International Collaboration on Cancer Reporting

# Guidelines for the Development of ICCR Datasets

## TABLE OF CONTENTS

## Document history

| Version | Description | Date |
|---|---|---|
| Version 0.1 | Initial draft | August 2012 |
| Version 0.2 | Refinement of initial draft | September 2012 |
| Version 0.3 | Review by ICCR | October 2012 |
| Version 0.4 | ICCR team updates included | October 2012 |
| Version 0.5 | Refinement of ICCR updates | November 2012 |
| Version 0.6 | Final version for open consultation | November 2012 |
| Version 0.7 | Edits to synchronise this document with roles and responsibilities document | August 2013 |
| Version 0.8 | Updates following ICCR DSC review | September 2013 |
| Version 0.9 | Incorporation of dataset updates | November 2013 |
| Version 1.0 | Approved by ICCR DSC | November 2013 |
| Version 1.1 | DAC formation figure added, draft modifications made to new edition/version updates | November 2014 |
| Version 1.2 | Final updates to the new edition/version updates | March 2015 |
| Version 1.3 | Updates to DAC nomination and composition and inclusion of scope | June 2015 |
| Version 2.0 | Approved by ICCR DSC | June 2015 |
| Version 2.1 | Suggested changes to scope to include non-invasive entities in some circumstances | September 2015 |
| Version 2.2 | Suggested changes to scope to include non-invasive entities in some circumstances | October 2015 |
| Version 2.3 | Changes approved by ICCR DSC | October 2015 |
| Version 2.4 | Revisions based on new terminology core/non-core and the inclusion of the Series Champion role | June 2016 |
| Version 2.5 | Revisions to include licence of copyright to the ICCR | October 2016 |
| Version 2.6 | Revisions to address DAC non-responders | December 2016 |
| Version 2.7 | Revisions to include<br>a. process of TNM errata<br>b. resource appointment process<br>c. translation of ICCR datasets | August 2018 |
| Version 2.8 | Changes approved by ICCR DSC | October 2018 |
| Version 2.9 | Suggested changes by DAC issues working group meeting 24/25 January 2019 | February 2019 |
| Version 2.10 | Changes approved by ICCR DSC | March 2019 |
| Version 2.11 | Suggested updates for yearly review | February 2020 |
| Version 2.12 | Changes approved by ICCR DSC | February 2020 |
| Version 3.0 | Proposed changes to the dataset update process and suggested updates per the yearly review | February 2021 |
| Version 3.1 | Approved for publication | March 2021 |
| Version 3.2 | Proposed changes per the yearly review | March 2022 |
| Version 3.3 | Approved for publication | April 2022 |
| Version 3.4 | Changes approved by ICCR DSC | April 2023 |
| Version 3.5 | Changes approved by ICCR DSC | May 2024 |
| Version 3.6 | Change to definition of core elements approved by ICCR DSC | July 2024 |

**Abbreviations**

| | |
|---|---|
| DSC | Dataset Steering Committee |
| DAC | Dataset Authoring Committee |
| IARC | International Agency for Research on Cancer |
| ICCR | International Collaboration on Cancer Reporting |
| NHMRC | National Health and Medical Research Council |
| LIS | Laboratory Information System |
| WHO | World Health Organization |
| QA | Quality Assurance |
| CAP | College of American Pathologists |
| USA | United States of America |
| RCPath | Royal College of Pathologists |
| RCPA | Royal College of Pathologists of Australasia |
| ISO | International Organization for Standardization |

## 1. Purpose

The purpose of this document is to describe the development process of International Collaboration on Cancer Reporting (ICCR) cancer datasets. The aim is to ensure that the datasets produced for different tumour types have a consistent style and content, and contain all the parameters needed to guide management and prognostication for individual cancers.

This document will be updated periodically as required in order to maintain its currency and to take advantage of improvements in process which will be achieved as the collaborative process progresses.

## 2. Introduction

For a number of years, datasets for the pathology reporting of cancer have been published by many organisations around the world, at national and institutional levels. In the United States of America (USA), the College of American Pathologists (CAP) currently publishes more than 70 'Checklists' for synoptic reporting of all major cancers.[1] In the UK, the Royal College of Pathology (RCPath)[2] publishes cancer datasets and in Australia, the Royal College of Pathologists of Australasia (RCPA) publishes structured protocols for cancer reporting.[3] Moreover, a number of European nations have active programs of a similar nature. These various protocols define the detailed pathology and staging data essential for histological diagnosis, patient management and prognosis with the intention that it is complete, concise, reproducible and in line with international standards and current knowledge. Since all evidence-based cancer protocols are necessarily derived from international peer-reviewed literature, it is inevitable that cancer protocols produced by these various organisations will contain similar data elements, albeit with minor variations.

Recognising that standardised cancer datasets are a prerequisite for national and international benchmarking in cancer monitoring and management, and that pathology reports provide key information on tumour classification, staging and prognostic data, the initial ICCR quadripartite alliance was established to examine the practicability of developing international, evidence-based pathology datasets for all major cancers.

The ICCR recognised that there were benefits that could be gained from international extension of this process:

- 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.
- In developing a single international standard it becomes possible to engage 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 greatly facilitates electronic implementation by standardising Laboratory Information System (LIS) data structures, terminology bindings and electronic messaging. =

**Dataset elements**

Each cancer dataset comprises a series of elements which are important for the clinical management, staging or prognosis of the cancer e.g., tumour diameter, lymphovascular invasion, or fundamental to the histological diagnosis and conclusion e.g., macroscopic tumour details. Each element is included on the consensus of the DAC.

An element may be designated as core or non-core by the DAC as described below.

**CORE elements**

Core elements are those which are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the National Health and Medical Research Council (NHMRC) levels of evidence[4] document – see Appendix A). In rare circumstances, where level III-2 evidence is not available an element may be made a core element where there is unanimous agreement by the DAC. An appropriate staging system e.g., Pathological TNM staging would normally be included as a core element.

Molecular and immunohistochemical testing is a growing feature of cancer reporting. However, in many parts of the world this type of testing is limited by the available resources. In order to encourage the global adoption of ancillary tests for patient benefit, International Collaboration on Cancer Reporting (ICCR) includes the most relevant ancillary testing in ICCR Datasets as core elements, especially when they are necessary for the diagnosis. Where the technical capability does not yet exist, laboratories may consider temporarily using these data elements as non-core items.

The summation of all core elements is considered to be the minimum reporting standard for a specific cancer.

**NON-CORE elements**

Non-core elements are those which are unanimously agreed should be included in the dataset but are not supported by level III-2 evidence. These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management.

Key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion e.g., macroscopic tumour details, may be included as either core or non-core elements by consensus of the DAC.

**Permitted responses**

Permitted responses refer to the range of standardised responses that are used to describe an element e.g., present, absent.

**Evidence**

A review of evidence in the latest peer-reviewed literature is necessary to ensure that the dataset contains the most recent, validated information pertaining to a given cancer. Where applicable, citations must be included to direct the reader to the evidence justifying inclusion of a data item in the dataset.

The extended NHMRC levels of evidence published by Merlin T, Weston A, et al. 2009[4] is used (Refer to Appendix A).

Where no reference is provided, the authority is the consensus of the DAC.

**Commentary**

Commentary is explanatory text, diagrams or tables that clarify the elements used to:

- define the way an item should be reported, to ensure clarity and conformity;
- explain why an item is included (e.g., how does the item assist with clinical management or prognosis of the specific cancer);
- cite published evidence in support of the element; and
- state any exceptions or issues.

Commentary is designed to provide contextual guidance to the reporting pathologist.

## 3. DATASET SCOPE

In general, ICCR datasets cover malignant entities, either alone or in association with other pre-cancerous or non-invasive components.

Dataset scope does not cover non-malignant entities alone except in certain circumstances:

- For anatomical areas such as the heart and central nervous system, benign tumours are included in the scope as even a benign condition has serious prognostic implications.
- Tumours of uncertain malignant potential.
- In cases where in situ neoplasia is relevant the scope may cover both invasive and non-invasive tumour components.

## 4. DATASET DEVELOPMENT PROCESS

This section explains the process of developing ICCR cancer datasets. The process, described in detail below, involves:

1. Selection of a Dataset Series Champion, for the development of a suite of datasets across a specific anatomical area/organ system
2. Selection of the chair(s) of the DAC
3. Selection of the DAC members and for each dataset
4. Review of relevant, published cancer datasets and key publications
5. Draft a proposed dataset
6. Committee review of the draft dataset to identify areas of agreement and discord, to focus further discussion
7. Undertake a series of committee discussions to agree and finalise the dataset
8. Format the dataset to the ICCR standard
9. ICCR quality review prior to open consultation
10. Open consultation of the dataset
11. Feedback on the dataset
12. Publication of the dataset on the ICCR website following ratification by the ICCR Dataset Steering Committee (ICCR DSC)
13. Publication of an academic review in a peer reviewed journal.

**Step 1: Selection of a Dataset Series Champion, for the development of a suite of datasets across a specific anatomical area/organ system**

For the development of a suite of datasets in a specific anatomical area that are to be developed synchronously, the ICCR DSC will select an appropriately qualified expert pathologist to the role of Series Champion. The Series Champion will engage with all of the ICCR DAC in the series, as well as provide advice and support to the ICCR DSC on matters relating to the specific anatomical series under development.

Representatives on the DSC committee are requested to provide the ICCR DSC with names of potential candidates. This will include those authors engaged in the relevant International Agency for Research on Cancer (IARC)/World Health Organization (WHO) Classification of Tumours 'Blue book' series. ICCR DSC members should also consult with relevant organisations and societies during this nomination process. Potential candidate(s) will be circulated to the ICCR DSC for review and a final determination of candidate will be made at the next meeting. The final determination will take into account the desired personal attributes, geographical representativity and position responsibilities as documented below. Once agreed by the committee, an informal approach to the candidate will be made, and following its acceptance, a formal invitation from the ICCR will be sent.

The role of Series Champion is vital to the success of ICCR dataset development and as such the candidate will have the following essential personal attributes:

- have demonstrated leadership and expertise in the specific anatomical area to be developed (proven based upon bibliography);
- have editorial experience;
- be authoritative, interactive and consensual in approach; and
- be available to lead the development process of the dataset suite.

**Step 2: Selection of the Chair of the Dataset Authoring Committee (DAC)**

The ICCR DSC, having selected a specific cancer dataset or datasets for development, will identify, in consultation with the Dataset Series Champion if appointed, an appropriately qualified expert pathologist to take on the role of Chair of the DAC. On occasion two pathologists may be appointed as co-chair, particularly if more than one dataset is to be developed or updated by the one DAC.

The Chair should:

- have acknowledged expertise and leadership in the specific cancer field;
- have experience in writing academic papers in peer-reviewed journals, or previous experience in the development of structured reporting guidelines for the specific cancer;
- be an advocate of structured reporting;
- be committed to undertaking elements of writing the dataset as necessary within the specified timeframe;*
- be able to manage and lead the development of the dataset; and
- be able to gain consensus.

*It should be noted that in the event that the Chair is experiencing difficulties in meeting development timeframes, a co-Chair may be appointed to assist at the discretion of the ICCR DSC.

**Step 3: Selection of the Dataset Authoring Committee (DAC) members**

The Chair of the specific DAC, will identify potential domain specialists in consultation with the ICCR DSC – refer to Figure 1. The ICCR DSC will consult with the Dataset Series Champion, if appointed, in the discussion and decisions related to the appointment of the DAC.

The domain specialists will consist of pathologists and usually one or more relevant clinicians such as a surgeon, medical oncologist or radiation oncologist. The DAC should comprise approximately 8-12 people, however in some highly specialised areas the group may be smaller.

Identification of domain specialists should take into account the following criteria:

- a level of expertise *in the specific cancer* such as:
    - experience in writing or reviewing academic papers in peer-reviewed journals
    - authorship of relevant WHO or staging publications
    - previous experience in the development of structured reporting guidelines
    - high volume practical experience i.e., subspecialisation in the specific area
    - participation in clinical trials and other published research in the relevant field.
- geographic and linguistic diversity;
- gender diversity; and
- the inclusion of both seasoned experts as well as up and coming pathologists in the field.

In addition, all domain specialists should:

- be committed to structured reporting in pathology.
- be committed to reviewing the dataset during its development process and providing feedback in a timely manner. Feedback must be provided via email or attendance at the first DAC meeting to meet ICCR DAC contribution criteria. Please refer to the procedure for non-responders in section 8 of the *Roles and Responsibilities for the ICCR dataset development process* document.
- be committed to participate in writing of the dataset and associated journal article, as necessary.
- able to work in a culturally diverse team.

Nominations of potential domain specialists by the DAC Chair, Dataset Series Champion or ICCR DSC should include relevant supporting information as to their level of expertise or experience according to the above criteria, if requested by the ICCR DSC.

The ICCR DSC, in consultation with the Dataset Series Champion if appointed, will review and validate the list of nominated domain specialists. Once ratified, invitations will be extended to the domain specialists of the DAC. On agreeing to participate, domain specialists are asked to sign:

a. a conflict of interest document to ensure an impartial participation in the development process, and
b. a license of copyright to the ICCR to allow ICCR to use, copy and publish the dataset. (Note this does not transfer ownership of the copyright in the content which remains with the author).

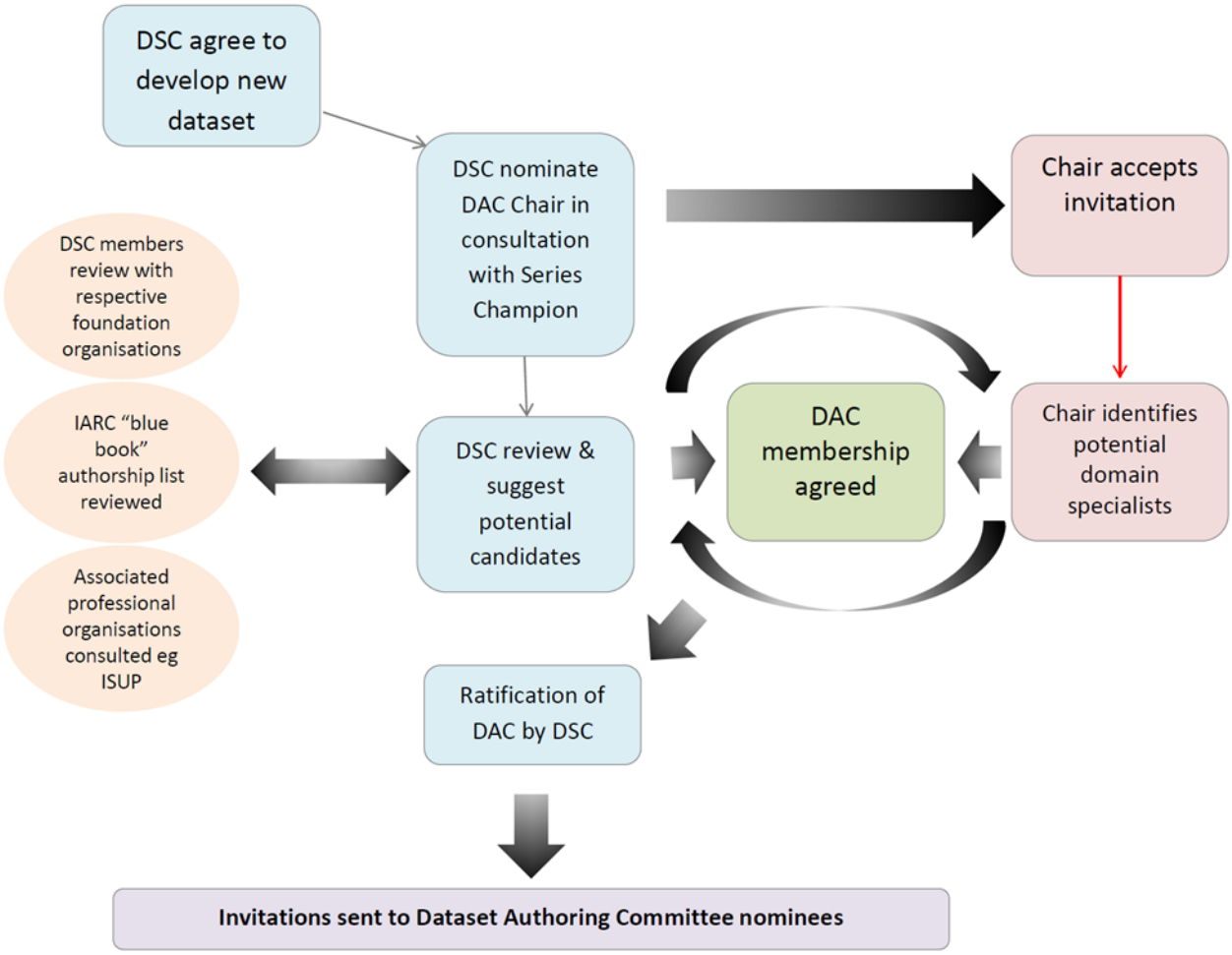


**Figure 1: ICCR Dataset Authoring Committee formation.**

**Step 4: Selection of the ICCR DSC representative**

The ICCR DSC representative role is to act as a liaison between the DSC and DAC, to consult the DSC on overarching dataset decisions and ICCR standards; and support the chair with any issues of this nature.

The ICCR DSC representative should:

- provide guidance and support to the Chair as applicable, regarding ICCR standards and authoring committee participation.
- undertake a quality assurance role, overseeing the process specifically around the nomination of core/non-core elements and evidentiary review.
- work with the Project Manager throughout the process to resolve any of the above.

There is particular value for this role in providing representation on issues where DAC members have requested that the DSC review an ICCR standard (such as units of measurement), or the categorisation of elements (such as ancillary testing elements) etc.

**Step 5: Review of existing, relevant, published cancer datasets**

A search for all published cancer datasets covering the specific cancer to be developed is undertaken by the ICCR Project Manager. This scan includes review of datasets, protocols or checklists published in review articles or other international websites.

This set of cancer datasets forms the foundation for a comparative review in which elements which are core (required) in any one or more of these datasets is extracted for consideration along with all responses and commentary.

**Step 6: Draft a proposed dataset**

An initial document of proposed elements is developed by the ICCR Project Manager in conjunction with the Chair of the DAC. This document puts forward proposed elements following review and consideration of the mandatory/required/core elements from each of the submitted/published datasets (Step 3). Of particular importance is how each dataset has approached a particular topic (e.g., extent of invasion), what responses have been used and what evidentiary support is provided.

The proposal aims to incorporate the best approach of each of the protocols/datasets/proformas in as simple a manner as possible. Each proposed element includes a recommendation as to whether the element should be core or non-core, the proposed responses; evidentiary support for those elements proposed as core and any commentary to assist in conformance and understanding of the element.

**Step 7: DAC review of the proposed dataset to identify areas of agreement and discord, to focus further discussion**

In this step the proposed elements from Step 5 including responses, evidentiary support and commentary are formatted into an interactive document (e.g., active PDF), which is circulated to the DAC who are asked to provide the following feedback on each proposed element:

- Whether or not they agree to the element name with the opportunity to comment on any issues they feel are important to document and which will direct further discussion.
- Whether or not they agree with the response type and values for the proposed element with the opportunity to propose alternative or amended responses.
- Whether the element should be core or non-core. A review of the evidentiary support (at Level III-2 evidence or greater) included for any core element should be undertaken and expanded where possible.
- Any commentary deemed essential for inclusion with the element, to ensure conformity in measurement or meaning of the element may be included at this step or may be added following DAC discussion in a later step.
- Whether there are additional elements not described in the proposed dataset which should be considered by the DAC.

**Step 8: Undertake a series of committee discussions to agree and finalise the draft dataset**

The DAC will usually require around three meetings (by teleconference/web meeting) to produce a robust draft of the dataset. During the calls individual elements are discussed and notes are recorded. Selected members may be asked to provide further information or undertake additional investigation of the evidence.

**Step 9: Formatting the dataset to the ICCR standard**

The cancer datasets are published in a specific format called a REPORTING GUIDE ('guide') which includes the elements, responses and all explanatory text.
The potential users of the datasets may not have continued access to the internet and, therefore, the English version of each guide is published in three formats as follows:

1. A hyperlinked guide to be viewed online (a valid internet connection is required). Explanatory text associated with an element is available by clicking on the 'open book' icon.
2. A bookmarked guide which can be downloaded and viewed on screen or printed. When printed, the notes can be looked up manually. When viewed on screen the bookmarked notes enable navigation to the explanatory text.
3. A MS Word document which includes the dataset content to assist with implementation.

Different text characteristics are used to visually differentiate 'core' elements from 'non-core' elements in both guides.

The ICCR Project Manager will develop the guides from the final draft dataset document produced in Step 7. Development includes:

- Seeking permissions to include copyright material in the dataset e.g., Figures, Tables, TNM staging, WHO Classification of Tumours etc.
- Check for errata of any co-dependent publication (such as TNM staging, WHO classification) and include the latest errata publication date in the dataset.
- Review of the elements and responses against the *ICCR Harmonisation Guidelines* document to ensure conformance to standard terminology across all of the ICCR datasets.
- Citing all references.

The draft guide is circulated to the DAC for final review and approval to proceed to open consultation. All members of the DAC must give their approval of the draft guide before the ICCR can proceed to open consultation.

**Step 10: ICCR quality review prior to open consultation**

Once finalised, the draft guides are reviewed by the ICCR DSC.

ICCR draft datasets are circulated to the ICCR DSC as a quality assurance review for the purpose of:

- Ensuring a quality process has been followed and the resultant dataset meets the standards of the ICCR as determined by the ICCR DSC.

- The number and type of elements (core and non-core) are reasonable and not onerous.
- The dataset is suitably formatted for public review.
- The dataset content is:
    - not contradictory,
    - matches between the guide and the notes,
    - fully referenced.

ICCR DSC members may circulate the draft dataset to their organisation/committees for review. However, any comments received will be considered alongside those received during open consultation.

A minimum of 50% of member organisations represented on the ICCR DSC is required to proceed to open consultation of any given dataset/suite of datasets.

The DSC Quality Assurance (QA) sub-committee provides an in depth review of the draft dataset at this time.

Feedback on the draft dataset from the ICCR DSC and/or the DSC QA sub-committee may necessitate amendments, in agreement with the Chair of the DAC.

**Step 11: Open consultation of the dataset**

Once approved to proceed to open consultation, the guides are posted as draft documents to the ICCR website for a period of eight weeks. Notifications are sent out to key ICCR stakeholders with the link and instructions for review and feedback.

**Step 12: Feedback on the dataset**

Feedback from open consultation is collated and reviewed by the DAC. Responses are formulated and amendments made to the dataset. Final approval by all members of the DAC is required to progress publication of the dataset.

All feedback received and responses from the DAC are anonymised and made available on the website when the datasets are published.

A final review of errata of any co-dependent publication, such as TNM staging and WHO classification, will be undertaken and the errata publication date updated in the dataset.

**Step 13: Publication of the dataset on the ICCR website**

The datasets are finalised after Step 11 and are submitted to the ICCR DSC for ratification and then published on the ICCR website. A minimum of 50% of member organisations represented on the ICCR DSC is required to proceed to publication of any given dataset/suite of datasets.

Each dataset is published in English as two guides (described in Step 9), and in addition, to facilitate implementation, a MS Word version of the information is provided.

On publication, the bookmarked versions of those datasets scheduled for translation are provided to an International Organization for Standardization (ISO) accredited organisation capable of translating the datasets into other languages. Once approved for publication, these are published to the appropriate language pages on the ICCR website.

**Step 14: Publication of an academic review in peer reviewed journal**

The final step in the process is for the DAC to produce an article for peer review publication in a journal on the dataset explaining the rationale behind the dataset elements.

Authorship of the manuscript should be confined to the DAC membership to ensure concurrency with the dataset.

Authorship of the manuscript will generally be in the order of chair of the group/lead author, followed by DAC members in alphabetic order, with the Series Champion last. In some cases, the ICCR DSC representative is included (if they have been an active contributor to the development). The ICCR Project Manager is included in the authorship list, most usually as second author.

Manuscripts are submitted to applicable peer review journals as recommended by the DAC.

The ICCR DSC will retain oversight of the development of any article produced from this process.

## 5. PERMITTED MODIFICATIONS

**Core and Non-core elements**

The use of the terms core and non-core, are based on the availability of the evidence in support of the element. Implementation of these terms may vary between organisations.

**Additional elements**

The ICCR has initially focused on the needs of clinicians defining those reporting elements which are core and non-core for the clinical management, staging or prognosis of cancer.

However, there are other elements which are not included in the ICCR datasets but which users may wish to include in their local datasets. These elements fall into three categories:

1. Additional core or non-core elements which are necessary to reflect the complete diagnostic picture.
2. Those elements which are important to be *recorded* but not necessarily included in a report. This assumes that there is the capability in the LIS in use to record data elements which may or may not be included in the actual report and that the report can be tailored according to the intended audience.
3. Those elements which are required for national or local reporting or research.

Use of the ICCR datasets does not preclude recording any of the above elements as part of the reporting process.

## 6. UPDATES TO DATASETS

Datasets will be scheduled for update in synchrony with revisions to the WHO Classification of Tumours.

Additional updates may also be undertaken as a result of harmonisation of datasets within a series, an error, changes to dependent publications, such as staging systems or significant changes in clinical or diagnostic evidence, or management related to a specific cancer.

**New edition**

A new edition of a dataset is categorised as either a *minor* or *major* revision depending on the type of modifications required.

Minor revision

A minor revision may be initiated by such changes as:

1. The addition of a new non-core element;
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 (for example, Tumour Dimensions to Maximum Tumour Dimension or a response that does not substantially change its meaning (for example, changing a response from 'absent' to 'not identified'); or
4. The downgrading of a core element to a non-core element.

Major revision

A major revision is generated by such changes as:

1. Updates to dependent publications such as to:
    a. The WHO Classification of Tumours; and/or
    b. Staging systems e.g., International Union Against Cancers (UICC), American Joint Committee on Cancer (AJCC), and International Federation of Gynecology and Obstetrics (FIGO).
2. Upgrading of a non-core element to a core element.
3. The addition of a core element e.g., as a result of new scientific evidence, evidence-based changes in cancer management, or new ancillary tests.
4. The deletion of any element (core or non-core).
5. 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.

**Public consultation**

A minor update will not require a period of public consultation before publication.

For a major update that is limited to changes directly related to modifications to dependent publications, a period of public consultation may not be required.

A major update which includes changes related to modifications to dependent publications as well as one or more criteria listed above may require a period of public consultation.

The final decision as to whether a major update requires a period of public consultation will be made by the ICCR DSC, in consultation with the Series Champion, Chair of the relevant DAC and ICCR Project Manager.

**Update process**

For all revisions, a Chair will be appointed by the ICCR DSC to oversee the update process. This may be the Chair of the original DAC or a new Chair. The Chair, in conjunction with the Series Champion, will recommend domain specialists to participate in the DAC. This may include members of the original DAC, as well as new members. Once the process of dataset revision is completed, the dataset will be approved by the ICCR DSC for publication on the ICCR website.

Those datasets scheduled for translation will be provided to the designated translating organisation for translation of the update into other languages. Once approved for publication, these updated datasets will be published to the appropriate pages on the ICCR website.

**ICCR errata**

This form of update is used to correct minor errors within a published dataset, such as corrections of spelling, punctuation or typography, or to update cited references that have moved from 'in press' to being published.

An errata update will be undertaken as needed. The ICCR DSC will appoint a ICCR Project Manager to oversee the update. The ICCR Project Manager will liaise with the original Chair of the DAC, where necessary. Once completed, the dataset will be published to the ICCR website.

**Errata and updates to co-dependent publications**

Staging and classification systems are integral to ICCR Datasets. However, these systems are subject to continued review, periodic revision and publication of errata.

To ensure accuracy in ICCR datasets, each dataset which includes a staging or classification system will include the date of the errata/corrigenda that was reviewed and incorporated into the dataset.
In addition, a yearly review of staging errata and corrigenda, and any updates or revisions to staging and classification systems that have occurred in the previous year, will be undertaken and discussed by the ICCR

DSC. Those modifications deemed important to include in the datasets will be identified and updates to affected datasets scheduled.

**Numbering**

Each revision of a specific dataset, whether categorised as minor or major, will be denoted by an incremental number e.g., ICCR Lung Cancer Dataset 2.0 denoting the 2nd published edition of the Lung Cancer Dataset. It is also represented by a new ISBN and publication date.

An errata revision, as it is minor in nature, is represented by an incremental update to the revision number of the dataset e.g., ICCR Lung Cancer Dataset 2.1 denotes an errata update to the 2nd published edition of the Lung Cancer Dataset. The publication date for an errata revision remains the same as the publication date of the edition, as does the ISBN.

## 7. Patient identification

The following are the agreed minimum patient identification data included in the datasets:

- Given Name (forename)
- Family Name (surname, last name)
- Date of Birth
- Patient identifier e.g., medical record number, national identification number etc.
- Request date
- Accession/Laboratory Number.

Local and National requirements may influence the configuration of these elements and necessitate the inclusion of additional elements or the replacement of some of these elements. Use of the ICCR dataset does not preclude any of these changes and the patient demographic list above is provided as a guide only.

## 8. ICCR Harmonisation Guidelines

As part of the ICCR process, harmonisation of the cancer data element names as well as the responses is undertaken to ensure consistency across all datasets. Common cancer elements e.g., tumour site, margin status and response terms e.g., 'absent' versus 'not identified', are defined and recommended uses and groupings of responses are documented for application across all datasets. The ICCR Harmonisation Guidelines are not a comprehensive list of all possible terms but rather seek to describe common terms and may differ with specific use cases.

## 9. IMPLEMENTATION CONSIDERATIONS

Successful implementation of the ICCR cancer datasets requires consideration of the following elements:

- Local and national pathology reporting standards
- Interdisciplinary communication
- Electronic implementation
- Change management
- Governance.

## 10. STAKEHOLDERS

Lead organisations will be used to disseminate notifications for open consultation. Stakeholders may include:

- Pathologists and their professional organisations
- Clinicians and their professional or subspecialist organisations
- Cancer registries
- Patients and their organisations
- Special interest groups.

## REFERENCES


1 College of American Pathologists (2024). *Cancer protocols and checklists.* Available from https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates (Accessed 12th March 2024).

2 Royal College of Pathologists (2024). *Cancer datasets and tissue pathways.* Available from: https://www.rcpath.org/profession/guidelines/cancer-datasets-and-tissue-pathways.html (Accessed 12th March 2024).

3 Royal College of Pathologists of Australasia (2024). *Cancer Protocols.* Available from: www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer/Cancer-Protocols (Accessed 12th March 2024).

4 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).

# APPENDIX A NHMRC EVIDENCE HIERARCHY

**NHMRC Evidence Hierarchy: designations of 'levels of evidence' according to type of research question (including explanatory notes)**

| 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:<br>▪ Non-randomised, experimental trial[9]<br>▪ Cohort study<br>▪ Case-control study<br>▪ 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:<br>▪ Non-randomised, experimental trial<br>▪ Cohort study<br>▪ Case-control study |
| III-3 | A comparative study without concurrent controls:<br>▪ Historical control study<br>▪ Two or more single arm study[10]<br>▪ 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:<br>▪ Historical control study<br>▪ 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**

1 Definitions of these study designs are provided on pages 7-8 *How to use the evidence: assessment and application of scientific evidence* (NHMRC 2000b*)*.

2 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.

3 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 (e.g., cannot allocate groups to a potential harmful exposure, such as nuclear radiation), then the 'Aetiology' hierarchy of evidence should be utilised.

4 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 (e.g., 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 (i.e., 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 (i.e., 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 e.g., 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.

**Source:** *Merlin T, Weston A, Tooher R. Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence'. BMC Medical Research Methodology, 2009.*