Structured Pathology Reporting of Cancer Protocol Release Strategy

Version: 1.0
Dated: Apr 2010

Document History

Version	Description	Date
Version 0.1	Initial draft for review by project group	Feb 2010
Version 1.0	Final version for publication on web	Apr 2010

Purpose

The purpose of this document is to describe the approach to be undertaken to update and re-release existing protocols.

Background

Phase 1:

In June 2007, a National Round Table was held to discuss the use of structured pathology reporting of cancer throughout Australia. All who were present at The Round Table agreed that structured reporting of cancer cases in anatomical pathology and haematology is likely to contribute to better cancer control through improvements in:

- Clinical management and treatment planning
- Cancer notification, registration and aggregated analyses
- Research.

The Cancer Institute NSW secured funding in February 2008 from the Dept of Health & Ageing (Quality Use of Pathology Programs) to work with the RCPA and Cancer Australia to develop an initial 6 reporting protocols (lung, melanoma, breast, colorectal, lymphoma and prostate) and a framework to guide development of the protocols, in partnership with national clinician and pathologist organisations. At the conclusion of the first phase of the project, six cancer protocols had been developed in addition to a comprehensive framework for the future development of cancer protocols.

Phase 2:

A second round of funding from the Dept of Health and Ageing (Quality Use of Pathology Programs) has been applied for, to promote and expand the use of structured reporting of cancer. The planned program of work will include developing further protocols in conjunction with international bodies; undertaking a national program of education on the developed cancer protocols (breast, melanoma, lung, lymphoma, colorectal and prostate); and developing a recommended report format in which to report the structured information from the protocols. This program of work will be overseen by the Royal College of Pathologists Australasia with clinical consultation from the Cancer Institute, and in conjunction with Cancer Australia.

Objectives

The objectives of this release strategy are to:

- Explain the process of creating a new edition and what constitutes a new or updated edition of the published cancer protocols
- Document key features such as referencing, style guides, numbering etc to be maintained during updates to published protocols
- Describe the process flow for the release of an updated protocol
- Provide a guide to the expected release schedule for updates to published protocols.

Editions

Each published structured pathology reporting protocol is described by a bi-part version number eg V1.1. The first number indicates the edition and the second indicates a specific update to that version.

A new edition is created based on the following:

- Changes to any standard or guideline wording or numbering including deletions, new additions etc.*
- Changes to the *meaning* of any commentary eg new method of calculation.

- Changes to any core dependent document eg updated AJCC Cancer Staging information.

An update to an edition may be released for the following reasons:

- Formatting updates
- Minor modifications including:
  - Minor corrections eg spelling, punctuation,
  - Reference updates
  - Rewording of commentary which does not change the meaning but is for the purposes of clarification only.

*The numbering of standards and guidelines are protocol edition dependent; any modification to the wording of a standard or guideline or to the numbering of either should require the creation of a new edition. This will ensure the integrity of the standards and guidelines over time.

Maintenance features

1. References

All references for all protocols except breast are maintained in a single Endnote database. Breast remains in a separate Endnote database due to the original authoring process.

Using Endnote provides easy re-use of references within documents as well as a providing a means to keep a consistent style across documents.
Updates to references are kept separately to avoid confusion in the longer term as to references used in a particular document. For example, when AJCC released 7th edition – both the 6th and the 7th edition had references in Endnote; the 6th edition was not overwritten with the updated version.

References are kept linked during the authoring process and a linked version is kept after publication for the update process. An unlinked protocol is published.

Linking is the process of maintaining a direct association between the Vancouver style numbering and the Endnote reference – this allows easy update and re-numbering when additional references are added.

2. Style guide

The format of the protocols is based on the National Pathology Accreditation Advisory Council (NPAAC) style guide.

The style guide can be reviewed at:

http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

Specific style requirements are included below:

a. References

All references are in Vancouver style as follows:

With text:

- *AJCC Cancer Staging Manual,* 7th edition, American Joint Committee on Cancer, 2009[9]

In the Reference section at the end of the protocol:

9 Edge S, Byrd D, Compton C, Fritz A, Greene F and Trotti A (2009). *AJCC Cancer Staging Manual 7th edition*. Springer-Verlag, New York.

Specific requirements for copyright material may be required – for example, AJCC require that copyright material include specific wording on the page in which the text/table/diagram is used and also that any reproduction of text is verbatim to the manual.

b. Text fonts

Are as follows:

Where used	Example	Style
Chapter/section heading	**1 Clinical information**	Arial 20 point, bold
Subheading	**Benefits of structured reporting**	Arial 14 point, bold
Minor heading	**Secretariat**	Arial 12 point, bold
General text	This protocol defines the relevant information to be assessed and recorded in a pathology report for colorectal cancer. Mandatory elements (standards) are differentiated from those that are not mandatory but represent best practice (guidelines).	Verdana 10 point
Standards	**S2.09 The presence or absence of tumour perforation must be recorded.**	Verdana 10 point, bold
Guidelines	G2.03 A block containing tumour should be nominated for further ancillary studies.	Verdana 10 point

c. Tables

Tables should be numbered according to the standard or guideline and if applicable the specific commentary that it relates to. For example,

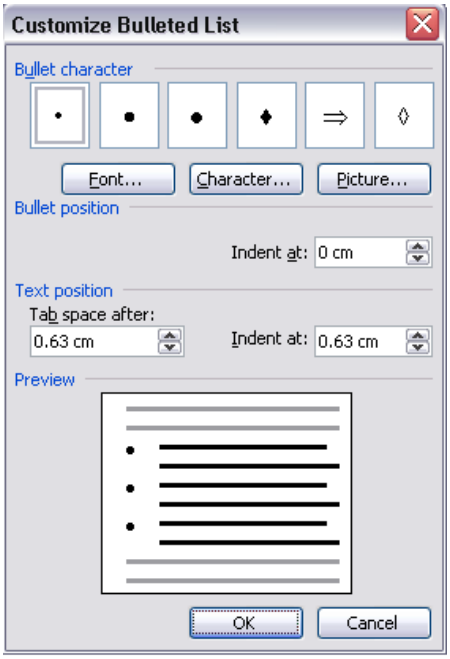
Table CS3.03a Pathological tumour (T) classification for colorectal cancer

The table should be sited as close to the commentary as possible, preferably immediately following.

The table header should be repeated if a table continues over a page.

d. Bullet points

Bullets should use:



For example:

- It provides correlation with previous investigations.
- It indicates whether a non-peritonealised (circumferential) margin is likely to be present.
- The natural history and treatment of rectal cancer differs significantly from colonic cancer.

Bullet points should be spaced with 6pt after.

e. Diagrams

Diagrams should be numbered according to the standard or guideline and if applicable the specific commentary that it relates to. For example,

CS2.10b The anterior aspect of the rectum is covered by peritoneum down to the peritoneal reflection. On the posterior aspect the nonperitonealised margin extends upwards as a triangular shaped bare area containing the rectal arteries, which then continues up to the start of the sigmoid mesocolon (see Figure S2.10b).

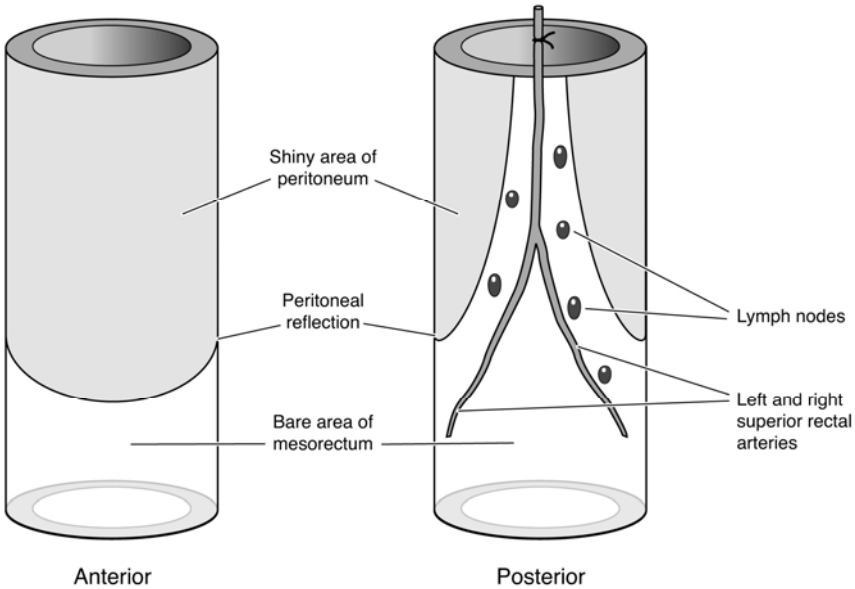


Figure S2.10b Site of non-peritonealised margin (bare area of mesorectum) in relation to the peritoneal reflection

The figure with number should be referred to in the text as per the above example.

f. General style requirements

- Use italics for all enzymes, the scientific names of animals or plants.
- Use eg not e.g.
- Use ie not i.e.
- Use quotes for direct reproduction of text where used as part of commentary.

3. Standard and Guideline Numbering

All standards and guidelines are numbered within the protocol according to the chapter in which they appear and the order in which they are documented eg S1.03 is the 3rd standard in chapter 1. Commentary is added by the use of a, b, c etc.

However, this numbering of standards and guidelines should be reviewed in the context of the edition of the protocol in which it is documented. The checklists - those external to the main protocol document - will be numbered according to both the edition number and the standard or guideline. For example:

E1S1.03 – refers to edition 1 of the specific protocol and the 3rd standard in chapter 1.

This edition specific numbering is important as numbering of standards and guidelines may change overtime as new editions are released. For example, the release of 7th edition AJCC cancer staging manual in Oct 2009 brought with it a change for the documentation of Clark level in the Melanoma protocol from a standard to a guideline – this not only changed the numbering for this specific item but also for all subsequent items in that chapter.

Updates to numbering should be noted as part of the summary of changes in the notification of a new edition.

Release Process

The update of an edition of a protocol or the development of a new edition of the protocol is a five step process:

1. Input

The update to, or creation of, a new edition may be driven by one or more of the following:

- Updates to the cancer staging information eg release of a new edition of AJCC.
- Feedback from end users (via email or via the protocol review form on the webpage)
- Information obtained by the chair or authoring expert committee eg changes in testing or other procedures
- Agreement through international collaboration which may prompt changes in wording; naming conventions; standards or guidelines.

2. Review

Information from input sources will be reviewed on a periodic basis (6monthly) by the relevant expert chair, lead author and authoring expert committee.

Feedback from end users via email or via the protocol review form will be documented in the feedback excel spreadsheet published to the structured pathology reporting project webpage at:
www.rcpa.edu.au/Publications/StructuredReporting/Feedback.htm
Responses to the feedback will also be posted. Updates to the feedback excel will be posted quarterly by the Structured Pathology Reporting Project Manager.

Information requiring updates from the Chair, lead author or authoring expert committee; updates to the cancer staging information or updates from agreement with other international bodies will be described in the "Updates since last edition" section of the updated protocol as and when it is released.

3. Updated Protocol

The chair of the cancer committee and lead author of the protocol will determine what, of the input received, will result in updates to the protocol. A broad release schedule is included in the section below.

Updates to an existing edition or the development of a new edition of a protocol may involve updates to:

- The protocol – including the "Updates since last edition" section of the updated protocol
- Checklist - in Chapter 6 of the protocol which includes all of the standards and guidelines relevant to the pathology report.
- Guide – a simple checklist for reporting pathologists to 'tick' off to ensure all relevant items are included in their report.

- Paper form – used to record the relevant items of a report.
- Electronic forms – used to record the relevant items of a report.
- Archetypes
- Feedback Excel

*Archetypes are a 'map' which is used by a Laboratory Information System to populate an HL7 message according to the cancer protocols. The National e-Health Transition Authority commissioned Ocean Informatics to create archetypes from each of the cancer protocols. As the protocols are updated the archetypes must also be updated.

Updates to the protocols will be undertaken by the authoring expert committee with the assistance of the Structured Pathology Reporting Project Manager.

4. Approval

The updated or revised protocol will undergo review by the authoring expert committee, the Cancer Services Advisory Committee (CanSAC) and Anatomical Pathology Advisory Committee (APAC). Final approval will be sought from the RCPA council. their approval is required prior to publication on the webpage.

5. Notification

Following review by the expert committee, CanSAC and APAC and RCPA council the revised protocol and other applicable documents will be posted to the Structured Pathology Reporting webpage:
www.rcpa.edu.au/Publications/StructuredReporting/CancerProtocols.htm
with the version number indicated and the words (UPDATED and the date) next to the hyperlinked name of the protocol.

Once posted to the webpage, a notification will be sent as follows:

- For updates to the protocols only, a notification will be included in the next Structured Pathology Reporting newsletter.
- For new editions, a notification email will be sent to all stakeholders and a notification will be included in the next Structured Pathology Reporting newsletter.

Release Schedule

A new or updated edition of each protocol will be undertaken as follows:

- An initial review and update 12months from the first publication date.

- General review and release 3 yearly from the first publication date.

- New edition update on release of the 8th and subsequent editions of the AJCC cancer staging manual.

Updates to editions may be released earlier than this review period if deemed applicable by the chair, lead author and authoring committee.