RCPA

The Royal College of Pathologists of Australasia

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FINAL REPORT: PATHOLOGY INFORMATION, TERMINOLOGY AND UNITS STANDARDISATION (PITUS) 18-20 PROJECT

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1. Contents

2. Glossary of terms & acronyms

ACRONYM	DETAIL
AACB	Australian Association of Clinical Biochemists
ADHA	Australian Digital Health Agency
AIHI	Australian Institute of Health Innovation
AP	Australian Pathology
CDA	Clinical Document Architecture
CSIRO	Commonwealth Scientific and Industrial Research Organisation
Exemplar Reports	A set of mock pathology reports designed as a visual aide to assist LIS vendors and laboratories with conformance against RCPA SPIA, NPAAC and NATA design elements
FHIR^{R}	HL7 Fast Healthcare Interoperability Resources
GP	General Practitioner
HISO	Health Information Standards Organisation
HL7 AU	Health Level 7 Australia
ICCR	International Collaboration on Cancer Reporting
ICT	Information Communication Technology
IEQA	Informatics External Quality Assurance
KIMMS	Key Incident Management and Monitoring System
LIS	Laboratory Information System
LOINC^{R}	Logical Observation Identifiers Names and Codes
MSIA	Medical Software Industry Association
MyHR	My Health Record
NATA	National Association of Testing Authorities, Australia
NCTS	National Clinical Terminology Service
NCTS Tool Development Requirements	A document drafted to assist laboratory software vendors, FHIR SMEs and implementers to author, maintain and validate RCPA SPIA information models and terminology reference sets in one central location without error; to improve efficiency, quality and integrity of RCPA SPIA terminology and related dataset maintenance and; to support laboratory accreditation processes
NPAAC	National Pathology Accreditation Advisory Council Australia

ACRONYM	DETAIL
NZPOCTQAG/ARQAG	New Zealand Point of Care Testing Quality Advisory Group/Auckland Region Quality Assurance Group
PDF	Portable Document Format
PITUS	Pathology Information, Terminology and Units Standardisation
PoCT	Point of Care Testing
PPA	Public Pathology Australia
PTAP	Pathology Terminology Adoptions Program
QUPP	Quality Use of Pathology Program
RACGP	The Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia
RCPA Best Practice Guidelines	The Guidelines aim to improve patient safety by improving the ability to locate specific pathology results and to assist clinicians more readily identify clinically significant results for the grouping of selected tests on rendered pathology reports, such as those sent to GP desktop software and the MyHR
RCPAQAP	Royal College of Pathologists of Australasia Quality Assurance Programs
Rendered/ing	The format of a document or graphic as displayed or printed
SIDM	Society to Improve Diagnosis in Medicine
SMEs	Subject Matter Experts
SNOMED-CT	Systematized Nomenclature of Medicine - Clinical Terms
SPIA	Standards for Pathology Informatics in Australia
SPIA Report Rendering Compliance Checklists	A combined list of relevant RCPA SPIA, NPAAC and NATA design elements used to assess rendered pathology report compliance
UCUM	The Unified Code for Units of Measure
URL	Uniform Resource Locator
WG	Working Group

3. Executive summary

This is the Final Report for the Pathology Information, Terminology and Units Standardisation (PITUS) 18-20 Project, the third phase of the RCPA PITUS Projects. PITUS 18-20 was initiated to align with the Department of Health's published national E-Health strategy, including the MyHealth Record (MyHR) and Quality Use of Pathology Program (QUPP) by focusing on activities that support quality consumer services, quality pathology requesting and quality pathology practice.

This Project was designed specifically to measure the utility of the existing RCPA standardised pathology reporting terminology in laboratory practice with particular interest in those laboratories able to provide rendered pathology reports via PDF to MyHR. To do this, the Project split assessing the levels of SPIA adoption and compliance into separate activities, with adoption assessed in 2018 via a self-reporting survey. SPIA compliance rates were assessed with the assistance of the RCPAQAP in 2020 via two audits for 55 Chemical Pathology and Serology quality assurance reports. A comparison of 23 key report elements highlighted variability in SPIA compliance rates across individual laboratories/organisations, with the highest SPIA compliance found for the display of SPIA preferred units (100%); and the least compliant for the display of all requested tests and their status at 29%. Following on from the results of the SPIA compliance audits, the Project developed and published a number of resources designed to assist laboratories, software vendors and Fast Healthcare Interoperability Resources (FHIR) implementers with improving SPIA compliance rates and to highlight the benefits of interoperability. The Exemplar Reports, SPIA Compliance Checklists, Best Practice Guidelines and NCTS Tool Development Requirements are all accessible on the RCPA website.

PITUS 18-20 reviewed, developed and published updates to the RCPA SPIA terminology reference sets including new terms for SARS-CoV-2 testing, arterial and venous blood gas requesting and reporting, and a comprehensive suite of 210 allergen requesting terms. In total, there are now 1285 requesting terms, 1650 reporting terms and 2766 microorganisms available in the RCPA SPIA terminology reference set resources which are freely available via a link to the NCTS website from the PITUS Downloads page to assist with interoperability using standardised terminology within Australia.

During the timeline of the Project, the following activities were completed:

- Undertook a survey and two audits to assess the current levels of adoption and compliance of the RCPA SPIA pathology terminology reference sets and SPIA Guidelines. The survey targeted 13 facets of SPIA adoption while the levels of SPIA compliance were assessed for one set of Chemical Pathology results, one Serology result and one structured Anatomical Pathology report.
- Engaged with medical software vendors, pathology providers, medical profession colleges and other key pathology stakeholders through a series of targeted webinars and workshops aimed at promoting SPIA, SPIA adoption, and interoperability for electronic implementation.

- Transformed the RCPA SPIA terminology reference sets endorsed by PITUS 15-16 into FHIR and published these to the NCTS website.
- Expanded the existing content of the RCPA SPIA terminology requesting and reporting reference sets by an additional 900 reporting terms and 481 requesting terms.
- Drafted and published Best Practice Guidelines for the grouping of selected pathology tests on a pathology report (a minimum of one test per discipline) to assist GPs when searching for pathology tests used within the MyHR. These Guidelines are supported by two new resources, the RCPA SPIA Exemplar Reports and the RCPA SPIA Report Rendering Compliance Checklists which SPIA implementers can utilise to improve SPIA compliance for tests outlined in the Checklists.
- Collaborated with the RCPA Quality Assurance Programs (RCPAQAP) to complete a trial for a new Informatics External Quality Assurance (IEQA) program to assess laboratory compliance of the Structured Pathology Reporting of Cancer (SPRC) Colorectal cancer report against the RCPA published Colorectal cancer reporting terminology reference set.
- Published updated version of the RCPA SPIA terminology reference sets after resolving discrepancies identified by the Australian Digital Health Agency (ADHA)'s audit of currency and integrity against international pathology terminology codes (SNOMED-CT and LOINC).
- Scoped and published the NCTS Tool Development Requirements that could be used to manage the authoring and maintenance of the RCPA SPIA pathology terminology reference sets.
- Designed and published a suite of RCPA SPIA Exemplar Reports, providing a new method for linking pathology results to reliable information sources such as Lab Tests Online AU and the RCPA Manual for Use and Interpretation of Pathology Tests using standardised pathology reporting terminology codes.

Key challenges encountered during the Project:

- The SARS-CoV-2/COVID-19 pandemic highlighted the increased global demand for subject matter experts to review and develop a range of international resources such as LOINC reporting terms and SNOMED-CT requesting terms for SARS-CoV-2 testing, and for technical experts to undertake the translation of the RCPA SPIA terminology reference sets for SPRC protocols into FHIR resources. An extremely limited pool of specialist resources is currently available to undertake these activities, emphasising the ongoing need to identify and expand the pool of specialists required in this important area and to educate consumers of pathology data of their importance.

- Whilst there is wide variation within Australian laboratory information system (LIS) software, the adoption of standardised pathology terms using LOINC, SNOMED and UCUM has been proven to enhance interoperability[1]. The enhancements made to the RPCA SPIA terminology reference sets throughout PITUS 18-20 has amplified the value

of this tool, however working group (wg) members and key stakeholders have indicated that without an NPAAC mandate for adoption and financial support, software vendors are unlikely to assign overstretched resources to undertake the LIS enhancements required for implementation.

- According to responses received in a separate survey performed by the RCPA SPRC 17-20 Project, only seven percent (7%) of Australian laboratories described their LIS as being capable of reporting at the highest level (Level 5-6) of structured pathology reporting. Similarly, the IEQA trial undertaken to assess the compliance of structured Colorectal Cancer reporting against the published RCPA Colorectal Protocol was unable to secure a sample HL7 message at Level 5-6, again emphasising the need for standardised SPRC reporting in Australia. While the IEQA trial was successful from an automated compliance perspective, the mock data utilised did not reflect current SPRC reporting and therefore the results provided limited value to the Project despite the effort required to complete the undertaking. A key barrier to higher level structured reporting continues to be the lack of top-level policy directive; without a mandate, widespread Level 5-6 implementation is unlikely to be realised within Australian anatomical pathology laboratories which subsequently constrains the potential value of standardised anatomical pathology reporting.
- Although the full translation of the five selected SPRC protocols into FHIR resources was not able to be completed within the Project timeline, the initial FHIR mapping of each SPRC protocol content to SNOMED and LOINC terms was able to be tested by an anatomical pathologist and software developer who provided valuable feedback on the current limitations and perceived benefits of this work. An extremely limited pool of FHIR experts is currently available in Australia; competing priorities for the FHIR developer with international COVID-19 work meant significant delays in commencing this task.

4. Project Statement

4.1 Background

Previous PITUS projects have worked closely with public and private pathology providers implementing requesting and reporting standards. Both have identified the need for safer communication and sharing of pathology requesting and reporting data, and the need to improve the use and interpretation of pathology test results.

While there is an increasing tendency towards the aggregation of laboratory data in the Australian health sector, the usefulness of this data is limited due the wide variability in test reporting practice for pathology tests. Inconsistencies can be seen in test names, units, reporting intervals (decimal places), reference intervals (normal test value ranges) and the types of clinical comments included in pathology reports. This variability has the potential to create confusion and misunderstanding as pathology results are now viewed by a wider audience, including requesting doctors, patients, nurses, pharmacists, dieticians and other allied health workers. Additionally, pathology data is becoming more likely to be sent electronically to databases such as practice software, national or regional repositories and personal health records. In these settings, data from several laboratories may be combined into a single record and removed from, or at least separated from, the original supporting information (name, units, reference intervals etc). At the very least, report variation can waste clinician time, but potentially can have a much graver impact with respect to increased patient safety risks.

The complexities surrounding the standardisation of pathology terminology required to safely implement pathology data in the MyHR was again emphasised in a Pulse+IT article in 2017[2]. The article focussed on the adversities faced by pathology providers in the approach required to implement standardised pathology terminology within local LISs and to the MyHR. To further improve health outcomes for the Australian community, the PITUS Projects have been steadfast in progressing standardised pathology terminology and driving interoperability through an increasing range of initiatives. Significant advances with HL7 FHIR are expediting the goal of interoperability which is the essential component needed to facilitate the pathology standardisation process for software vendors and SPIA implementers alike.

4.2 Project Outline

The RCPA identified the need for safer communication and sharing of pathology requesting and reporting data not only to improve the quality of pathology reporting but importantly to improve patient health outcomes. These improvements may then be further leveraged to increase the efficacy of data analysis for a variety of uses, such as contract tracing for specific SARS-CoV-2 variants.

To meet this need, the RCPA firstly had to determine current levels of adoption and compliance of the RCPA SPIA terminology reference sets within pathology laboratories. To do this, the Project completed a survey and two audits, analysed compliance feedback and provided the results back to individual laboratories to inform staff of their laboratory's SPIA compliance rates.

A range of promotional and educational activities were undertaken to further increase awareness of the benefits for using standardised pathology requesting and reporting standards. The development of the Best Practice Guidelines, the SPIA Exemplar Reports, SPIA Compliance Checklists and NCTS Tool Development Requirements provided LIS implementers with valuable educational resources to assist with SPIA adoption. Workshops, webinars, teleconferences and newsletters were the main communication tools used to reach pathology providers, LIS vendors, medical colleges, and other pathology stakeholders.

To facilitate local uptake of the RCPA SPIA terminology reference sets, the RCPA SPIA terminology reference sets published by PITUS 15-16 Project were translated into a set of FHIR resources, published to the NCTS website in 2019. The FHIR translations enable users to author, maintain and validate RCPA SPIA terminology reference sets and related electronic messages within their own systems.

In undertaking these specific activities, the PITUS 18-20 Project supported the goals of the QUPP to improve health outcomes for the Australian public by increasing the quality of existing pathology terminology and access to FHIR translations. Both serve to increase interoperability which ultimately benefit not only the patient, but also pathologists and clinicians, national cancer screening registries, software vendors and researchers alike.

5. Scope

The main aim of the PITUS 18-20 Project was to improve health outcomes for the Australian public through access to quality pathology services. To do this, the Project focused on evaluating the work of previous PITUS projects as the starting point to demonstrate the value of implementing standardised pathology terminology with respect to interoperability, the sustainability of this value, and opportunities to promote and educate stakeholders of the benefits of standardised pathology requesting and reporting.

The Project's focus on interoperability was key to:

- Assessing the consistency in use of the SPIA Guidelines particularly in the electronic pathology reports that are sent to the MyHeath Record;
- Introducing new quality initiatives to improve reporting and recording pathology test results to support more effective clinical interpretation;
- Providing clear guidance for laboratories regarding improving interoperability between independent computer systems used for pathology requesting and reporting; and
- Developing and publishing outstanding terminology to improve standardisation across all disciplines of pathology.

Standardised pathology information structures and terminologies enhances the recording, decision support, communication and analysis of pathology. In particular the ability to provide semantic interoperability between computers, enables assurance of the fidelity of communication and computer aided support.

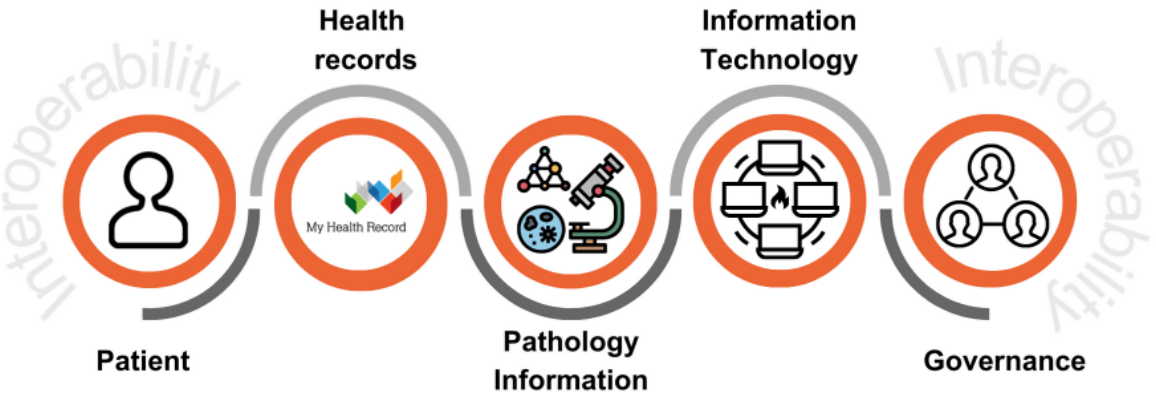

Figure 1: Standardisation and Interoperability

The National Pathology Accreditation Advisory Council (NPAAC) has acknowledged the increasing complexity of pathology information that is required for personalised management of patients, essentially that reports are clear, complete, concise, and conform to standards to ensure optimal patient treatment and outcomes. Standardised data

elements and methods of measurement are required to ensure that all necessary information is available in the report, each data element has been measured consistently and conforms with agreed SPIA Guidelines. While standardised and complete data aggregated at population level is essential for public health management, NPAAC does not currently mandate implementation of the SPIA Guidelines.

6. Governance and Reporting

6.1 Governance Structure

The governance model established incorporates formalised relationships, mostly at a national level. This governance structure provided the mechanism for communication and support, incorporating interconnectivity to national organisations as well as international organisations such as SNOMED International, Regenstrief (LOINC), the International Collaboration on Cancer Reporting (ICCR) and HL7 International to support long term development and expansion. A diagram of the governance model is set out in Figure 2 below:

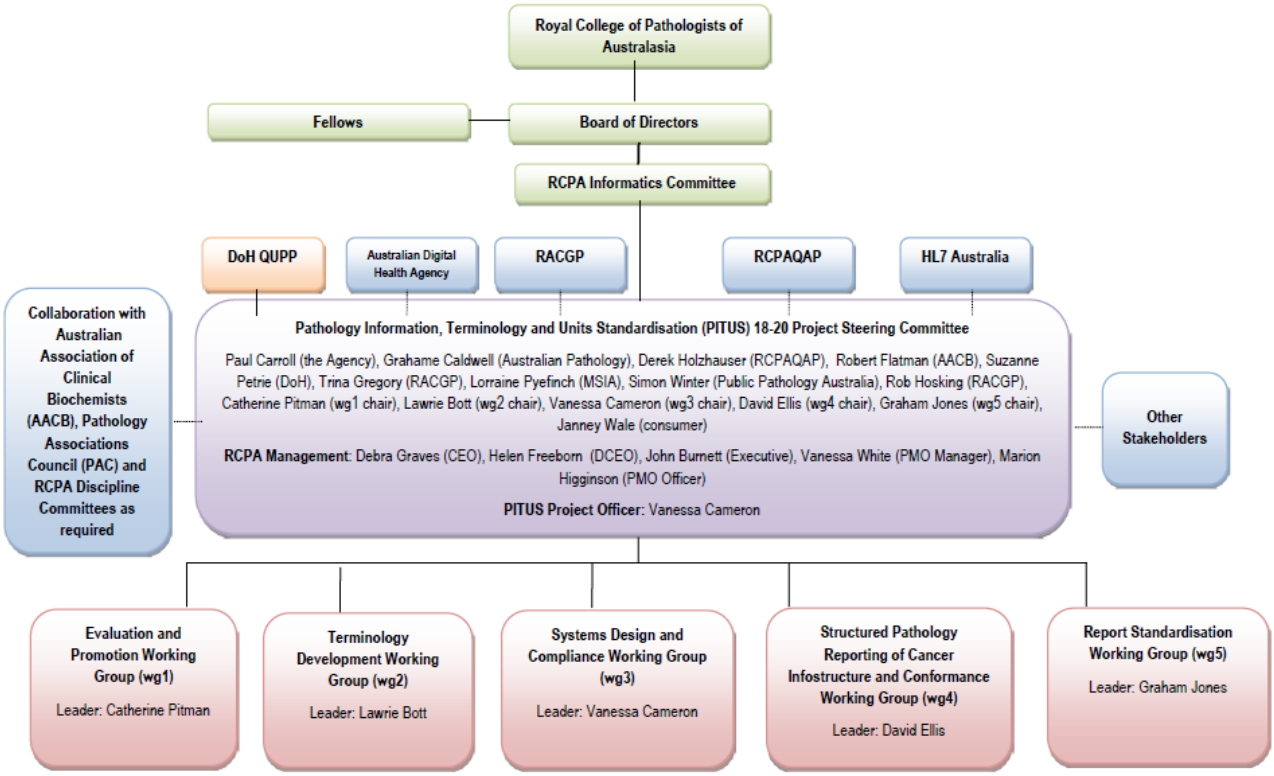

Figure 2: PITUS 18-20 Governance structure

6.2 Steering Committee

The Steering Committee was responsible for the coordination and oversight of the Project, and for promoting all Project publications (e.g. newsletters and relevant documents) and activities at conferences and other related events through associated networks. A total of five Steering Committee meetings were held throughout the duration of the Project. The Steering Committee endorsed two new Terminology Reference Sets, namely RCPA SPIA Blood Gas Terminology Reference Set and RCPA SPIA Requesting Allergens Terminology Reference Set as well as two additional iterations of the existing RCPA SPIA Terminology Reference Sets, v3.1 and v4.0.

PITUS 18-20 divided the workload amongst five working groups with the chairs of each working group also members of the Steering Committee.

The five working groups were:

WG1 – Evaluation and Promotion

WG2 – Terminology Development

WG3 – Systems Design and Compliance

WG4 – SPRC Infostructure and Conformance

WG5 – Report Standardisation.

6.3 Stakeholders

- Australian Association of Clinical Biochemists (AACB) – as the national peak professional body representing Chemical Pathology in Australia, AACB provided subject matter expertise in the development of harmonised blood gas terminology and extending the existing RCPA SPIA Chemical Pathology Terminology Reference Set and Requesting Terminology Reference Set content.

- ADHA – a statutory authority who have developed a collaborative environment to accelerate adoption and the use of innovative digital services and technologies e.g. via MyHealth Record.

- Australian Institute of Health Innovation (AIHI) – the Institute conducts world-class research to catalyse performance improvement in Australian and international healthcare services and systems such as the use of digital pathology and artificial intelligence.

- Australian Institute of Medical Scientists (AIMS) – the national peak body representing and educating Australian medical scientists to equip members and the profession with the tools, information and networks to ensure the provision of quality and world class medical science services in Australia and overseas.

- Australian Pathology (AP) – as the national peak body for private pathology in Australia, AP is committed to the provision of high quality, safe and accessible pathology service to all Australians and have assisted with promoting the benefits of standardised pathology requesting and reporting.

- Business analysts representing numerous organisations have provided their services in developing the NCTS Tool Development Requirements, the Best Practice Guidelines and were core members of the terminology development working parties.

- Colorectal Surgical Society of Australia and New Zealand (CSSANZ) – The Society and its members promote the best evidence-based practice in order to improve the treatment of patients; their representatives collaborated with RCPA to assist with validation of the

mapping and development of terminology used for Telstra Health's National Cancer Screening Registry for Colorectal Cancer based on the RCPA Colorectal Cancer Protocol.

- Commonwealth Scientific and Industrial Research Organisation (CSIRO) – an Australian Government corporate entity, the CSIRO have collaborated on several PITUS activities, including evolving the RCPA SPIA Terminology Reference Sets into a set of FHIR Resources and drafting the NCTS Tool Development Requirements.

- Health consumers are the ultimate beneficiaries for improving the quality use of pathology services, their voices are necessary to safeguard the value and benefits of PITUS work.

- Health informaticians representing both public and private sector have provided their expertise in the review and expansion of the RCPA SPIA terminology reference sets, in particular the terminology needed to support standardised SARS-CoV-2 requesting and reporting in Australia.

- HL7 Australia – supports the creation and effective use of health informatics standards in Australia and is the local affiliate of HL7 International. HL7 Australia members are representative of those using and benefiting from HL7 Standards in Australia, driving healthcare interoperability.

- ICCR – produces common, evidence-based pathology datasets for cancer reporting through collaboration between Pathology Colleges, Societies and major international cancer organisations. The PITUS and SPRC Projects have worked with the ICCR to develop standards for tumour classification, staging, prognostic and predictive information.

- International Health Terminology Standards Development Organisation (IHTSDO) – SNOMED International owns, administers and develops SNOMED CT, the main terminology used to develop the RCPA SPIA Requesting terminology reference sets.

- Lab Tests Online AU (LTO) – in partnership with AACB, DoH and RCPA, LTO provides consumers of health data with accurate and authoritative information about pathology testing. Their members have collaborated with PITUS to enhance and advocate the use of the RCPA SPIA terminology reference sets.

- Laboratory information managers – representatives from public and private sector provided insight into their experiences with implementing the RCPA SPIA Standards and terminology reference sets and provided assistance to standardise SARS-CoV-2 requesting and reporting terminology.

- Laboratory instrumentation and reagent manufacturers – representatives from blood gas and Point of Care Testing analysers provided their support and input into discussions raised at the RCPA AACB Blood Gas Reporting Interactive Workshop.

- Laboratory quality managers – representatives from public and private sector provided insight into their experiences with implementing the RCPA SPIA Standards and

terminology reference sets and provided assistance to standardise SARS-CoV-2 requesting and reporting terminology.

- Medical Software Industry Australia (MSIA) – the representative for Australian commercial software industry which develops, supplies and services information management products for healthcare practitioners, service providers and organisations. MSIA has promulgated the work of PITUS and acted as a conduit between government and industry to standardise laboratory information software.

- Northern Territory Core Clinical Systems Renewal Program (CCSRP) – representatives have assisted with Chemical Pathology terminology development and the drafting of the RCPA SPIA Exemplar Reports. PITUS 18-20 provided resources to assist CCSRP with specification development and implementation of their new laboratory information system; once their system is implemented, the Norther Territory will be the first state/territory to fully comply with the RCPA SPIA standards for pathology requesting and resulting.

- Public Pathology Australia (PPA) – the national peak body for public pathology, members have promoted various PITUS activities to their stakeholders at national and state levels.

- RACGP – representatives have contributed significantly to the Project with the development of the Best Practice Guidelines, the selection of the 13 PTAP tests and promotional activities of wg1, also in echoing GP concerns related to pathology requesting and reporting.

- RCPA – the leading organisation representing pathologists and senior scientists in Australasia whose mission is to improve the use of pathology testing to achieve better healthcare. The RCPA Project Management Office oversees the management of the PITUS, SPRC and other pathology-related projects.

- RCPA Informatics Committee – members have assisted to organise and deliver two Pathology Informatics workshops and have provided subject matter expertise regarding quality, safety and good practice in the use of pathology information, standards development and adoption.

- RCPA Lay Advisory Committee – members have provided input to develop the Best Practice Guidelines and support with PITUS promotional activities.

- RCPA SPRC Project – representatives provided substantial input with terminology mapping for the FHIR translations of five SPRC protocols, mapping of the pathology terminology for the National Bowel Cancer Screening Registry (NBCSR), input into the Bowel Histopathology Integration Guide and selection of terminology for National Cervical Screening Registry.

- RCPAQAP – members were pivotal with: the design and distribution of a survey which established the baseline Standards for SPIA adoption rates within Australian pathology laboratories; running two SPIA compliance assessments using RCPAQAP data for Chemical Pathology and Serology; developing manual and automated SPIA IEQA compliance checking programs for the Colorectal cancer SPRC protocol.

- Regenstrief Institute – owns, administers and develops LOINC, the main terminology used to develop the RCPA SPIA Reporting terminology reference sets.

- Society to Improve Diagnosis in Medicine (SIDM) – members promoted PITUS 18-20 activities while speaking at conferences dedicated to leading change to improve diagnosis and eliminate patient harm due to diagnostic error.

- Software vendors – members representing a range of clinical and laboratory software companies utilised in Australia assisted with the development of standardised pathology terminologies, provided deidentified data to develop the Best Practice Guidelines and valuable feedback on the NCTS Tool Development Requirements.

- Telstra Health – in collaboration with Sonic Healthcare, the Project facilitated the development and review of dozens of new SNOMED-CT terms relating to Pathology Sites, Polyp Types and Polyp Severity to assist Telstra Health with implementation of the National Bowel Cancer Screening Program (NBCSP) based on the RCPA Colorectal Cancer Protocol; the Project also assisted with the development of standardised terminology for National Cancer Screening Registry for Cervical Cancer.

7. Project Activities

The Project sought to address three key areas, namely Implementation, Audit and Promotion; Standards Development and Implementation improvement; and Quality Assurance and Sustainability. Specific activities were completed throughout the Project to support these.

7.1 Implementation, Audit and Promotion

The Project established the level of SPIA adoption and compliance in Australian laboratories by undertaking two separate activities: 1) developing a survey to better understand laboratory awareness and attitudes toward SPIA, including the levels of adoption and utility of the existing RCPA SPIA terminology reference sets; 2) undertaking SPIA compliance audits on RCPAQAP quality assurance reports for Chemical Pathology and Serology.

SPIA Survey 2018 - Implementation

A self-reporting Survey was developed and forwarded to all NATA accredited laboratories to identify laboratory awareness and attitudes toward SPIA, including the levels of adoption and utility of the existing RCPA SPIA terminology reference sets. The survey was distributed electronically to 155 prospective participants, representing over 95% of accredited Australian pathology laboratories. Participation was not mandatory and 88% of all NATA accredited laboratories/organisations completed all or part of the SPIA Survey.

From the responses received, it was encouraging to note that the two largest private laboratory organisations and 78% of public sector pathology laboratories had adopted the main elements of SPIA e.g. standardised requesting terminology and codes, standardised reporting terminology and codes, standardised units of measure, harmonised reference ranges and report rendering, or were in the process of implementing those elements. Of the main SPIA elements listed above, the reported rates of SPIA adoption were: 71% for requesting terminology and codes; 71% for reporting terminology and codes; 77% for standardised units of measure; 87% for harmonised reference intervals; and 72% for report rendering.

Major recommendations from the Survey included:

- Improving SPIA awareness in the public, private and catholic sectors could be undertaken by engaging with key members of the MSIA, HL7 Australia, RACGP and pathology laboratories;
- To improve compliance, the RCPA and other stakeholders recommended NPAAC mandate SPIA adoption;
- Increasing adoption rates where laboratories indicated there were no plans to adopt any of the SPIA standards should be addressed by seeking opportunities and forums to collaborate with current SPIA champions to promote benefits.

The SPIA Survey Report was developed and submitted to the Department of Health in January 2019; a summary is available on the PITUS website.

RCPAQAP Compliance Audits

In collaboration with the RCPAQAP, two audits were undertaken for the most critical SPIA report elements for 46 Chemical Pathology (2019) and nine Serology (2020) external quality control reports to provide greater clarity of SPIA compliance rates within NATA accredited pathology laboratories.

A comparison of key report elements for 46 Chemical Pathology external quality control reports confirmed high SPIA compliance for the display of the following report elements: SPIA preferred units (100%); date and time of report release displayed (96%); date and time of specimen collection displayed (96%); patient identifiers displayed on each report page (96%); requester name and identifier displayed (96%); patient sex displayed (96%); interpretation of results (93%); and use of headings differentiated from test names (91%). The least compliant report elements identified by the audit were: standardised date format (dd-mmm-yy) at 34%, and the display of all requested tests and their status at 29%.

A subsequent compliance check of key SPIA report elements was undertaken for nine Hepatitis B Serology external quality control reports from 2020. Analysis of the compliance check demonstrated the following four report elements were 100% compliant: The use of specific patient identifiers displayed on each report page; patient sex was displayed; no reports utilised underlining to highlight / flag specific results; no reports utilised the asterisk (*), plus (+) or minus (-) characters to highlight / flag specific results.

Currently, there are a total of 63 SPIA compliance elements which may be included in any general pathology report. To allow comparison between the audit results for both Chemical Pathology and Serology external quality control reports, an analysis of the 23 most common SPIA report elements were agreed and undertaken. The basis for selecting the 23 elements for comparison was constrained to those applicable to both Chemical Pathology quantitative reporting (measured levels of analytes e.g. Sodium 146 mmol/L) and Serology qualitative reporting (descriptive observations of analytes e.g. ‘positive’ or ‘not detected’). Refer to Image 1 below, SPIA Compliance report for Chemical Pathology and Serology audits for a listing of the report elements audited and the compliance outcomes.

Despite the limited scope of compliance checking, the compliance results can be extrapolated for both as indicative SPIA compliance rates for all atomic results on the basis that, within the same laboratory, the Guide to Requirements for Rendered Reports stipulates pathology report layouts should be consistent between disciplines and over time, with report header, footer and basic formatting for atomic reports tending to be replicated across pathology disciplines. It is likely that SPIA compliance averages are quite high (90% or above) across all pathology disciplines for the following three report elements:

- Headings should be used and must be differentiated from test names.

- Patient identifiers must be displayed on each page of report (NPAAC e.g. full name, sex, DOB, or age if DOB not available).
- Interpretation of results must be displayed where appropriate.

Similarly, it is likely that SPIA compliance averages are quite low (50% or below) across all pathology disciplines for the following two vital report elements:

- Dates must use format dd-mmm-yy.
- All requested tests and their status must be displayed (e.g. interim, preliminary, or final).

Overall, the SPIA compliance audit findings revealed the most compliant laboratory report supplied for the audit contained 89% of the 23 key SPIA report elements analysed while the least compliant report supplied contained only 37% of key SPIA report elements, demonstrating a wide variation in SPIA reporting compliance amongst laboratories and the need to improve SPIA adoption rates. Refer to Figure 3 below for the outcomes of the comparison of the 23 SPIA Report elements across both audits.

NB: For Anatomical Pathology, Cytology and Genetic Pathology, reports are often formatted in a Word document and are therefore less likely to be consistent in layout; as such, SPIA compliance for these disciplines, cannot be extrapolated on the same basis.

To supplement the findings from the SPIA compliance audits, the Project undertook the development and publication of the Exemplar Reports and SPIA Compliance Checklists to assist laboratories, software vendors and FHIR implementers understand the benefits of interoperability and how improvements in SPIA compliance rates can be accomplished.

The RCPA SPIA Exemplar Reports were initially designed to provide laboratory staff and software vendors with visual representations of SPIA compliant reports for a range of disciplines with respect to report formatting. The development and publication of the Best Practice Guidelines provide clear guidance for improving interoperability between independent computer systems used for pathology requesting and reporting, enabling clinicians to more easily compare pathology test results from different providers. However the Project has recommended these resources could also be used as a quality initiative to support more effective clinical interpretation with the addition of relevant hyperlinks for each report to Lab Tests Online AU and the RCPA Manual.

RCPA SPIA compliance audit comparison of 23 Report Elements checked across RCPAQAP survey campaigns for Liquid serum chemistry (UECs) and Serology (HBsAb)		
Report Elements checked	July 2019 UEC Compliance rating (46 reports reviewed)	August 2020 HBsAb Compliance rating (9 reports reviewed)
Overall Report Design		
Headings **should** be used and must be differentiated from test names	42 (91%)	8 (89%)
Dates **must** use format dd-mmm-yy	11 (24%)	4 (44%)
Page numbers and the total number of pages for full report **must** be displayed (e.g. 1 of 5)	40 (87%)	4 (44%)
Report header or footer information displayed on each report page		
Patient identifiers **must** be displayed on each page of report (NPAAC e.g. full name, sex, DOB, or age if DOB not available)	44 (96%)	9 (100%)
Sample episode unique identifier e.g. sample accession or episode number, **must** be displayed to allow traceability	43 (93%)	7 (78%)
Sex (Male, Female, Intersex or indeterminate, Indeterminate, Other, Not stated/inadequately described) **must** be displayed where available	44 (96%)	9 (100%)
Identification of Medical Pathology Service performing tests **must** be displayed (NPAAC: identity of the designated provider / Medical Pathology service issuing the report e.g. acc#)	36 (78%)	3 (33%)
Requester name & unique identifier (provider number/practice address) **must** be displayed	44 (96%)	6 (67%)
Requester contact details **should** be displayed	44 (96%)	1 (11%)
Date (and time if available and relevant to patient care) of specimen collection **must** be displayed where supplied	44 (96%)	7 (78%)
Date and time of specimen receipt into Medical Pathology service **should** be displayed	16 (35%)	5 (56%)
Date and time of report release **must** be displayed	44 (96%)	6 (67%)
All requested tests and their status e.g. interim, preliminary, or final **must** be displayed	21 (46%)	1 (11%)
Elements of Observations		
SPIA Preferred term(s) **should** be utilised for test names	42 (91%)	6 (67%)
Guidance values must be bounded by parenthesis, not be in italics and have no spaces	40 (87%)	1 (11%)
The numbers used for guidance must be rendered with the same number of decimal places as per corresponding result	43 (93%)	1 (11%)
Specimen type **must** be displayed. It may be part of the test header (NPAAC: tissue or fluid tested, and where relevant, its state (fresh, frozen, fixed)	41 (89%)	5 (56%)
Rendering of Observations		
Numeric results **must** be right justified (columnar) with corresponding guidance values and units displayed to the right of results where applicable	30 (65%)	3 (33%)
The column displaying units **must** be headed 'Units', must be left justified and be to the immediate right of the 'Reference' column	25 (54%)	3 (33%)
A single asterisk ('*') and the '+' and '-'characters should not be used for flagging results	27 (59%)	9 (100%)
Underlining of results should not be used for highlighting results	27 (59%)	9 (100%)
Comments		
• Interpretation of results must be displayed where appropriate	43 (93%)	8 (89%)
• Information provided on how to obtain further advice	42 (91%)	6 (67%)

Figure 3: SPIA Compliance report for Chemical Pathology and Serology audits

Education and Promotion

Webinars and Workshops

A total of 25 webinars and seven workshops were delivered during the Project, targeting members of the MSIA and pathology providers, medical colleges, and other pathology stakeholders. The seven workshops were held in collaboration with the MSIA, AACB, HL7 Australia and RCPA Informatics AC which focused on promulgating the benefits of SPIA adoption as these relate to:

- The benefits of computer system interoperability
- Implementation advice and perceived barriers to adoption of the RCPA SPIA Standards
- Harmonisation of Chemical Pathology tests
- Interoperability resources and tools
- Achieving Standardised Blood Gas Reporting
- Patient-centric models of care
- Pathology Information, Terminology and Units Standardisation Project
- Structured Pathology Reporting of Cancer FHIR translations
- Advanced concepts for Pathology Informatics
- Pathology report formatting
- HL7 pathology messaging.

Newsletters

PITUS Update newsletters were another tool used to promote the Project. Seven newsletters were circulated and published under the Project between September 2018 and November 2020. Newsletters were emailed directly to pathologists and RCPA advisory committees via the RCPA newsletter, Pathology Today, the RCPAQAP, RACGP e-Health working group, Australian Pathology, Public Pathology Australia, the MSIA, NATA accredited laboratories and to other interested stakeholders via the RCPA website.

RCPA PITUS website

Considerable content was added to the RCPA PITUS website since October 2018, to further promote the work of PITUS 18-20. New content includes:

- Best Practice Guidelines
- NCTS Tool Development Requirements
- RCPA Endorsed COVID-19 terms
- SPIA Compliance Checklists (basic and comprehensive)
- SPIA Exemplar Reports (16) with accompanying HL7 v2, FHIR and CDA messages
- Working Group Updates (monthly)
- SPIA Survey 2018 Summary.

7.2 Standards Development and Implementation improvement

The RCPA SPIA terminology reference sets were formally updated twice during the Project. In total, 418 additional or updated SNOMED-CT requesting terms and 900 LOINC reporting terms were approved with SPIA v3.1 and SPIA v4.0 including terms for SARS-CoV-2 (COVID-19) testing, arterial and venous blood gas requesting and reporting and a comprehensive suite of 210 requesting allergen terms. Allergens were added in response to the gap noted by several laboratories performing allergy testing where the existing single test request 'RAST' was deemed not only to be too broad, but also redundant with more advanced methodologies often utilised. At the completion of the Project, there are now a total of 1639 requesting terms, 1301 reporting terms and 2766 microorganisms available in the RCPA SPIA terminology reference set resources which are freely available via a link from the PITUS website to assist with interoperability within Australia. Only 28 reporting terms and 12 requesting terms for Chemical Pathology were not reviewed during the timeline of this Project, however, will be noted for inclusion in future SPIA iterations. The updated RCPA SPIA terminology reference sets are expected to be published on the NCTS website in late February or March 2021.

The RCPA SPIA terminology reference sets published by PITUS 15-16 were transformed into a set of FHIR resources in 2019 enabling these to be easily imported and managed by individuals to facilitate data exchange and improve interoperability. In addition, to better assist implementers of clinical or laboratory information systems, the ADHA has drafted several documents which are accessible on the NCTS website, including the NCTS Guide for Implementers. HL7 Australia has also published a working specification available to assist FHIR implementers, the Australian Base Implementation Guide (AU Base 2) and the HL7 Australia FHIR Implementation Guide, both of which are accessible on the HL7 Australia website. PITUS 18-20 Project developed the following material intended to assist all pathology implementations, not just FHIR implementations:

- NCTS Tool Development Requirements
- Best Practice Guidelines
- SPIA Exemplar Reports
- SPIA Compliance Checklists.

Additional collaboration with the RCPA SPRC Project was undertaken to develop pathology reporting terminology reference sets for the following SPRC protocols:

- Polypectomy and local resections of the colorectum
- Colorectal cancer
- Cervical cancer
- Endometrial cancer
- Ovary, Fallopian tube and Peritoneum cancers.

With the assistance of HL7 Australia and the FHIR founder, transformation of the five SPRC protocols listed above into FHIR resources was initiated in June 2020 with completion expected by the end of October 2020. Regrettably there were several delays with the delivery of this body of work due to competing priorities of the FHIR founder and also due to

the constraints in anatomical pathology terminology development of associated terminology by LOINC and IHTSDO/SMOMED. This terminology development was undertaken separately through the ICCR for three of the five SPRC protocols specified for this Project, and the full translation to LOINC and IHTSDO/SMOMED of the five selected SPRC protocols was not completed in time for use within the PITUS 18-20 Project. selection, which impacted FHIR transformation as all the required terminology was not yet available. Completion of FHIR translation was originally anticipated by the end of October 2020, then extended to the end of March 2021. Although a large amount of this work was undertaken, it is not 100% complete in the ideal context of what the Project aimed to achieve. The initial FHIR mapping of each SPRC protocol content to SNOMED and LOINC terms was able to be tested by an anatomical pathologist and software developer who provided valuable feedback on the current limitations and perceived benefits of this work. Going forward, the intention is not to discard this body of work, rather the RCPA, in conjunction with future SPRC Project resources, will monitor the progress of terminology development for these five protocols with a plan to authenticate the work once complete. Following authentication these FHIR resources will be published to both the HL7 Australia website and the RCPA website with the intent to facilitate standardisation and interoperability of structured pathology reporting for cancers for FHIR implementers.

7.3 Quality Assurance and Sustainability

As listed in 6.2 above, the Project created and published the following materials to serve as quality assurance tools and to assist LIS implementers to manage the RCPA SPIA terminology reference sets, FHIR resources and to implement the SPIA Standards:

The Best Practice Guidelines were developed for grouping selected tests on rendered pathology reports, such as those sent to GP desktop software and the MyHR, improving the ability to easily locate specific pathology results and to assist clinicians more readily identify clinically significant results.

The NCTS Tool Development Requirements document provides an analysis of the tools, systems and information models required to author and maintain the RCPA SPIA terminology reference sets utilising HL7 FHIR.

A suite of SPIA Exemplar Reports were developed for each PTAP test with the inclusion of a URL link to Lab Tests Online AU at the bottom of each report, providing a method for linking pathology results to reliable information sources, as well as a visual representation of SPIA compliant reports for a range of disciplines with respect to report formatting. In collaboration with ADHA, HL7 V2, FHIR and CDA, representations of each Exemplar Report can assist software vendors with the design of SPIA compliant HL7 messages.

The two SPIA Compliance Checklists (basic and comprehensive) were designed to provide staff and implementers with a quick reference to relevant RCPA SPIA, NPAAC and NATA design elements used to assess rendered pathology report compliance. The RCPAQAP provided feedback to all laboratories who participated in the two audits using the SPIA

Compliance Checklists and the related SPIA Exemplar Report tool to demonstrate where SPIA compliance could be improved.

A combined manual and automated compliance check of electronic SPRC Colorectal cancer messages was completed in collaboration with RCPAQAP in October 2020. 61 SPRC report elements were checked for SPIA compliance with a validation report provided to the PITUS 18-20 Project Team. The report highlighted the following inconsistencies: Colorectal reporting terminology; LOINC codes; HL7 message hierarchy issues; and date formatting. This report emphasised the need for improved standardisation within SPRC resulting and reporting in order to reduce the risk of misinterpretation of the pathology reports and to increase the value of pathology reports sent to National Cancers Screening Registries.

An interim release of the RCPA SPIA terminology reference sets (v3.1) was published to the NCTS website in September 2019 which included removal of redundant or duplicated terms and the inclusion of newly endorsed terms, resolving any discrepancies identified by the ADHA's audit of their currency and integrity against international pathology terminology codes. SPIA v4.0 is pending approval, once approved it will be published on the RCPA Website. It incorporates references to the new materials published by PITUS 18-20 providing implementers with the ability to utilise these resources to improve SPIA implementation.

8. Project Outcomes

8.1 Knowledge Development and Advancement

PITUS 18-20 was successful in expanding the content of each RCPA SPIA terminology reference set considerably with approximately 95% of routine pathology tests currently undertaken in Australian laboratories now mapped to SNOMED-CT and LOINC terminology, including terminology for SARS-CoV-2 testing. The Project supported terminology standardisation around the globe via collaborations with the international IHTSDO/SNOMED and LOINC terminology community.

SPIA implementers have been provided with several new tools and resources to facilitate authoring, maintenance and validation of the RCPA SPIA terminology reference sets and related electronic messages within their own systems. These being: the NCTS Tool Development Requirements, Best Practice Guidelines, SPIA Exemplar Reports and SPIA Compliance Checklists which are enabling interoperability to improve pathology reporting for clinicians and consumers using MyHR and other clinician systems receiving data from multiple pathology providers.

The delivery of workshops and webinars in collaboration with industry experts provided opportunities for pathologists, scientists, laboratory software vendors, analyser vendors and other interested parties to increase their knowledge of SPIA with particular focus on interoperability. The main benefits associated with the practice of standardised pathology requesting and reporting in Australia can be summarised as:

- Access to patient data from a range of providers – ensures integrity of pathology data to improve clinical decision support
- Standardised requesting removes ambiguity in clinical testing process, improving turnaround times for result reporting
- Standardised reporting improves the quality of data available to a range of users including public health and cancer registries
- Structured reporting removes the potential for misinterpretation as clinicians view reports in a range of unfamiliar or widely variable formats.

The Project facilitated knowledge sharing via collaborations with the QUPP-funded RCPA SPRC 17-20 Project to complete five terminology reference sets (see Section 6.2). The collaboration between these Projects to develop FHIR resources correlating with SPRC protocols facilitated the modernisation of these tools to enhance electronic health exchange in Australia. This is one of the means by which the Project is keeping abreast of cutting-edge digital technology to support pathologists stay current with the most advanced trends and international standards.

As a result of the collaboration with the National Cancer Screening Registry National Bowel Cancer Screening Program, the SPRC colorectal excision biopsy (polypectomy) protocol histopathology value lists were updated, then mapped to SNOMED-CT by PITUS 18-20. This work is expected to have a direct impact on improving patient health outcomes in Australia through the provision of standardised and coded electronic data elements direct to

national registries, removing the need for additional coding to be undertaken with non-standardised reports, thus expediting the entire pathology reporting process.

Outcomes from the joint RCPA /AACB Achieving Standardised Blood Gas Reporting Workshop facilitated by the Project included implementing the recommendations reflected in the AACB Draft Guidelines: Harmonised Arterial and Venous Blood Gas Reference Intervals and utilising the standardised terminology documented in the newly developed RCPA SPIA Blood Gas terminology reference set. Pathologists, scientists, analyser and PoCT vendors attending acknowledged the overall benefits to be realised by clinicians and patients resulting from this standardisation work.

The Project determined the current levels of adoption and compliance of the RCPA SPIA terminology reference sets for the majority of NATA accredited laboratories as of December 2018. Overall, the SPIA compliance audit findings revealed the most compliant laboratory report supplied for the audit contained 89% of the 23 key SPIA report elements analysed while the least compliant report supplied contained only 37% of key SPIA report elements, demonstrating the wide variation in SPIA reporting compliance amongst laboratories and the need to improve SPIA adoption rates. This data provided a solid understanding of SPIA awareness and utility within the Australian pathology sector at the time of writing this report. The promotional and educational endeavours undertaken by PITUS 18-20 together with the new tools and resources designed to assist with SPIA implementation provides those remaining laboratories who have not yet attempted SPIA implementation with appropriate guidance, support and incentive to continue to enable an increase in SPIA uptake.

In undertaking these activities, the PITUS 18-20 Project supported the goals of the QUPP by enhancing the quality pathology services, through improved interoperability and new educational tools and resources being available to a multitude of pathology consumers.

8.2 Metrics of success

The benefits and effects of the various engagement and promotional activities undertaken with stakeholder groups throughout the Project has been realised with rising PITUS and SPIA awareness evidenced in a number of ways: 1) the number of laboratories indicating the intent to adopt SPIA, 2) the large number of delegates attending workshops and webinars i.e. 208 delegates attending the RCPA AACB blood gas standardisation workshop on 03 December 2020 and 78 participants attending the Australian Clinical Terminology User Group session on SPRC FHIR translations on 21 October 2020, and 3) the highest number of visits to the PITUS website to date.

PITUS Website statistics

The average number of unique page visits increased by 50% from 2019 to 2020. In 2020, the 12-month total number of page visits reached 1008 as compared with 672 page visits during 2019; refer to Figure 4 below.

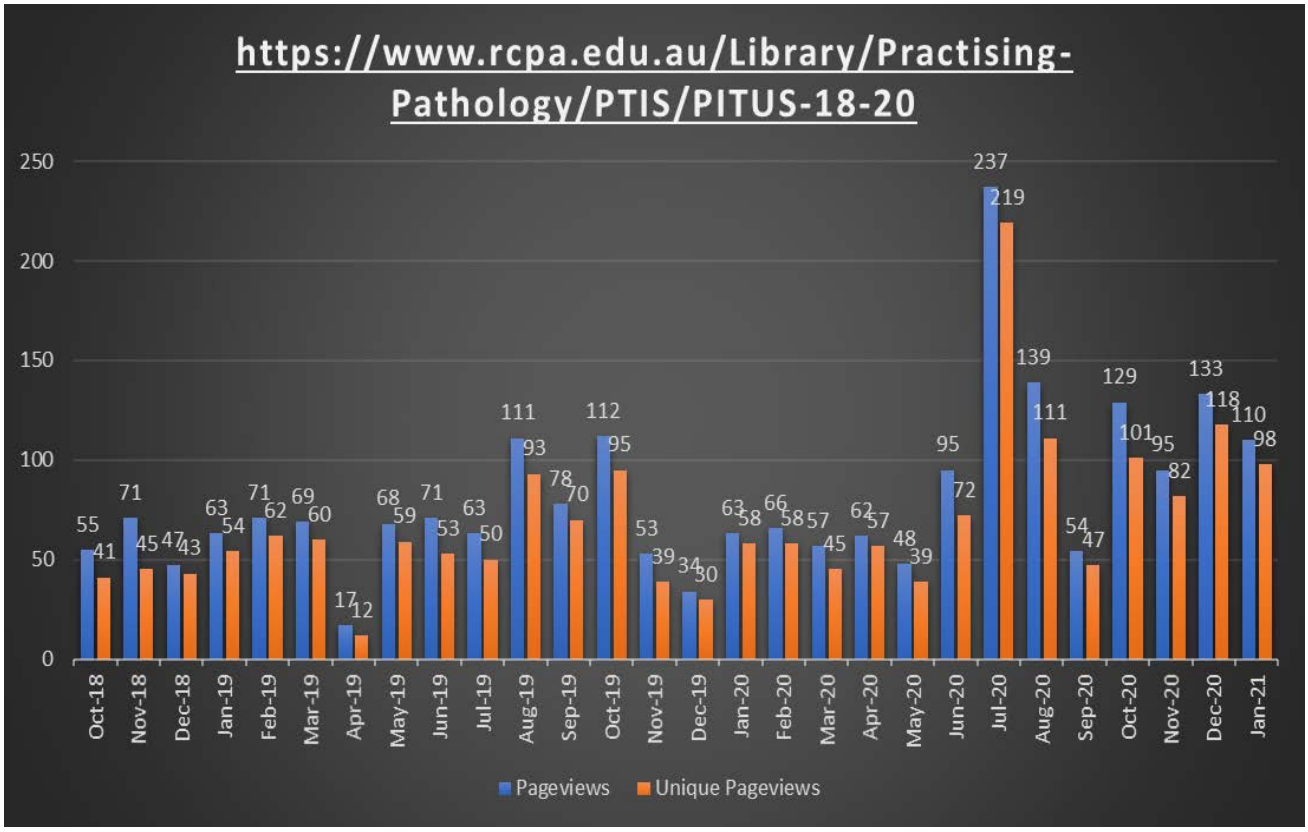

Figure 4: PITUS Website total number of page visits October 2018 – January 2021

There were many additions to the PITUS 18-20 website throughout the Project, including: monthly Project Status update, newsletters, COVID-19 Endorsed terms, Presentations, Best Practice Guidelines and NCTS Tool Development Requirements. The statistics available on the number of page visits for the RCPA SPIA Exemplar Reports demonstrated significant interest, with a total of 857 page visits from the first iteration of the Exemplar Reports in June 2020 to the final set published in December 2021.

9. Project Challenges

Initial challenges encountered during the Project were the result of progress delays due to the complexity and collaborative nature of certain deliverables, but subsequently, significant delays in project activities were seen as a direct impact of the ongoing pandemic throughout 2020. The SARS-CoV-2/COVID-19 pandemic highlighted the increased global demand for subject matter experts to review and develop a range of international resources such as LOINC reporting terms and SNOMED-CT requesting terms for SARS-CoV-2 testing, and for technical experts to undertake the translation of the RCPA SPIA terminology reference sets for RCPA Structured Pathology Reporting of Cancer (SPRC) protocols into FHIR resources. In addition, the development of new SNOMED-CT terms for anatomical pathology, specifically relating to RCPA SPRC protocols was constrained by the progress of the ICCR, with their resources also impacted by the pandemic. An extremely limited pool of skilled subject matter experts currently available to undertake these activities is an ongoing risk and will require urgent action to identify and upskill specialists in this area.

Whilst there is great variation in Australian laboratory information system (LIS) software, the adoption of standardised pathology terms via the RPCA SPIA terminology reference sets (using LOINC, SNOMED and UCUM) has been proven to enhance interoperability[1]. Although the expansion of the RPCA SPIA terminology reference sets under PITUS 18-20 has increased the value of this tool, PITUS working group members, as well as broader ranging contributing stakeholder groups including ADHA, RCPAQAP, HL7 Australia, software vendors, public and private laboratory pathologists, senior scientists, health informaticians etc, support the requirement for an NPAAC mandate for SPIA adoption and financial support. Without this directive, software vendors are unable and unlikely to assign overstretched resources for this body of work.

According to responses received in a survey by the SPRC 17-20 Project, only seven percent (7%) of Australian laboratories described their LIS as being capable of reporting at the highest level (Level 5-6) of structured pathology reporting. These low capability levels were also evidenced by the PITUS 18-20 Project as it was unable to secure a sample HL7 message at this level for the IEQA trial to assess structured Colorectal cancer pathology report against the RCPA published Colorectal cancer reporting information model and terminology reference set. While the IEQA trial was successful from an automated compliance perspective, the mock data utilised did not reflect current SPRC reporting and therefore was of limited value at this time. A key barrier to higher level structured pathology reporting is the lack of top-level policy requirements; without a mandatory directive, widespread Level 5-6 implementation is unlikely to be realised in Australian anatomical pathology laboratories which constrains the potential value of standardised anatomical pathology reporting. Mandating this level of reporting would not only advance current reporting practices but would also improve clinical interpretation of these reports, one of the goals of the Project.

Initial progress with wg5 Report Standardisation work was slow due to the enormous variation in HL7 messages (segments, codes, etc) in use throughout Australian laboratory information systems and practice management software. This issue was highlighted again

in the SPIA compliance audit results where reports provided by the same organisation but produced at different laboratory sites demonstrated wide variation in the use of report headers, tests displayed and overall report formatting.

Drafting of the Best Practice Guidelines proved more difficult than originally expected due to wide ranging professional opinions and difficulty in obtaining sample reports from a broad cohort of pathology providers. Although the guidelines produced are still of value to implementers, these did not include decisions on the use of multi-level flagging and standardised characters to flag specific results, as consensus was not achieved within the timeline of the Project due to competing priorities of pathology resources during the COVID-19 pandemic.

The COVID-19 pandemic also forced the cancellation or postponement of scheduled activities such as the 2020 Pathology Informatics Seminar and Pathology Update 2020, reducing the number of face-to-face networking and promotional opportunities originally anticipated by the Project to specifically focus on increasing SPIA awareness and uptake of the RCPA SPIA Standards.

Timing was unfortunate for the Project with respect to the only outstanding deliverable, the translation of the five selected SPRC protocols into FHIR resources. This body of work cannot be completed without development of the remaining LOINC and SNOMED terms. With an extremely limited pool of FHIR experts currently available in Australia and competing priorities of the FHIR and terminology developers with international COVID-19 work, this task was not able to be completed as anticipated. With the assistance of ADHA, the initial work completed on the five FHIR spreadsheets is expected to be published on the NCTS website in the coming months.

10. Future Directions

10.1 RCPA SPIA terminology reference set and development

PITUS 18-20 expanded the content of the RCPA SPIA terminology reference sets substantially, exceeding Project expectations. A total of 418 requesting terms and 900 reporting terms were added to the RCPA SPIA terminology reference sets. There was however insufficient time to complete further discretionary terminology review and mapping for 148 Immunopathology Flow Cytometry reporting terms, an area requiring highly specialised expert review and some of the more esoteric Chemical Pathology tests generally referred overseas for testing, approximately 6% of all Chemical Pathology terms. These terms and any further terminology requests relating to new methodology or viruses etc have been identified for future projects.

10.2 Engagement with key stakeholders

The RCPA will give consideration to aligning future pathology informatics projects with a number of key stakeholders to demonstrate to the broader pathology and consumer community the benefits realisation when adopting standard compliance through interoperability. In the absence of NPAAC mandating SPIA standards, the RCPA could engage with a small number of public and private laboratory pilot sites to support, demonstrate and advocate the benefits of interoperability for the patient, pathologist and referring clinician.

The RCPA is also considering undertaking discovery work on what a patient-centred model of care could resemble for the pathology sector whilst considering the concept of “valuable” from the perspectives of:

- The patient
- The requesting clinician
- The laboratory pathologist and scientist.

Direct to patient reporting by the pathology sector that has arisen through the COVID-19 pandemic has created a new mechanism for pathologist engagement with the patient, and whether this approach could or should be replicated in other areas of pathology such as pathology informatics and interoperability. This new reporting process could create an opportunity for the RCPA to engage proactively in determining what patient-centred care may resemble for pathologists with regard to accessing patient results, decision support and treatment options.

10.3 Widespread adoption via top-down leadership

The Draft Fourth Edition of the NPAAC ‘Requirements for Information Communication and Reporting’ was circulated for public comment in December 2019. If enacted, this document

would mandate the use of RCPA SPIA terminology for all pathology requesting, reporting and preferred units.

Until a national requirement for SPIA adoption is legislated, significant progress towards implementation of standardised pathology requesting and reporting is thought to be unlikely. Similarly, there is limited comprehension surrounding benefits realisation through implementing standardisation, and as such, large scale investment is unlikely to be justified. Widespread investment in structured pathology requesting and reporting capability by Australian laboratories is not considered to be achievable without government mandates to regulate the modernisation of LISs.

The RCPA is dedicated to advancing LIS interoperability between pathology providers and consumers (General Practitioners, pathology stakeholders and patients) via SPIA adoption and compliance. Greater interoperability and standardisation has the potential to reduce test requesting duplication and inappropriate pathology ordering, which in turn may reduce the burden on Medicare. Interoperability will also improve report analysis and interpretation, thereby increasing system efficiencies with direct benefits for the patient, pathology providers and clinicians. The RCPA will continue to advocate for SPIA adoption and interoperability within pathology communities to assist with realising the benefits for safe sharing and use of information between pathology providers and associated stakeholders.

11. Appendices

11.1 Documentation produced during PITUS 18-20

11.1.1 RCPA SPIA Survey Report v1.0

11.1.2 Best Practice Guidelines

11.1.3 NCTS Tool Development Requirements

11.1.4 SPIA Report rendering compliance checklist - basic

11.1.5 SPIA Report rending compliance checklist - comprehensive

11.1.6 RCPA SPIA v4.0 (pending final approval)

11.1.7 RCPA SPIA Exemplar Reports with HL7 v2, FHIR and CDA messages

11.1.8 RCPA SPIA Terminology Reference Sets

11.1.9 PITUS Update Newsletters

11.1.10 RCPA Endorsed COVID-19 terms

11.1.11 PITUS Working Group Updates

12. References

1. Skrocki M, (2013) Standardization Needs for Effective Interoperability. Transactions of the International Conference on Health Information Technology Advancement 2013 Vol.2 No.1

2. McDonald K, (2020) HL7 Australia releases localised standard for pathology messaging. *Pulse+IT* May 2017