Structured Pathology Reporting of Cancer Protocol Release Strategy

Version: 2.1
Dated: Apr 2016

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
Version 2.0	Update post ICCR – initial draft	Oct 2015
Version 2.1	Update based on new update process	Apr 2016

Purpose

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

Background

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.

After the initial success of the pilot funding in 2010, second and subsequent rounds of funding from the Department of Health and Ageing (Quality Use of Pathology Programs) were obtained to build on this foundation.

Objectives

The objectives of this release strategy are to:

- Explain the process of creating a new edition and what constitutes a new or updated revision of the published cancer protocols, and
- Document key features such as referencing, style guides, numbering etc to be maintained during updates to published protocols

International Collaboration on Cancer Reporting

In 2011, the International Collaboration on Cancer Reporting (ICCR) was formed by the Royal Colleges of Pathologists of Australasia (RCPA) and the United Kingdom (RCPath), the College of American Pathologists (CAP) and the Canadian Association of Pathologists-Association Canadienne des Pathologists (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), and later joined by the European Society of Pathology (ESP) , with a view to reducing the global burden of cancer dataset development and reduplication of effort by the different international institutions that commission, publish and maintain standardised cancer reporting datasets. The ICCR recognised that a coordinated effort on cancer reporting would offer synergies and have far–reaching benefits for those involved as well as for those countries that are not in a position to develop their own datasets. The development of a single internationally agreed dataset for each tumour has the following benefits:

- Dataset production by a single organisation avoids reduplication of cancer pathology dataset development in many different jurisdictions. Producing datasets is a significant burden upon each country and creates risks for interoperability and international comparison.

- Datasets created with international governance will be available to developing countries that have insufficient resources to develop their own.
- Internationally derived datasets are essential for international data comparison and benchmarking.
- In developing a single international standard the ICCR can engage the best international expertise and ensure that there is a common meaning and definition for all data elements with consistent application of value lists.
- The creation of a single, defined, evidence-based dataset for each cancer simplifies, and will reduce the cost of electronic implementation by standardising laboratory information system data structures, terminology bindings and electronic messaging in the longer term
- The ICCR can facilitate timely revision of datasets in light of ever more rapidly emerging predictive biomarkers.

The international agreed ICCR datasets provide the single best way for the existing dataset producers (RCPath, CAP, RCPA and others) to align and synchronise their protocols, as global standardisation of pathology information is a prerequisite for all international epidemiological research and benchmarking in cancer management.

The ICCR was incorporated as a not-for-profit organisation in September 2014.

The ICCR datasets are published to the ICCR website and made freely available for use worldwide.

Website: iccr-cancer.org

The RCPA commenced incorporating the international standards from the ICCR into its protocols from 2014.

Edition numbering

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

Updates to protocols

Protocols will be scheduled for review and possible revision every 3 years at a minimum. Updates before the date of formal review may also be undertaken as a result of errors, changes to dependent publications such as the WHO Classification of Tumours or staging systems e.g. FIGO, AJCC/ UICC, or significant changes in clinical or diagnostic evidence or management related to a specific cancer.

Updates will fall into one of 2 categories – protocol revisions and correction of errata.

1. Protocol revisions

Each revision for a specific protocol will be denoted by an incremental number e.g. Lung Cancer Structured Reporting Protocol v2.0 denoting the 2nd published edition of the Lung Cancer Protocol.

A revision is categorised as either *major* or *minor* depending on the need for a period of public consultation.

1a. Minor revision

A minor revision may be initiated by such changes as:

1. The addition of a new guideline.
2. Rewording of commentary which does not change the meaning of an element, but further clarifies it.
3. A change to the name of an element or a response that does not substantially change its meaning (for example, changing the response from “absent” to “not identified”), or
4. The downgrading of a standard to a guideline.

This type of update will not require a period of public consultation before publication.

1b. Major revision

A major revision is generated by such changes as:

1. Upgrading of a guideline to a standard
2. The addition of a standard e.g. as a result of new scientific evidence, evidence-based changes in cancer management or new ancillary tests.
3. The deletion of any element.
4. A change in the commentary which alters the meaning of the element, the response/s or the way in which the response is recorded. If a value/response is changed by the description provided in the commentary or the way in which a calculation or measurement must be made, this requires a major revision.

This type of update will require a period of public consultation before publication.

2. Corrections of Errata

This form of update is used to correct minor errors within a published protocol, such as corrections of spelling, punctuation or typography, or to update cited references that have moved from 'in press' to being published. As the change in this type of update is minor in nature it is represented by an incremental update to the revision number of the protocol e.g. Lung Cancer Structured Reporting Protocol v2.1 denotes an errata update to the 2nd published edition of the lung cancer protocol.

An errata update will be undertaken as needed.

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 reference material is kept separately to avoid confusion in the longer term as to references used in a particular document. For example, when AJCC released it's 7th edition – both the 6th and the 7th edition were recorded separately 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.

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,

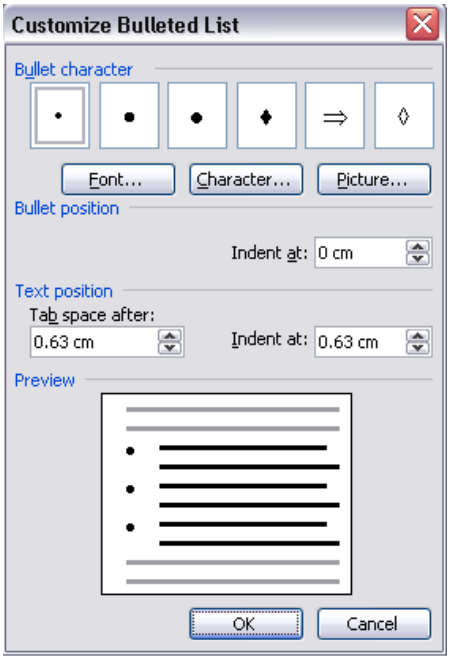
Table CS3.03a Pathological tumour (T) classification for colorectal cancer

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).

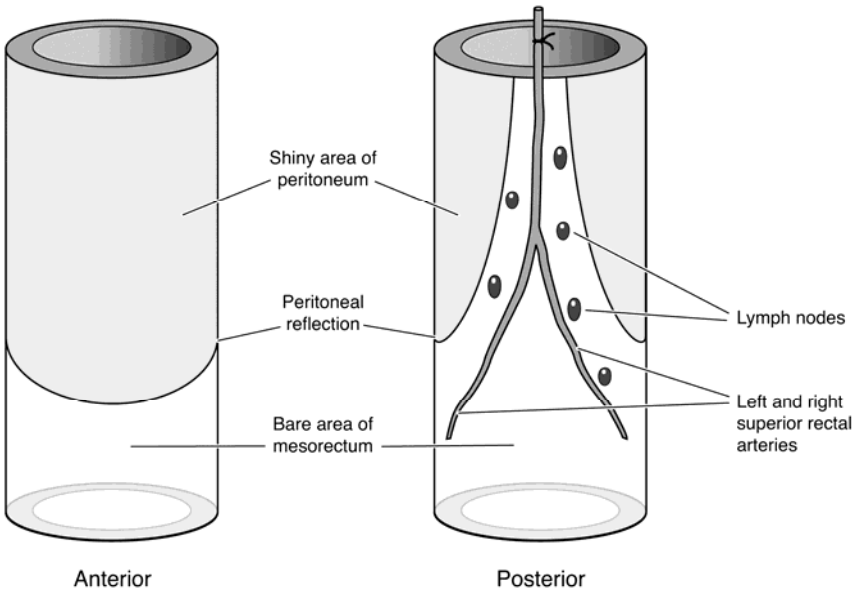


Figure S2.10b Site of non-peritonealised margin (bare area of mesorectum) in relation to the peritoneal reflection

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.

This edition context 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.