed by the Council of the RCPA at its February 2013 meeting. All member organisations of the Pathology Associations Council participated in the development work and have been generally supportive.

In addition support has been received from the Medical Software Industry Association.

3.3.2 Marketing and Communications

A number of channels were used to promote the project and its work. Some of these appear in Appendix J – Publications and presentations. These include:

Project Newsletters

Two project newsletters with news from the PUTS project to the Pathology industry and associated organisations were distributed to key stakeholders and RCPA Fellows and trainees during the project period. These appear at Appendix J – Publications and presentations

Publications

A paper entitled The Australian Pathology Units and Terminology Standardisation Project – An Overview was written and published in Clinical Biochemistry Reviews Vol 33 August 2012.

Another paper written by the Chair of the Units Working Group Graham Jones on units for drugs in Australia is in press with the Medical Journal of Australia.

The February 2013 issue of Pulse Magazine was devoted to pathology and radiology. There were three articles directly referencing the work of PUTS. One of those was a contribution from the Medical Software Industry Association giving strong support for the project and adoption of its work.

Conferences

A paper was given at the Pathology Update 2012 in Sydney on the Project by the Biochemistry Working Group Chair Robert Flatman.

Michael Legg presented work from the Genetics Working Group at an International Meeting on 'Practical, Preventive, Predictive and Personalised Medicine' in St Petersburg in June 2012 and the AACB annual meeting in Melbourne November 2012

Michael Osborne will be presenting a paper on the project to the April 2013 IHTSDO working meeting in Copenhagen.

3.4 Knowledge management, workforce and research

Knowledge management

The national plan for pathology terminology standardisation had a sub-project which was to establish the capacity to maintain and distribute all pathology terminology and other information. This capability is not yet available so the College has published material for public comment on its own website and will make the outputs from the PUTS Project available hereafter.

Research Projects

A number of projects undertaken by the College including the recent work on genetic testing and bioinformatics have highlighted the need for the work being undertaken to standardise pathology terminology.

3.5 Project deliverables

Deliverables from the PUTS Project are provided at:

- Appendix A – The Australian Pathology Units and Terminology Standards and Guidelines
- Appendix B – APUTS Request Terminology and Codes
- Appendix C – APUTS Report Terminology and Codes – Anatomical Pathology
- Appendix D - APUTS Report Terminology and Codes – Chemical Pathology
- Appendix E – APUTS Report Terminology and Codes – Genetic Pathology
- Appendix F – APUTS Report Terminology and Codes – Haematology
- Appendix G – APUTS Report Terminology and Codes – Immunopathology
- Appendix H – APUTS Report Terminology and Codes – Microbiology

4 MANAGEMENT OF FUNDS

4.1 Financial statement and reconciliation

The draft financial statement and reconciliation for the project forms Appendix L – Financial Statement.

5 NEXT STEPS

Work toward the standardisation of pathology requesting and reporting has been underway for more than 20 years. While significant and valuable further progress has been made with the PUTS Project there remain a number of opportunities for improvement. This is especially so in the uptake of standards and standardisation.

It is critical to provide all the artefacts necessary before compliance and conformance can be put in place to achieve full semantic interoperability. While close, there remain barriers to interoperability between systems which will be further addressed by the projects proposed under the new Pathology Information Terminology and Units (PITUS) Project.

The deliverables from the PITUS project will also support increased consumer involvement and provide the infrastructure and tools to make the provision and consumption of pathology services safer and easier.

In the end however it is facilitating and supporting uptake and implementation of standards that will break down the existing barriers. A number of aspects of this project directly address this most difficult of areas of standardisation. The group of organisations assembled for this project and led by the College is most likely to influence and effect those changes seen as beneficial.

The PUTS Project Steering Committee, as part of its work, considered the next steps that should be taken⁴. They subsequently developed a plan which itself forms a component of the broader plan of the Informatics Advisory Committee (IAC) of the College. The plan of the RCPA IAC showing the context of the PUTS and PITUS projects, what has been achieved so far and what is being proposed with PITUS can be found at Appendix K – RCPA Informatics Project Plan.

The RCPA will work with members of the Pathology Associations Council, NEHTA and the Department to build on and extend the work of the Pathology Units and Terminology Standardisation (PUTS) project in the Pathology Information Terminology and Units (PITUS) Project. It will make use of the established and successful clinical governance structure and project team of PUTS and is supported by the PUTS Steering Committee. In particular the PITUS project will review and improve on implementation of the Standards developed for requesting and reporting pathology by PUTS and extend the policies and standards in those areas considered of clinical value where this can be achieved in the time-frame proposed.

The aim of the PITUS Project is to continue the development of standards for information in pathology requests and reports and to facilitate their uptake by pathology practices and their customers to allow safer and better quality use of pathology.

The purpose of the project is aligned to that of the Department's Quality Use of Pathology and E-Health Programs and the PITUS Project is a necessary requirement for the broader E-Health Program's success and the Pathology MoU Agreement.

The challenge in standardising as opposed to standards-development alone is to get uptake. An important strategy is to make it easy for implementers to conform and comply. Development of the RCPA knowledge management systems for sharing the output of these information based projects is a critical element of that process. This will also provide NEHTA with guidance as to how this function might be done more generally for their artefacts. The project as proposed is not intended to duplicate any existing functionality.

⁴ To prevent any potential conflict of interest the DoHA member of the Steering Committee withdrew from the meeting when this matter was discussed

5.1 RCPA policy development

Referrals will be improved by having a preferred list of common requested tests implemented in GP desktop software that are consistently described to avoid confusion and coded so that decision support for requesting can be developed. A separate project looking at how request decision support would be done has commenced and includes RACGP, NPS and NEHTA. The PITUS sub-project on Request Terminology implementation is an important piece of info-structure to facilitate request decision support. Structured requesting is aimed at improving the testing and advice that is provided by pathology practices and to ensuring that the inferred clinical question is going to be answered. Evaluating the newly developed terminologies and APUTS Standard from the PUTS project will allow refinement based on real use and quality improvement.

Reporting will be improved by developing standards for the display of pathology reports on paper and/or screens to address issues that have been identified by the RACGP and other report recipients - namely the direction of time on the page for cumulative reports, the way that important results are identified and how identifiers and demographics are shown. Information model development and structured reporting will provide artefacts for the standardised communication of pathology (so-called semantic interoperability). The outputs will provide NEHTA with knowledge and artefacts they need for their work on pathology and discharge summaries. These structured reports and their underlying information models and linked terminologies provide the prospect for improving both the efficiency and effectiveness of reporting to registries. Efficiencies should be available for both the laboratories in having only one way of reporting to maintain and for the registries in being able to share tools and undertake less mapping and knowledge work especially for national reporting. Evaluating the newly developed terminologies and APUTS Standard from the PUTS project will allow refinement based on real use and quality improvement.

5.1.1 In scope for PITUS year 1

Governance

Expand governances to include more customer voice from report recipients

Structured reporting protocols

The RCPA Structured Pathology Reporting project is about to start with a new structured bone marrow report protocol. It was decided to delay publication of the PUTS bone marrow template in order to align the template with the new SPR protocol.

ePathology

Complete the development of terminology used in requesting and group them into logical sets for ease of implementation

Develop information models for requesting and so begin work on structured requesting. Initially this will look at how to indicate and convey relevant history/clinical notes and body site and explore requesting by clinical question in one discipline

Develop standards for report rendering addressing cumulative reports, abnormal indicators and demographics

Review communication and display for reference intervals

Policy and Practice

Provide terminology support for the Decision Support Project that forms part of the Pathology Agreement

5.1.2 PITUS after year 1 and other projects

See Appendix K – RCPA Informatics Project Plan for projects covering: Governance; Structured reporting protocols; ePathology; Laboratory Information Systems; Bioinformatics; Translational informatics; and Policy and Practice

5.2 Informatics standards development

5.2.1 In scope for PITUS year 1

Standards Australia

NPAAC

NEHTA

Fully define and refine report information models (Detailed Clinical Models) using NEHTA authoring tools and repository

IHTSDO-Regenstrief

International Agency for Cancer research

Pathology Colleges

5.2.2 PITUS after year 1 and other projects

See Appendix K – RCPA Informatics Project Plan for projects covering: Standards Australia; NPAAC; NEHTA; IHTSDO-Regenstrief; International Agency for Cancer research; and Pathology Colleges

5.3 Standards and policy adoption

5.3.1 In scope for PITUS year 1

Policy endorsement

Adoption of policy by RCPA Fellows

Marketing and communication

System implementation trials

Proof of concept implementation of request terminology into GP practice software

Proof of concept implementation of a small set of terms used in chronic disease management

Evaluation

Check implementation of the Australian Pathology Units and Terminology Standard and its products. Review implementation, maintain and improve artefacts

Review the implementation of standards developed to make the comparison of certain biochemistry tests safer

Check implementation of APUTS, terminology and units standards and review their implementation and improve

*Machine readable standards delivery**Domain standardisation*

Begin the development of standards necessary for the standardisation of pathology reports to registries in Australia. In particular for Cancer Registries - structured cancer reports, and for the Public Health Laboratory Network microbiology terminology and information models

*Compliance Conformance and Accreditation***5.3.2 PITUS after year 1 and other projects**

See Appendix K – RCPA Informatics Project Plan for projects covering: Policy endorsement; Adoption of policy by RCPA Fellows; Marketing and communication; System implementation trials; Evaluation; Machine readable standards delivery; Domain standardisation; Compliance Conformance and Accreditation.

5.4 Knowledge management, workforce and research**5.4.1 In scope for PITUS year 1***Workforce**eLearning**Knowledge management*

Develop and implement a system to make more 'ready to use' policy and standards related to Pathology Information, Terminology and Units and where possible link this to NEHTA's Clinical Terminology and Information Unit

*Research Projects***5.4.2 PITUS after year 1 and other projects**

See Appendix K – RCPA Informatics Project Plan for projects covering: Workforce; eLearning; Knowledge management; and Research Projects

APPENDIX A – THE AUSTRALIAN PATHOLOGY UNITS AND TERMINOLOGY STANDARDS AND GUIDELINES

The Australian Pathology Units and Terminology Standards and Guidelines v1.2

APPENDIX B – APUTS REQUEST TERMINOLOGY AND CODES

APUTS Request Terminology and Codes v1.0

APPENDIX C – APUTS REPORT TERMINOLOGY AND CODES – ANATOMICAL PATHOLOGY

APUTS Report Terminology and Codes – Anatomical Pathology v1.0

APPENDIX D - APUTS REPORT TERMINOLOGY AND CODES – CHEMICAL PATHOLOGY

APUTS Report Terminology and Codes – Chemical Pathology v1.0

APPENDIX E – APUTS REPORT TERMINOLOGY AND CODES – GENETIC PATHOLOGY

APUTS Report Terminology and Codes – Genetic Pathology v1.0

APPENDIX F – APUTS REPORT TERMINOLOGY AND CODES – HAEMATOLOGY

APUTS Report Terminology and Codes – Haematology v1.0

APPENDIX G – APUTS REPORT TERMINOLOGY AND CODES – IMMUNOPATHOLOGY

APUTS Report Terminology and Codes – Immunopathology v1.0

APPENDIX H – APUTS REPORT TERMINOLOGY AND CODES – MICROBIOLOGY

APUTS Report Terminology and Codes – Microbiology v1.0

APPENDIX I – MINUTES OF THE STEERING COMMITTEE

MINUTES OF THE STEERING COMMITTEE

APPENDIX J – PUBLICATIONS AND PRESENTATIONS

Publications and presentations

APPENDIX K – RCPA INFORMATICS PROJECT PLAN

RCPA INFORMATICS Project PLAN

APPENDIX L – FINANCIAL STATEMENT

FINANCIAL STATEMENT