

Guidelines for authors of structured cancer pathology reporting protocols

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Authorship

This document was produced by the Framework Committee, of the National Structured Pathology Reporting for Cancer Project, first convened on 7 May 2008.

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Introduction

This document is designed for use by expert committees developing a new protocol or revising or updating an existing protocol for structured pathology reporting of cancer. The aim is to ensure that protocols produced for different tumour types have a consistent look and feel, and contain all the parameters needed to guide management and prognostication. In line with structured reporting, protocols contain core elements, headings and checklists, organised in a standardised way. However, there is also scope for authors to add free text or narrative where necessary (e.g. to explain areas of uncertainty or complexity).

Maintenance of the Protocol

As cancer medicine is a rapidly evolving area there will be an ongoing need to revisit the content of a structured reporting protocol to ensure that the data items remain relevant and to allow for the addition of new elements. It is recommended that protocols be revised within a maximum of 5 years, although rapid changes in a specific area may dictate earlier revision.

Structure of the document

The remaining chapters of this document:

- explain how this document should be used (*Using the guidelines*)
- outline the established process that expert committees should follow to develop a protocol (*The protocol development process*)
- provide guidance for writing specific sections of the protocol (*Guidelines for chapter content*).

This document also contains the following appendixes:

- Appendix A – explains the need for structured reporting
- Appendix B – details the process used to develop this document
- Appendix C – lists the members of the National Round Table for Structured Pathology Reporting.
- Appendix D – lists the cancer committees and chairman.

A list of the references used to develop this document is given after the appendixes.

Using the guidelines

This section provides a guide to the protocol template. An expert committee developing or revising a structured cancer reporting protocol should use these guidelines in conjunction with the template and at least one existing protocol, as described below.

This section also provides guidance on writing standards, guidelines and commentary.

Template

Expert committees developing or revising a protocol for structured pathology reporting should use the template provided. The template includes the required style and layout – including all headings and content – for producing a protocol. Table 2.1 lists the different types of information included in the template, and explains how each type of information should be used.

Table 2.1 Types of information given in the template

Type	Style	Purpose	Action required
Draft text	Normal font	Provide protocol authors with set text (e.g. for introduction to each section)	Leave in protocol and amend if required
Prompts	Italics, within angle brackets	Indicate where protocol-specific text is required	Replace text within angle brackets with appropriate text (e.g. the text '<Insert cancer name> structured reporting protocol' would be revised in a protocol on colorectal cancer to read 'Colorectal cancer structured reporting protocol'). When you start to write, place your cursor before the first angle bracket; the text will then be in the appropriate format.
Instructions	In box	Provide protocol authors with direction on type of information that should be included in the protocol	Follow instructions (e.g. write relevant standards, guidelines or commentary); delete instructions once text is written.

The template structure is similar to that used by the National Pathology Accreditation Advisory Council (NPAAC). The NPAAC format has been used because it is familiar to pathologists and will mean that the cancer protocols could potentially be incorporated into NPAAC standards.

Existing protocol

When developing a protocol, expert committees should use at least one endorsed structured protocol as an example. The website of the Royal College of Pathologists of Australasia (RCPA) has links to protocols for colorectal, breast, lung, lymphoma, melanoma and prostate cancer.^a

Writing content

Each protocol must contain the following sections, which are set out in the template:

- preliminary material (scope, abbreviations, definitions, introduction and authority and development)
- the main body of the protocol (seven chapters)
- an appendix (pathology request form)
- references.

Where possible, the template also provides draft text (as explained above in table 2.1); for example, to introduce each chapter, or to give standards that will be common to all protocols. The expert committee will flesh out the protocol with the standards and guidelines appropriate for the specific cancer.

The definitions of a standard, guideline and commentary are given in the template. The main thing to remember in writing these is that:

- anything that is mandatory is a standard (usually these contain the word ‘must’)
- anything that is optional is a guideline (usually these contain the word ‘should’)
- commentary is only used where it is needed to clarify the standards and guidelines, provide examples and help with interpretation.

Evidence

A review of evidence in the latest peer-reviewed literature is necessary to ensure that the protocol contains the most recent and evidence-validated information. Citations must be included where applicable to direct the reader to the evidence for inclusions in the protocol.

The extended NHMRC levels of evidence published by Merlin T, Weston A, et al. 2009¹ provides a guide for authors. (Refer to Appendix E)

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

^a <http://www.rcpa.edu.au/Publications/StructuredReporting/CancerProtocols.htm>

References

All references used must be cited and included in the protocol in the relevant section. In order to streamline this process it is advisable to include references in an EndNote library which will facilitate reformatting and reuse when required.

Copyright

During the authoring process, care should be taken to note where permission for use needs to be sought for the use of diagrams, tables, or blocks of text from copyright material which is to be included in the cancer protocol eg AJCC cancer staging definitions.

Prior to publication, copyright must be sought for any identified material. Of particular note, any material from AJCC 7th edition must be quoted verbatim if permission is to be granted.

Protocol development process

This section explains the process of developing or revising a protocol. The process, described in detail below, involves:

- selecting an expert committee and identifying stakeholders (Step 1)
- developing a draft protocol (Step 2)
- undertaking publication preparation (Step 3)
- undertaking an initial review (Step 4)
- undertaking and review open consultation (Step 5)
- finalising of protocol for publication (Step 6)
- having the protocol signed off by the advisory committee (Step 7)
- obtaining endorsement of the protocol (Step 8)
- publishing the protocol on the RCPA website (Step 9).

Step 1 – Select an expert committee and stakeholders

Lead author

The chair of the specific cancer committee, under which the protocol is being developed will invite an appropriately qualified person to undertake the lead authorship. Please refer to Appendix D for the cancer committees and chairman.

A chair may choose to be the lead author for a particular protocol.

The lead author should:

- have acknowledged expertise and leadership in the specific cancer
- have experience in writing academic papers
- be an advocate of structured reporting
- be committed to undertaking elements of writing the protocol as necessary
- be able to manage and lead the development of the protocol
- be able to gain consensus.

Expert committee

The chair of the specific cancer committee, in conjunction with the lead author, will invite members to the expert committee for the development of the protocol.

The following people are needed for the committee (minimum numbers of members are indicated in brackets):

- lead author who will act as chairperson of this committee (pathologist)

- chair of the relevant cancer committee under which this protocol is developed (if not the lead author).
- pathologists (3, including a representative of the RCPA)
- surgeon (1)
- radiation oncologist (1)
- medical oncologist (1)
- haematologist (1) – where appropriate
- other (e.g. medical scientist), at the chairperson’s discretion

Group members should:

- have acknowledged expertise and leadership in the specific cancer
- have experience in writing academic papers
- be committed to reviewing the protocol and providing feedback
- be committed to undertaking elements of writing the protocol as necessary.

Where feasible, group membership should be geographically representative of Australasia.

International Liaison

On each protocol development expert committee, representation from international bodies such as the College of American Pathologists will be invited to participate. The role of liaison is to provide advice and discussion on the components of the protocol with a view to reaching agreement on components of the protocols in particular, mandatory items and naming conventions.

Generalist Pathologist Review

During the course of development, the draft protocol should be submitted to the committee of generalist pathologists, who are not experts in the specific cancers under discussion. This review is intended to provide balance to the expert team and ensure that the resultant protocol is applicable to all levels of use Australasia-wide.

Stakeholders

It is prudent to identify relevant stakeholders early in the process and notify them that protocol development or revision is underway, to ensure that relevant people and organisations have input. The expert committee should inform stakeholders that they will be given the opportunity to review the protocol and give feedback at the open consultation stage (see below).

Generic stakeholders are listed in Appendix A. The committee should also identify tumour-specific stakeholders (e.g. The Urological Society of Australia and New

Zealand for prostate cancers; and The Haematology Society of Australia & New Zealand for lymphoma). Stakeholders should include a representative from each laboratory specialising in anatomical pathology across Australia. A list of these can be obtained from the RCPA.

Stakeholders should be invited to nominate a representative to review the protocol before it is endorsed.

Step 2 – Develop a draft protocol

The expert committee will usually require about four or five meetings (by teleconference or webex) to produce a final draft of the protocol, as follows:

- *First meeting* – Develop the standards and guidelines using as reference points this document, the accompanying template, an endorsed structured cancer pathology reporting protocol and any other relevant protocols (local, national and international).
- *Second meeting* – Confirm the standards and guidelines, and discuss the content of the commentary. Ask various members to submit commentary and associated references.
- *Subsequent meetings* – Review work undertaken and confirm final draft.

Step 3 – Undertake publication preparation

Publication preparation includes:

- Seeking permissions to include copyright material in the protocol eg AJCC, WHO etc
- Seeking copyright permission from the expert committee members for their authorship,
- Applying for, and entering in publication numbers ie International Standard Book Number (ISBN)
- Undertaking proof reading including references, formatting etc

Step 4 – Undertake an initial review

The initial review will be undertaken by the Anatomical Pathology Advisory Committee (APAC) and Cancer Services Advisory Committee (CanSAC) of the RCPA. Its purpose is twofold:

- a) a detailed review of the standards in each developed protocol to ensure their consistency and reasonableness and that their use is reserved for core items essential for the clinical management, staging or prognosis of the cancer, and
- b) a review the protocol overall and evaluate and comment on whether it meets its intended purpose and is deemed to be ready for a period of public consultation.

This step may involve amending the protocol.

Step 5 – Undertake and review open consultation

Details of the open consultation are as follows:

Who:	All stakeholders (RCPA Fellows, Lab heads, APAC, CanSAC, Project Working Party, cancer-specific groups, general consultation)
Documentation to be reviewed:	Draft protocol
Format of review:	Via RCPA website. Structured feedback form to be emailed with comments.
Scope:	Detailed review of all elements of protocols, including pathological content
Timeframe:	4 weeks
Feedback to:	Protocol committee

This step may involve amending the protocol, comments and the responses must be documented and made available at final publication.

Step 6 – Finalisation of protocol for publication

Finalisation of the protocol involves:

- a final review and check by the lead author and expert committee after all modifications from step 5 are made.
- development of the accompanying guide and form
- update of the feedback form which includes comments from open consultation and responses.
- preparation of the website for publication.

Step 7 – Sign off by advisory committee

Details of the sign off by the advisory committee are as follows:

Who:	APAC and CanSAC
Documentation to be reviewed:	Final protocol
Format of review:	Documents emailed for endorsement or posted as draft to the website
Scope:	High level review based on amendments following steps 4 and 5. Endorsement to be sent to RCPA council for final endorsement.
Timeframe:	1 week

Step 8 – Final endorsement

Details of the final endorsement process are as follows:

Who:	RCPA Council
Documentation to be reviewed:	Final protocol
Format of review:	To be approved at Council Meeting or by circulation of the protocol or url to the website to Councillors
Scope:	RCPA endorsement of the protocol
Timeframe:	2–4 weeks (estimated)
Feedback to:	CanSAC, APAC and protocol committee

Step 9 Final publication of protocol

Final publication of the protocol should include:

- Posting of the protocol to the website or removal of “draft” from the posted protocol
- Posting of the feedback form with comments and responses
- Posting of the guide and form to the website
- Notification of finalisation to be sent to stakeholders.

Also desirable during the development process and prior to publication is for the lead author or chair to produce an article for publication on the key aspects of the protocol explaining the rationale as to why the key features/major prognostic factors were included in each of the protocols.

Guidelines for chapter content

The template contains the fixed (wording can be adapted to suit specific cancer) standards and guidelines that are part of all cancer protocols. This section provides guidance on cancer-specific information that expert committees should consider in protocol development or revision. It provides guidance for each of the chapters of a protocol (i.e. Chapters 1–7). For each chapter, this document provides background on the sorts of information the final protocol should contain, and explains why the information is necessary.

Protocol developers should use this section in conjunction with the template. It is best to read the appropriate section in this document first, and then work through the checklist that heads each chapter of the template. Comparison with previously published protocols may be useful.

When developing content, it is important to remember that standards should only be used where the information fits the definition of a standard (i.e. core items essential for the clinical management, staging, or prognosis of the cancer). Standards should not be used where the information given is based simply on the preference of individual pathologists. Protocol developers also need to consider the practicality and acceptability of any additional standards and guidelines.

Guidance for Chapter 1 – Clinical information and surgical handling

Specific measures for the clinical team

The protocol must describe any specific measures to be taken by the clinical team when collecting specimens.

- Where specific communication between clinician and laboratory is required before collection, this should be included in the protocol. An example is alignment with laboratory operations for allocation of fresh tissue for flow cytometry.
- Specific specimen handling and transport instructions should be provided, where appropriate.
- In cases where specific orientation of the specimen is standard procedure, the procedure should be referenced or described in detail.
- Specimen labelling requirements must be specified, where appropriate.

Clinical information for optimal pathology assessment

The protocol must describe the clinical information required for optimal pathology assessment for the specific cancer type being considered.

- Specific items might include, but are not limited to:
 - predisposing factors or cofactors
 - previous cancer diagnoses (date, biopsy number, laboratory, treatment)
 - presentation (screening procedure, incidental finding, or signs, symptoms and duration)
 - known sites of disease
 - current medication
 - diagnostic test results (diagnostic imaging and laboratory)
 - provisional clinical diagnosis
 - operative findings (procedure, tumour location, extent of spread)
 - surgical intent (curative or palliative).

Clinical information for staging

The protocol must include the requirement to record any clinical information that is needed for staging.

- The protocol should also make clear that the final American Joint Committee on Cancer (AJCC) stage is synthesized from a combination of clinical, macroscopic and microscopic data (see guidance on Chapter 5, below).

Proforma for a structured clinical request form

The protocol must provide a proforma for a structured clinical request form that can elicit all the above information.

- Guidance for the development of a structured pathology request form is given in Appendix 1 of the template.
- The proforma must contain all standards and should contain all guidelines given in the protocol.

Guidance for Chapter 2 – Specimen handling and macroscopic findings

Specific measures on receipt of specimen

The protocol must describe any specific measures to be taken on receipt of the specimen.

- Specific measures may include initial measurements and collection of fresh material for cytology, ancillary studies, specimen radiography, macroscopic photography, tissue banking or preparation for fixation.

Specific macroscopic findings

The protocol must describe the specific macroscopic findings relevant to the cancer type and specimen.

- Included here are descriptive findings and measurements – typically both specimen and tumour dimensions and proximity to margins – that are specific to the cancer and specimen type.
- The protocol must describe the details of anatomical landmarks and specimen orientation necessary for the dissection and sampling of the specimen that need to be recorded (see also relevant section of Chapter 1).
- The protocol may specify a convention for inking of margins and orientation where appropriate.
- In some cases a measurement, location or other parameter is captured both macroscopically and microscopically – in this case, to avoid confusion in the reporting or messaging processes, the macroscopic parameter should be preceded with the word “macroscopic” eg

Chapter 2: Macroscopic maximum tumour dimension

Chapter 3: Maximum tumour dimension

Macroscopic dissection and block selection

The protocol must outline any procedures for macroscopic dissection and block selection that are specific to the cancer and specimen type.

- Required sites for selection of blocks and block orientation may be included here.

Laboratory processing and sectioning of blocks

The protocol must address any specific and relevant requirements for the laboratory processing and sectioning of blocks.

- The protocol may specify section thickness and number of levels to be examined, particularly with reference to biopsies and sentinel lymph nodes.

Macroscopic information

The protocol must include the requirement to record any macroscopic information that is needed for staging.

- The protocol should also make clear that the AJCC stage is synthesized from a combination of clinical, macroscopic and microscopic data (see guidance on Chapter 5, below).

Guidance for Chapter 3 – Microscopic findings

Classification

The protocol must specify the tumour type and classification system.

- Classification of tumour type should be according to the World Health Organization (WHO) International Histological Classification of Tumours or, where appropriate, another internationally recognised system.
- For some cancers, such as lymphoma, tumour type is a product of multiple investigational modalities and is therefore recorded under ‘Synthesis’ (see guidance on Chapter 5, below).

Tumour grade

The protocol must indicate that the tumour grade must be reported, if appropriate for the given cancer.

- The protocol must specify the grading system to be adopted.
- The grading system specified should be the most current, endorsed version.

Staging

The protocol must include the requirement to record any microscopic information that is needed for staging.

- Microscopic information may include, but is not limited to:
 - tumour size and thickness
 - microscopic stage or extent of disease
 - clearance from margins
 - lymph node status.
- The final stage is synthesized from a combination of clinical, macroscopic and microscopic data and is reported under Chapter 5.
- For some cancers, such as lymphoma, staging may not be required.

Other microscopic parameters

The protocol must contain all other evidence-based microscopic parameters that have relevance to prognosis and management, and provide referenced commentary for their use.

- Parameters might include, for example:
 - vascular invasion
 - perineurial invasion.

Immunohistochemistry for microscopic findings

The protocol must make clear that immunohistochemistry used purely to enhance histological or morphological assessment rather than for ancillary information, should be recorded under microscopic, rather than ancillary, study findings

- Examples of immunohistochemistry used for this purpose include:
 - keratin stains to assess the depth of invasion of a carcinoma
 - S-100 stains to assess the depth of invasion of a melanoma
 - CD21 or CD35 stains to assess follicular architecture in lymphoma
 - p63 stains to assess invasion in breast or prostate carcinoma.

Guidance for Chapter 4 – Ancillary studies findings

For some cancers, ancillary studies play no part in current routine diagnosis and staging. In such cases, the text below can be omitted.

Specific ancillary tests

The protocol must describe the ancillary tests that should be performed for the specific cancer type.

- Examples of ancillary studies include many different tests, not necessarily performed in a histology laboratory, such as flow cytometry and cytogenetic and molecular investigations including in-situ hybridisation (ISH).
- There are many new and emerging tests that may be considered for inclusion in this section. Investigations that are research oriented and lack evidence for application in patient management should not be included in the protocol.

Information to be recorded

The protocol should describe the information to be recorded for each ancillary test.

- Certain ancillary studies may be subject to national or international reporting standards. These reporting standards should be followed, and should be specified where appropriate.

Immunohistochemistry for ancillary tests

Immunohistochemistry may be regarded as an ancillary test

- Immunohistochemistry is regarded as an ancillary test where it is used for quantitative measurement; for example:
 - measurement of oestrogen receptors or prognostic biomarkers
 - use of multiple panels of markers to determine lineage, clonality or tumour sub-typing (e.g. in the assessment of lymphoma).
- Where immunohistochemistry is performed only to enhance histological or morphological assessment and is not regarded as an ancillary test, it may be included in microscopic findings (see Chapter 3 above).

Guidance for Chapter 5 – Synthesis and overview

By definition, synthetic elements are inferential rather than observational. Some represent high-level information that is likely to form part of the report synopsis or key summary. For example, in some cancers, tumour type cannot be determined by microscopy alone and is synthesized from multiple classes of information:

- in primary bone sarcomas, knowledge of the clinical, radiological, microscopic and sometimes, ancillary study findings is a prerequisite for the determination of the tumour subtype.
- in haematological neoplasia, the tumour type, as defined by the WHO classification, is clinicopathological and is derived inferentially by combining the clinical history and microscopic findings with one or more ancillary studies.

Lower level data may also require synthesis. For example, both the lineage and clonality of a lymphoid neoplasm may be determined by immunohistochemistry, flow cytometry or molecular studies (or a combination of these techniques), some of which may give contradictory results. The final designation of lineage and of clonality is therefore synthesized from a consideration of all of these findings.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

Description of stage

The protocol must describe the AJCC tumour stage or, where appropriate, another internationally recognised system.

- The most current endorsed version and year of publication must be given in the protocol
- Explanatory notes should be provided to assist the reporting pathologist and to ensure uniformity in application of the staging method.
- For some cancers (eg. lymphoma), the pathology report does not contain or provide staging information and the standard is omitted from the protocol

Other data elements

The protocol must describe any other synthetic data elements required for the specific cancer type.

Guidance for Chapter 6 – Structured checklist

Contents and order

The protocol must contain a structured checklist that must contain the standards and guidelines detailed in the protocol which must be considered when reporting, including those where free text has been encouraged in the protocol.

- The checklist is a simplified version of the reporting protocol, organised to follow workflow sequence and designed to assist the pathologist during reporting.
- The order of the checklist should represent the logical sequence in which a pathologist would report the specific cancer.
- The checklist is not designed to be the final report; the final report is designed to optimise communication with the clinician.
- The protocol should indicate that an individual pathologist can modify or adapt the checklist, providing all 'standards' set out in the protocol are included in the final report.

Fields and value lists

The checklist should provide fields and value lists for discrete data elements.

- In preparing a list of values for a given field or data element for the structured checklist for the protocol, the points listed below should be considered.
 - Values should be mutually exclusive.
 - Values should be exhaustive; that is, they should contain every possible option. In some cases, the list of items will be too long to practically include in the checklist (e.g. there are more than 70 lymphoma subtypes). In such cases, the checklist should include only the most common items, plus an 'other' category at the end of the list with a space for free text. Lists of items that are too long can be included as appendixes to the protocol.
 - Each list must include provision for 'unknown', 'not applicable' or 'not specified' categories.

Consistency

All protocols must be consistent in format and naming. Descriptive headings used in the checklist should match those given in the protocol.

Guidance for Chapter 7 – Formatting of pathology cancer reports

The report format is substantially the same across all cancer types, and the approach to report formatting is largely generic. The approach is explained in Chapter 7 and Appendix 2 of the template. The expert committee may need to consider, however, whether certain types of information may be clearer if the protocol provides specific requirements for report formatting.

Optimisation of format

The protocol should explain that the report format should be optimised for each specific cancer.

- In cancer protocols where numerical or other values occur as repeating fields (e.g. prostate needle core biopsies), it may be appropriate to recommend specific formats for these elements. The use of tabular formats may however have implications for reproducibility across different IT systems

Consistency

The protocol should advise that the descriptive titles and headings used in the protocol and checklist should also appear in the report.

Example of a report

The protocol should include an example of a report.

- The report given in the protocol as an example must conform to the standards and guidelines given in the final version of the template.
- The sample report must also be de-identified.

Appendix A The need for structured reporting

Structured reporting has many benefits:

- for clinicians, it improves data completeness and provides decision support, reduces requests for repeat pathology and thus reduces waiting times, and is more user friendly so improves communication with patients
- for pathologists, it increases standardisation of clinical requests, improves ease of reporting for trainees and new pathologists, encourages data completeness, and supports best practice leading to more satisfied customers
- in terms of data informatics, it supports electronic transfer and e-health initiatives, and improves data extraction for cancer registries, clinical audits and research.

In recent years, structured pathology reporting of cancer has become commonplace. For example, the United Kingdom and the United States have defined processes for the development and review of structured reporting protocols; these processes are managed by the Royal College of Pathologists (RCP) and the College of American Pathologists (CAP), respectively. In the United States, the Commission on Cancer requires that '90% of pathology reports that include a cancer diagnosis contain the scientifically validated elements outlined on the surgical case summary checklist of the CAP publication *Reporting on Cancer Specimens*'²

In line with these international developments the Royal College of Pathologists of Australasia (RCPA) – through its Cancer Services Advisory Committee (CanSAC) – is implementing structured pathology reporting of cancer. The aim is to ensure that pathologists throughout Australasia have access to appropriate, nationally endorsed protocols.

Appendix B Development of the instructions and template

In June 2007, the Cancer Institute New South Wales (NSW) convened the National Round Table for Structured Pathology Reporting in Australia, with representatives from many key organisations (listed in Appendix C). A consensus statement from the meeting noted that structured reporting of cancer cases in anatomical pathology and haematology would contribute to better cancer control through improvements in clinical management and treatment planning, cancer notification, cancer registration, aggregated analyses and research. Participants agreed that a project should be undertaken with suitable clinical engagement, to build on current knowledge.

Subsequently, the Structured Pathology Reporting of Cancer Project was initiated with a memorandum of understanding between the Cancer Institute NSW, the RCPA and Cancer Australia. The aim of the project was to establish instructions and templates for protocol design that would serve as an Australasian standard and reflect current best practice in advanced health care.

The project team accessed multiple references, and reviewed both local and international reporting protocols. In particular, the team reviewed *Guidance on writing cancer datasets* – the document developed by the RCP to encourage a standard format for the cancer datasets developed in the United Kingdom³.

A workshop was held in May 2008 to refine the basic structure of the protocols and establish principles that should govern protocol development (shown in Box B1). The workshop included representatives from anatomical pathology, health informatics, medical software and project managers who had been responsible for guideline development and implementation.

During the Structured Pathology Reporting of Cancer Project, expert committees were set up to develop cancer-specific protocols. The chair of each group had the opportunity to appraise and critique the proposed outline and underlying principles.

This document and the accompanying template were written by a panel of pathologists, assisted by a specialist in health informatics and a medical writer.

CanSAC and APAC were responsible for the final review and endorsement of the instructions and template, after appropriate consultation with stakeholders.

Box B1 Principles of protocol development

RCPA structured cancer reporting protocols should:

- be flexible, and include mandatory and non-mandatory data elements
- be able to supplant existing methods of reporting, to avoid repetition of information in reports
- be evidence based and referenced (note: consensus of the expert group is acceptable where no higher level of evidence is available (Ref NHMRC levels of evidence))
- include discrete data elements where possible, but can include narrative elements if necessary, to convey complex information.
- advise that relevant pathology investigations performed from any one biopsy episode should be integrated into a single report
- not include data elements that are of research interest but lack published evidence or expert consensus. However, such elements can be added at a local level
- use national and international standards and classifications
- advise a different format for the recording of information in structured checklists and the report itself (the checklists and report have different functions, and therefore a different format)
- be consistent in the content and presentation of items common to different protocols.

Appendix C National Round Table

The table below lists the members of the 2007 National Round Table for Structured Pathology Reporting.

Name	Position	Organisation
Roger Allison	Executive Director for Cancer Services	Royal Brisbane and Women's Hospital
Maria Arcorace	Coding Manager, Central Cancer Registry	Cancer Institute NSW
Bruce Barraclough	eHealth Medical Director/CSIRO	Australian Cancer Network & CSIRO
Leslie Burnett	Chair	National Pathology Accreditation Advisory Council (NPAAC)
David Barton	Medical Advisor, Diagnostics & Technology Branch	Department of Health & Ageing
Jim Bishop	Chief Cancer Officer & CEO	Cancer Institute NSW
Neville Board	Manager, Cancer Information Systems	Cancer Institute NSW
Claire Cooke-Yarborough	Consultant Pathologist	NSW Central Cancer Registry
David Currow	Chief Executive Officer	Cancer Australia
David Davies	Joint A/Director Pathology	Sydney South West Area Health Service
Olivia de Sousa	Project Manager, EMR	Health Technology NSW
Sanji de Sylva	Clinical Consultant	Health Technology NSW
Warick Delprado	Director of Histology	Douglass Hanly Moir
Bob Eckstein	Head Anatomical Pathology	Pacific Laboratory Medicine Services (PaLMS)
David Ellis	Anatomical Pathologist	Flinders Medical Centre and Gribbles Pathology
Jill Farmer	Pathologist	The Integrated Cancer Research (ICR) Group
Helen Farrugia	Manager, Cancer Registry	Victoria Cancer Council
Karen Gibson	General Manager, Clinical Information	National E-Health Transition Authority (NEHTA)
Debra Graves	Chief Executive Officer	Royal College of Pathologists of Australasia
Narelle Grayson	Operations Manager, Central Cancer Registry	Cancer Institute NSW
Jane Grimm	Manager, Quality Use of Diagnostic Imaging (QUDI) Project	The Royal Australian & New Zealand College of Radiologists
Michael Guerin	President	Australian Association of Pathology Practices (AAPP)
Elizabeth Hanley	Senior Project Manager	Standards Australia
Nick Hawkins	Anatomical Pathologist	The Integrated Cancer Research (ICR) Group
James Kench	Senior Staff Specialist, Anatomical Pathology	Institute of Clinical Pathology and Medical Research (ICPMR)
Paul Kitching	Staff Specialist Anatomical Pathology	Prince of Wales Hospital Anatomical Pathology
Michael Legg	Director	Michael Legg & Associates
Beth Maccauley	Chief Operating Officer	Cancer Institute NSW
Peter MacIsaac	Health Informatics Consultant	MacIsaac Informatics Pty Ltd
Vincent McCauley	President	Medical Software Industry Association (MSIA)
Dean Meston	Manager, Pathology, Radiology and Medical Device Terminologies	National E-Health Transition Authority (NEHTA)

Name	Position	Organisation
Adrienne Morey	Director Anatomical Pathology, St Vincent's Hospital	for the Royal College Pathologists Australasia
Rosann Montgomery	Application Architect	NSW Health Department
Sian Munro	Project Manager	The Integrated Cancer Research (ICR) Group
Caroline Nehill	Program Manager	National Breast Cancer Centre (NBCC)
Jon Patrick	Chair Language Technology	University of Sydney, Faculty of Engineering
David Roder	Manager, Cancer Data Strategy Development	Cancer Australia
David Schanzer	Lead Analyst Programmer, Information Technology Division	Cancer Institute NSW
Sue Sinclair	Director, Cancer Services and Education	Cancer Institute NSW
Andrew Spillane	Surgeon	Royal Prince Alfred Hospital
Lisa Tan	Head Cytopathology	Pacific Laboratory Medicine Services (PaLMS)
Campbell Tiley	Haematologist, Gosford Hospital	for NSW Oncology Group (Haematology) and Australian Blood Cancer Registry
Steven Tipper	Project Coordinator, Medical and Scientific Unit	The Cancer Council of New South Wales
Robyn Ward	Director of Area Cancer Services	South Eastern Sydney & Illawarra Area Health Service
Peter Williams	Director, Architecture & Informatics, Strategic Information Management Unit	NSW Health Department
Roger Wilson	President	National Coalition of Public Pathology (NCOPP)
Yeqin Zuo	Manager, NSW Pap Test Register	Cancer Institute NSW

Appendix D Cancer committees and chairman

Cancer Committee	Chairman
Bone and soft tissue	Dr Chris Hemmings
Breast	Prof Michael Bilous
Gastrointestinal	Prof Bob Eckstein
Genitourinary	Prof James Kench
Gynaecological	Dr Nicholas Mulvany
Haematolymphoid	Dr Debbie Norris
Head/neck & endocrine	Prof Jane Dahlstrom
Neurological	Dr Michael Rodriguez
Ophthalmic	Dr Sonja Klebe
Paediatric tumours	Dr Susan Arbuckle
Pulmonary and mediastinum	Dr Jenny Ma Wyatt
Skin and adnexal	Prof Richard Scolyer

Appendix E NHMRC Extended levels of evidence¹

Level	Intervention ¹	Diagnostic accuracy ²	Prognosis	Aetiology ³	Screening Intervention
I ⁴	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ⁵ among consecutive persons with a defined clinical presentation ⁶	A prospective cohort study ⁷	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, ⁵ among non-consecutive persons with a defined clinical presentation ⁶	All or none ⁸	All or none ⁸	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial⁹ • Cohort study • Case-control study • Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> • Non-randomised, experimental trial • Cohort study • Case-control study
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study¹⁰ • Interrupted time series without a parallel control group 	Diagnostic case-control study ⁶	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> • Historical control study • Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) ¹¹	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Explanatory notes

- Definitions of these study designs are provided on pages 7-8 *How to use the evidence: assessment and application of scientific evidence* (NHMRC 2000b) and in the accompanying Glossary.
- These levels of evidence apply only to studies of assessing the accuracy of diagnostic or screening tests. To assess the overall effectiveness of a diagnostic test there also needs to be a consideration of the impact of the test on patient management and health outcomes (Medical Services Advisory Committee 2005, Sackett and Haynes 2002). The evidence hierarchy given in the 'Intervention' column should be used when assessing the impact of a diagnostic test on health outcomes relative to an existing method of diagnosis/comparator test(s). The evidence hierarchy given in the 'Screening' column should be used when assessing the impact of a screening test on health outcomes relative to no screening or alternative screening methods.
- If it is possible and/or ethical to determine a causal relationship using experimental evidence, then the 'Intervention' hierarchy of evidence should be utilised. If it is only possible and/or ethical to determine a causal relationship using observational evidence (eg. cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilised.
- A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence. Systematic reviews of level II evidence provide more data than the individual studies and any meta-analyses will increase the precision of the overall results, reducing the likelihood that the results are affected by chance. Systematic reviews of lower level evidence present results of likely poor internal validity and thus are rated on the likelihood that the results have been affected by bias, rather than whether the systematic review itself is of good quality. Systematic review *quality* should be assessed separately. A systematic review should consist of at least two studies. In systematic reviews that include different study designs, the overall level of evidence should relate to each individual outcome/result, as different studies (and study designs) might contribute to each different outcome.

- 5 The validity of the reference standard should be determined in the context of the disease under review. Criteria for determining the validity of the reference standard should be pre-specified. This can include the choice of the reference standard(s) and its timing in relation to the index test. The validity of the reference standard can be determined through quality appraisal of the study (Whiting et al 2003).
- 6 Well-designed population based case-control studies (eg. population based screening studies where test accuracy is assessed on all cases, with a random sample of controls) do capture a population with a representative spectrum of disease and thus fulfil the requirements for a valid assembly of patients. However, in some cases the population assembled is not representative of the use of the test in practice. In diagnostic case-control studies a selected sample of patients already known to have the disease are compared with a separate group of normal/healthy people known to be free of the disease. In this situation patients with borderline or mild expressions of the disease, and conditions mimicking the disease are excluded, which can lead to exaggeration of both sensitivity and specificity. This is called spectrum bias or spectrum effect because the spectrum of study participants will not be representative of patients seen in practice (Mulherin and Miller 2002).
- 7 At study inception the cohort is either non-diseased or all at the same stage of the disease. A randomised controlled trial with persons either non-diseased or at the same stage of the disease in *both* arms of the trial would also meet the criterion for this level of evidence.
- 8 All or none of the people with the risk factor(s) experience the outcome; and the data arises from an unselected or representative case series which provides an unbiased representation of the prognostic effect. For example, no smallpox develops in the absence of the specific virus; and clear proof of the causal link has come from the disappearance of small pox after large-scale vaccination.
- 9 This also includes controlled before-and-after (pre-test/post-test) studies, as well as adjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C with statistical adjustment for B).
- 10 Comparing single arm studies ie. case series from two studies. This would also include unadjusted indirect comparisons (ie. utilise A vs B and B vs C, to determine A vs C but where there is no statistical adjustment for B).
- 11 Studies of diagnostic yield provide the yield of diagnosed patients, as determined by an index test, without confirmation of the accuracy of this diagnosis by a reference standard. These may be the only alternative when there is no reliable reference standard.

Note A: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms (and other outcomes) are rare and cannot feasibly be captured within randomised controlled trials, in which case lower levels of evidence may be the only type of evidence that is practically achievable; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note B: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question eg. level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

Note C: Each individual study that is attributed a "level of evidence" should be rigorously appraised using validated or commonly used checklists or appraisal tools to ensure that factors other than study design have not affected the validity of the results.

References

- 1 Merlin T, Weston A and Tooher R (2009). Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence'. *BMC Medical Research Methodology* 9(34).
- 2 2004). *Cancer Program Standards 2004, Revised edition, Chapter 4, Standard 4.6, page 60.*
<http://www.facs.org/cancer/coc/cocprogramstandards.pdf>
- 3 <http://www.rcpath.org/resources/pdf/StandardFormatForCancerDatasets-Feb06.pdf>.