

Frequently Asked Questions

What does Synthesis mean?

Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.

In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more chapters in the protocol to derive new information. For example, tumour stage is synthesized from multiple classes of information – clinical (Chapter 1), macroscopic (Chapter 2) and microscopic (Chapter 3).

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to be included in the 'Diagnostic summary' section in the final formatted report.

Overarching case commentary, a key component in many cancer reports, is synthesis in narrative form

What is a standard?

Standards are mandatory items in the protocol. Their use is reserved for core items essential for the clinical management, staging or prognosis of the cancer. They are indicated by the use of the term 'must' in the protocol and are highlighted in bold print. Standards are prefixed with 'S' and numbered consecutively within each chapter (eg **S1.02**).

The summation of all standards represents the minimum dataset for the cancer.

What is a guideline?

Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are not essential for clinical management, staging or prognosis of a cancer, but are recommended.

Guidelines include key observational and interpretative findings that are fundamental to the diagnosis and conclusion. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail.

Guidelines are not used for research items.

In the protocols, guidelines are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).

Why include the obvious points everyone will report anyway e.g. laterality?

The protocols include both mandatory items or standards, as well as those items which are best practice (guidelines). To ensure each protocol is comprehensive and forms a minimum data set it must include those items which are obvious as well as those which may not be. Although the protocols have been created for pathologists, they are also essential for many other health professionals, including software engineers designing laboratory information systems, and those responsible for Australian eHealth implementation. The protocols therefore need to be inclusive.

Why not just use the CAP checklists?

There are local requirements, different naming conventions, and some legal considerations that precluded the adoption of the CAP checklists at this stage.

Discussions are in process to undertake collaboration with CAP and RCPATH to agree mandatory items; naming conventions etc for existing and future protocols which will drive a closer relationship in the future. In the longer term it is hoped there may be an international set of checklists.

Why did you use this format?

The format of the protocols is based on the National Pathology Accreditation Advisory Council (NPAAC) style guide. NPAAC plays a key role in ensuring the quality of Australian pathology services and is responsible for the development and maintenance of standards and guidelines for pathology practices. The style guide is used to create consistency across all NPAAC publications. It is the long term goal to have the Australasian cancer protocols accepted by NPAAC as a standard for use in all laboratories and therefore the style guide was adopted to facilitate this process.

The style guide can be reviewed at:

www.health.gov.au/internet/main/publishing.nsf/Content/health-mpaac-publication.htm

Why do we need the complex numbering?

The 'legalised' numbering system is part of the National Pathology Accreditation Advisory Council (NPAAC) style guide (see **why did you**

use this format?). The numbering of standards, guidelines and commentary will:

- Allow us to add and update standards and guidelines as new versions come into play over time, identifying what is a new standard or guideline and what is an updated version of an old standard or guideline.
- Easily identify standards (mandatory items) from guidelines (best practice) when reviewing or using the protocol and checklist.
- Allow sites implementing the checklists to add in local items - the numbers easily identify those items which are part of the cancer protocol and the lack of any identifying number will identify those which are local/site specific.

What am I allowed to change in the protocol or checklist?

You may download, display, print and reproduce the Protocol for your personal, non-commercial use or use within your organisation subject to the following terms and conditions:

1. The Protocol may not be copied, reproduced, communicated or displayed, in whole or in part, for profit or commercial gain.
2. Any copy, reproduction or communication must include the RCPA copyright notice in full. (see the copyright notice at the front of all of the protocols).
3. With the exception of Chapter 6 - the checklist, no changes may be made to the wording of the Protocol including any Standards, Guidelines, commentary, tables or diagrams. Excerpts from the Protocol may be used in support of the checklist. References and acknowledgments must be maintained in any reproduction or copy in full or part of the Protocol.
4. In regard to Chapter 6 of the Protocol - the checklist:
 - The wording of the Standards may not be altered in any way and must be included as part of the checklist.
 - Guidelines are optional and those which are deemed not applicable may be removed.
 - Numbering of Standards and Guidelines must be retained in the checklist, but can be reduced in size, moved to the end of the checklist item or greyed out or other means to minimise the visual impact.
 - Additional items for local use may be added but must not be numbered as a Standard or Guideline, in order to avoid confusion with the RCPA checklist items.

- Formatting changes in regard to font, spacing, tabulation and sequencing may be made.
- Commentary from the Protocol may be added or hyperlinked to the relevant checklist item.

Cancer Staging – why AJCC?

It was agreed, to avoid confusion and create consistency across protocols and to facilitate future collaboration with CAP and other international partners, that a single cancer staging system would be used and that system would be the American Joint Commission on Cancer (AJCC) TNM cancer staging system. Development of the UICC and AJCC TNM systems are now synchronized and, apart from a few small residual differences, they are essentially the same in version 7 (Nov 2009).

Why is cancer staging a standard?

In most cases staging has been included as a standard in the protocols, though there are exceptions, such as Lymphoma where staging depends on other parameters not usually known to the Anatomical Pathologist. Including staging as a standard has the advantage of ensuring that all the information required for Staging is included in the report (the "critical cut off's").

In some cases sufficient information may not be known to determine all the TNM parameters eg N in Melanoma, however this is catered for in the AJCC staging via the "x" classification eg Nx.

The "M" component, (previously referred to as "Mx" where the M status is unknown) is no longer included in pathology staging for TNM v7.

What are you doing to make the protocols consistent?

The Project team Framework Committee has developed and published Guidelines and a Template to ensure a common look and feel to all protocols as well as to ensure common content level. (please insert hyperlink) To further ensure a level of consistency across the protocols, the NPAAC style guide is used as the basis of the format (see **Why did you use this format?**). The NPAAC style was used to inform the design of the framework documents which provide a template for all protocol development.

The structured pathology reporting protocols for cancer are developed by a multidisciplinary expert committee. This means we have the best information and knowledge of the latest research to add to the protocols to achieve a very high quality document. However, international experience in the development of these types of protocols shows that involvement by general pathologists can add significant value to the

process by ensuring that the developed protocol is realistic and the reporting elements are achievable in the workplace. Therefore, the protocols will be reviewed by a general pathology group prior to publication commencing in 2011.

In addition the protocols are reviewed by the Cancer Services Advisory Council (CanSAC) and Anatomical Pathology Advisory council (APAC) from the RCPA to review for appropriateness, consistency and comprehension. A more detailed review by CanSAC is being introduced into the process during the second phase of protocol development. This review is designed to ensure that standards and guidelines are consistently applied across all protocols that Standards are core items essential for the clinical management, staging or prognosis of the cancer (see **What is a standard?**)

Am I liable if I don't use the protocol?

The RCPA has developed these protocols as an educational tool to assist pathologists in reporting of relevant information for specific cancers. While each protocol includes "standards" and "guidelines" which are indicators of 'minimum requirements' and 'recommendations' it should be noted that as a first edition these documents have not been through a full cycle of use, review and refinement. Therefore, during this initial cycle of use, the inclusion of "standards" and "guidelines" in each document is provided as an indication of the opinion of the relevant expert authoring group but should not yet be regarded as widely accepted peer professional opinion. The use of these standards and guidelines should be subject to the clinician's judgement in each individual case. The disclaimer at the front of each protocol (v1.1) includes wording to this effect.

Following the initial period of review and refinement of the protocols, it is intended that the documents be considered by NPAAC for inclusion in the laboratory accreditation process. It is at this time that the documents may move from "recommendations" to benchmark documents against which laboratory performance can be measured.

How do we record information which is not available at the time of reporting?

Often, recommended clinical information may not be provided in the pathology request form or may not be known at the time of referral. The relevant items of information have been included in the protocols because they can impact upon diagnosis, patient management or prognosis. It may be important that the pathologist record these as "unknown" so that the requesting clinician is aware that the report has been written without this knowledge. In time, the aim is to improve the

quality of pathology requests so that all known relevant information is given.

Delays inherent in ancillary tests may also prevent initial reporting of all information in one report.

Some pathologists delay the report until the information is obtained, others issue a supplementary or amended report when the information becomes available. The protocols do not offer a recommendation, other than to state clearly when critical information is not available, and what is known to be pending.

Do the protocols cover biopsies or resections or both?

This is specimen dependent. The scope of each protocol is determined during development with the expert committee, and depends largely on complexity. The scope of the protocol, depends on a number of factors such as whether:

- The specimen types can be handled similarly
- Whether the same information is obtained from the different specimen types
- Is cancer staging the same for all specimen types?

If the protocol becomes too complex and difficult to follow with a broad scope, the expert committee may consider splitting this into different protocols. For example the prostate covers radical prostatectomy but TUR and Core Biopsy are separate protocols.

Some protocols may cover both a core biopsy and resection specimen and this may mean that a significant proportion of the structured report may be deemed "not applicable" for the core biopsy, however, the need is to supply as much information as possible whatever the specimen provided.

How often are the protocols updated?

A release strategy document has been written and endorsed by the Cancer Services Advisory Committee. This document is posted to the RCPA website:

www.rcpa.edu.au/Publications/StructuredReporting/ProtocolDevelopment.htm

The purpose of the release strategy is to describe the approach to be undertaken to update and re-release existing protocols. It includes:

- An explanation on the process of creating a new edition and what constitutes a new or updated edition of the published cancer protocols
- Key features such as referencing, style guides, numbering etc to be maintained during updates to published protocols
- The process flow for the release of an updated protocol

- The expected release schedule for updates to published protocols.

Is there still a place for a narrative macroscopic report?

Yes – the standards and guidelines are used to drive the consistent and clear capture of data relevant to the specimen. The use of narrative or 'text' allows the user to further describe areas of uncertainty and to expand on the structured information to ensure that the information in the report is comprehensive. All protocols allow for narrative in all chapters in addition to synoptic elements.

Why are the clinical request forms so long? No-one will fill them in.

While it is acknowledged that it can be difficult to obtain all of the information needed on the request form (Appendix 1 in the protocols), the expert committees (which included surgeons and other clinicians) agreed that this information is required to adequately make an informed diagnosis (see **How do we record information which is not available at the time of reporting?**).

What is the checklist for? Is it the report?

The checklist (chapter 6 of the protocols) includes the data components of the standards and guidelines which must be considered when reporting, in the simplest possible form. It does not include any standards and guidelines related to specimen handling. The checklist is used as a summary of the key reportable items, sequenced in the order of a pathologist's workflow. The report can be formatted differently to the checklist, to optimize the communication of information to the clinician – for example, the diagnostic summary and staging are included at the end of the checklist as this information is necessarily derived from the information gathered throughout the examination of the specimen; the report format may have the diagnostic summary at the top of the document as this encapsulates the key findings needing to be communicated to the clinician. While having similar information the checklist and report have different objectives.

Guides for Reporting are also in production for reference but in a more compact form.

How do I find out more?

If you have other questions not addressed by the information on this website please email:

StructuredPathology@rcpa.edu.au

I'd like to participate in the development process – how do I do that?

If you would like to participate in the review process of upcoming protocols or development of future protocols please contact the Project Manager for structured pathology reporting project via email, to nominate your area of interest:

MeaganJ@rcpa.edu.au or StructuredPathology@rcpa.edu.au

Colorectal specific Q&A

What does the colorectal protocol cover?

The colorectal cancer protocol is not intended to apply to tumours of the appendix, small bowel and anus. Local excisions of colorectal carcinomas (polypectomies and TEMS) will be dealt with in a subsequent protocol.

Does the protocol include carcinoid tumours?

No- the protocol covers adenocarcinoma only. Carcinoids are not included in the World Health Organization – histological classification of tumours of the colon and rectum.

Doughnuts – are they important?

Although it has been recommended that doughnuts, if received, be microscopically examined, detailed examination is only important in cases where at gross examination the tumour is close to a resection margin.

Rectosigmoid Junction (S1.05) – is this an accepted term?

Yes. The expert committee is comprised of surgeons, other clinicians and pathologists. It was agreed that this term was acceptable to all parties including the surgeons.

Prostate specific Q&A

Why is PSA included as a guideline?

Prebiopsy PSA levels are a key factor in prognostic grouping in the 7th Edition AJCC TNM Staging system.

How much of a second tumour is involved with grading?

This is dealt with in detail in the Gleason Grading tables in S3.02 in the protocol.

When is a margin positive?

A positive surgical margin (PSM) is defined as cancer extending to an inked surface of the specimen. "Close" is not "positive". Carcinoma close to, but not involving the margin, should not be labelled as a positive margin because this feature has been shown to have no prognostic significance.

Extraprostatic extension – how is this defined as it can be difficult?

Extraprostatic extension (EPE) refers to the presence of neoplastic glands outside the prostate in the periprostatic tissue. The assessment of EPE can be difficult, as the prostate is not surrounded by a discrete, well defined fibrous capsule. The protocol includes a description on how EPE can be identified and diagnosed in several different situations. (S3.03)

How do you grade ductal carcinoma?

Intraductal carcinoma is graded in the Gleason grading system as 4, or 5 if comedonecrosis is present. (S3.02).

Melanoma specific Q&A

Are wider excision margins recommended?

This is not included in the protocol, however, it is covered in the NHMRC clinical practice guidelines for the management of melanoma.

How do you define peripheral edges?

Pathologists should attempt to identify the peripheral extent of the melanoma and assess its relationship to the margins of the specimen. However, in some melanomas, particularly those involving acral sites and those with a predominantly lentiginous growth pattern, the periphery of the epidermal component may be poorly defined making such assessment difficult and subjective.

The growth phase – can this be ignored?

Growth phase is not included in the protocol as this factor as a prognostic indicator, independent of the mitotic rate, is doubtful.