



International Collaboration on Cancer Reporting

Guidelines for the Development of ICCR Datasets

Version: 3.1



International Collaboration on Cancer Reporting

Table of contents

Purpose.....	4
1. Introduction	5
2. Dataset content.....	6
3. Dataset scope.....	8
4. Dataset development process.....	8
5. Permitted modifications.....	15
6. Updates to datasets	16
7. Patient identification.....	18
8. ICCR Harmonisation Guidelines.....	19
9. Implementation considerations	19
10. Stakeholders.....	20
References.....	21
Appendix A NHMRC Evidence Hierarchy.....	22



International Collaboration on Cancer Reporting

Document history

Version	Description	Date
Version 0.1	Initial draft	Aug 2012
Version 0.2	Refinement of initial draft	Sept 2012
Version 0.3	Review by ICCR	Oct 2012
Version 0.4	ICCR team updates included	Oct 2012
Version 0.5	Refinement of ICCR updates	Nov 2012
Version 0.6	Final version for open consultation	Nov 2012
Version 0.7	Edits to synchronise this document with roles and responsibilities document	Aug 2013
Version 0.8	Updates following ICCR Dataset Steering Committee Review	Sept 2013
Version 0.9	Incorporation of dataset updates	Nov 2013
Version 1.0	Approved by DSC	Nov 2013
Version 1.1	DAC formation figure added, draft modifications made to new edition/version updates	Nov 2014
Version 1.2	Final updates to the new edition/version updates	Mar 2015
Version 1.3	Updates to DAC nomination and composition and inclusion of scope	Jun 2015
Version 2.0	Approved by DSC	Jun 2015
Version 2.1	Suggested changes to scope to include non-invasive entities in some circumstances	Sept 2015
Version 2.2	Suggested changes to scope to include non-invasive entities in some circumstances	Oct 2015
Version 2.3	Changes approved by DSC	Oct 2015
Version 2.4	Revisions based on new terminology core/non-core and the inclusion of the Series Champion role	Jun 2016
Version 2.5	Revisions to include licence of copyright to the ICCR	Oct 2016
Version 2.6	Revisions to address DAC non-responders	Dec 2016
Version 2.7	Revisions to include <ul style="list-style-type: none"> a. process of TNM errata b. resource appointment process c. translation of ICCR datasets 	Aug 2018
Version 2.8	Changes approved by DSC	Oct 2018
Version 2.9	Suggested changes by DAC issues working group – meeting 24 th /25 th Jan 2019.	Feb 2019
Version 2.10	Changes approved by DSC	March 2019
Version 2.11	Suggested updates for yearly review	February 2020
Version 2.12	Changes approved by 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



International Collaboration on Cancer Reporting

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

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.



International Collaboration on Cancer Reporting

1. 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 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) has published 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 data structures, terminology bindings and electronic messaging.
- Development of a single agency with high-level input and good governance can facilitate timely revision and adoption of predictive pathology data as it emerges.
- Datasets created with international governance will be available to developing countries that have insufficient resources to develop their own.
- Internationally derived datasets carry sufficient authority to encourage uniform uptake of a single standard across the world.



International Collaboration on Cancer Reporting

It was agreed between the parties 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 quadripartite alliance of the College of American Pathologists (USA), The Royal College of Pathologists (UK), The Canadian Association of Pathologists in association with the Canadian Partnership Against Cancer (Canada) and The Royal College of Pathologists of Australasia signed an initial agreement to collaborate in February 2011 agreeing to work towards the standardisation of cancer datasets beginning with prostate, endometrium, melanoma and lung cancers, and based on the best approaches of each of the countries involved.

This pilot project was judged to be a success with the following achievements:

- Each Dataset Authoring Committee (DAC) was able to agree on a set of “Required” (now Core) and “Recommended” (now Non-core) elements for each cancer, including responses.
- The DAC, comprising internationally renowned experts in each field, were often able to simplify or improve the datasets and exclude outdated data elements.
- By using different processes for collaboration in each of the 4 expert groups, methods for international dataset development have been optimized for future collaboration.

The ICCR incorporated as a not-for-profit organisation in 2014 to support membership expansion and continued development efforts.

2. DATASET CONTENT

Each cancer dataset comprises the following components:

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



International Collaboration on Cancer Reporting

(NHMRC) levels of evidence⁴ 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 in the expert committee. An appropriate staging system e.g., Pathological TNM staging would normally be included as a CORE element.

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. 2009⁴ 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.



International Collaboration on Cancer Reporting

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
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



International Collaboration on Cancer Reporting

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.

The ICCR DSC will solicit names of potential candidates from representatives on the committee. 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 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.

The Chair should:

- have acknowledged expertise and leadership in the specific cancer field;
- have experience in writing academic papers 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



International Collaboration on Cancer Reporting

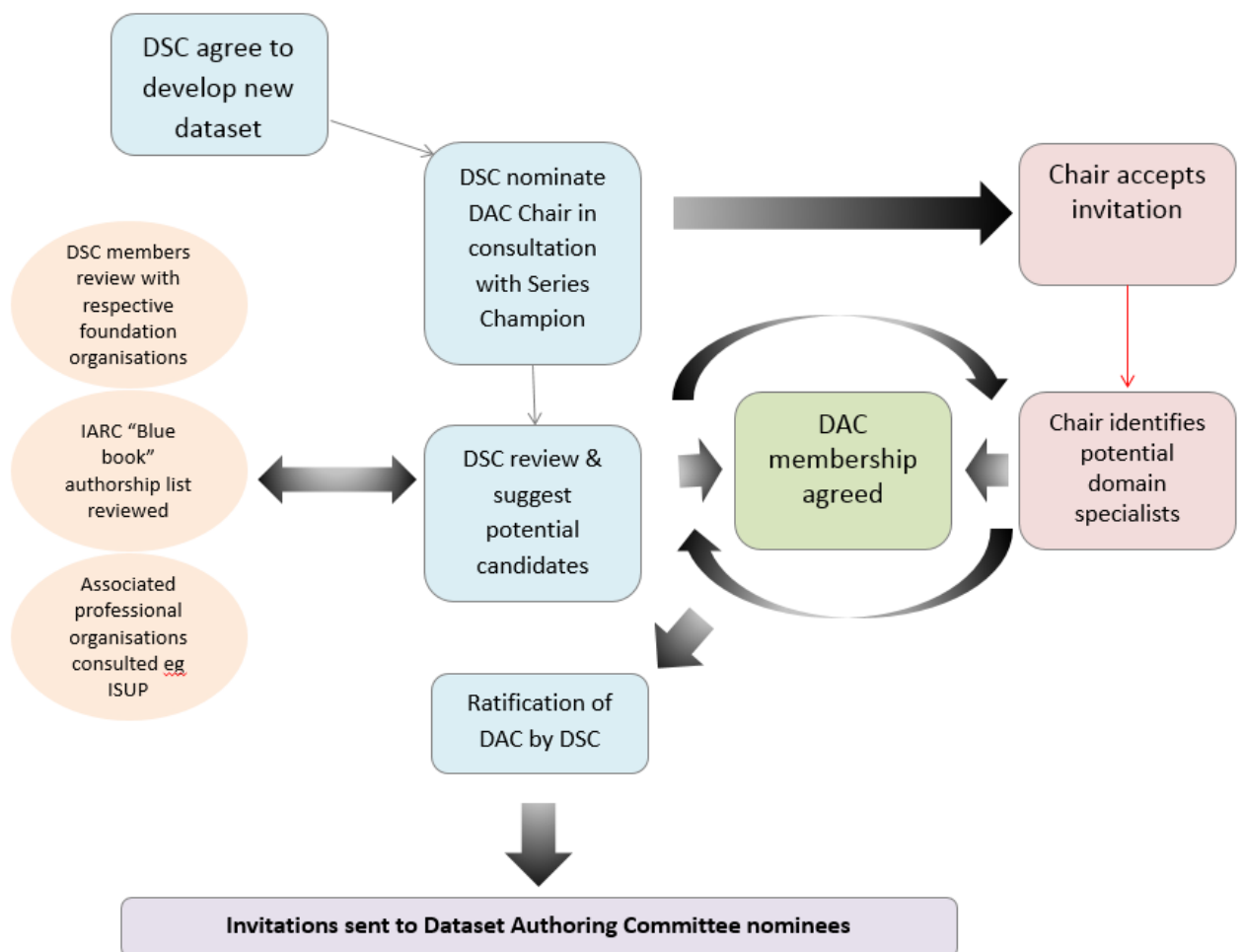
- be able to gain consensus.

*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.

Figure 1: ICCR Dataset Authoring Committee formation





International Collaboration on Cancer Reporting

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:

- representation of key stakeholder groups;
- geographic and linguistic diversity; and
- level of expertise *in the specific cancer* such as:
 - experience in writing or reviewing academic papers
 - 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.

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 1st DAC meeting to meet ICCR DAC contribution criteria. Please refer to the procedure for non-responders in section 7.
- be committed to participate in writing of the dataset and associated journal article, as necessary.

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).

Step 4: 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 Project Manager. This scan includes review of datasets, protocols or checklists published in review articles or other international websites.



International Collaboration on Cancer Reporting

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

Step 5: Draft a proposed dataset

An initial document of proposed elements is developed by the Project Manager in conjunction with the Chair, 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 6: 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 7: Undertake a series of committee discussions to agree and finalise the draft dataset



International Collaboration on Cancer Reporting

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 8: 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 two 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.

Different text characteristics are used to visually differentiate “CORE” elements from “NON-CORE” elements in both guides.

The 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, TNM staging, WHO Classification of Tumours etc.
- Check for errata of any co-dependent publication (such as TNM staging, WHO classification) and include the 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.

Step 9: ICCR quality review prior to open consultation

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



International Collaboration on Cancer Reporting

ICCR 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 are instructed to circulate the draft dataset to their organisation/committees for review only during the open consultation period to ensure comments can be processed appropriately.

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

Feedback on the dataset from the ICCR DSC may necessitate amendments, in agreement with the Chair of the DAC.

Step 10: Open consultation of the dataset

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

Step 11: 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 a majority 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 finalised.

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 12: Publication of the dataset on the ICCR website



International Collaboration on Cancer Reporting

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

Each dataset is published in English as 2 guides (described in Step 8), 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 13: 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, including, in some cases, the Series Champion and the ICCR DSC representative (if an active contributor). The ICCR Project Manager may be included in the authorship list based on the DAC chairs recommendation and their contribution to the manuscript.

Manuscripts are submitted to applicable 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.



International Collaboration on Cancer Reporting

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 3 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 Laboratory Information System (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:



International Collaboration on Cancer Reporting

- a. The WHO Classification of Tumours; and/or
 - b. Staging systems e.g., International Federation of Gynecology and Obstetrics (FIGO), American Joint Committee on Cancer (AJCC), and International Union Against Cancer (UICC).
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 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.



International Collaboration on Cancer Reporting

An errata update will be undertaken as needed. The ICCR DSC will appoint a Project Manager to oversee the update. The 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 categorized 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.



International Collaboration on Cancer Reporting

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.



International Collaboration on Cancer Reporting

10. STAKEHOLDERS

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

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



International Collaboration on Cancer Reporting

REFERENCES

- 1 College of American Pathologists (2021). *Cancer protocols and checklists*: Available from <https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates>. (Accessed 7th April 2021).
- 2 Royal College of Pathologists (2021). *Cancer datasets and tissue pathways*. Available from: <https://www.rcpath.org/profession/publications/cancer-datasets.html>. (Accessed 12th April 2021).
- 3 Royal College of Pathologists of Australasia (2021). *Cancer Protocols*. Available from: www.rcpa.edu.au/Library/Practising-Pathology/Structured-Pathology-Reporting-of-Cancer/Cancer-Protocols. (Accessed 12th April 2021).
- 4 Merlin T, Weston A and Toohar R (2009). Extending an evidence hierarchy to include topics other than treatment: revising the Australian 'levels of evidence'. *BMC Medical Research Methodology* 9(34).



International Collaboration on Cancer Reporting

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: <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ⁹ ▪ Cohort study ▪ Case-control study ▪ Interrupted time series with a control group 	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> ▪ Non-randomised, experimental trial ▪ Cohort study ▪ Case-control study



International Collaboration on Cancer Reporting

Level	Intervention ¹	Diagnostic accuracy ²	Prognosis	Aetiology ³	Screening Intervention
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> ▪ Historical control study ▪ Two or more single arm study¹⁰ ▪ Interrupted time series without a parallel control group 	Diagnostic case-control study ⁶	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> ▪ Historical control study ▪ Two or more single arm study
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard) ¹¹	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

Explanatory notes

- 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) and in the accompanying Glossary.
- 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 (eg. 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.



International Collaboration on Cancer Reporting

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

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

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



International Collaboration on Cancer Reporting

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: Hierarchies adapted and modified from: NHMRC 1999; Bandolier 1999; Lijmer et al. 1999; Phillips et al. 2001 (see Additional File 2).