



International Collaboration on Cancer Reporting

Guidelines for the Development of ICCR Datasets

Version: 2.8



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Abbreviations

ASCP	American Society of Clinical Pathology
CAP	College of American Pathologists
CAP (Canada)	The Canadian Association of Pathologists
CPAC	The Canadian Partnership Against Cancer
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
RCPA	The Royal College of Pathologists of Australasia
RCPATH (UK)	The Royal College of Pathologists (UK)
RCPI FoP	Royal College of Physicians of Ireland, Faculty of Pathology
ESP	European Society of Pathology
LIS	Laboratory Information System
WHO	World Health Organization

PURPOSE

The purpose of this document is to describe the development process of 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.



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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 cancers¹. In the UK, the Royal College of Pathology (RCPATH) publishes cancer datasets² and in Australia, the Royal Australasian College of Pathologists (RCPA) has published structured protocols for cancer reporting³. 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 International Collaboration on Cancer Reporting (ICCR) quadripartite alliance was established to examine the practicability of developing international, evidence-based pathology datasets for all major cancers.

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

- Dataset production by a single organization 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.



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It was agreed between the parties that a co-ordinated 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 Australia 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 was able to agree on a set of “Required”(now Core) and “Recommended” (now Non-Core) elements for each cancer, including responses.
- The Dataset Authoring Committees, 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 eg tumour diameter, lymphovascular invasion, or fundamental to the histological diagnosis and conclusion eg macroscopic tumour details. Each element is included on the consensus of the Dataset Authoring Committee. An element may be designated as core or non-core by the Dataset Authoring Committee as described below.

CORE elements



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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 NHMRC levels of evidence¹ 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 eg 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 eg macroscopic tumour details, may be included as either CORE or NON-CORE elements by consensus of the Dataset Authoring Committee.

Permitted responses

Permitted responses refer to the range of standardised responses that are used to describe an element eg 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. 2009¹ is used. (Refer to Appendix A)

Where no reference is provided, the authority is the consensus of the expert group.

Commentary

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



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- 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
- 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 Dataset Authoring Committee(s) (DAC)
3. Selection of the Dataset Authoring Committee 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



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12. Publication of the dataset on the ICCR website following ratification by the ICCR Editorial/quality committee
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 Dataset Steering Committee will select an appropriately qualified expert pathologist to the role of Series Champion. The Series Champion will engage with all of the ICCR Dataset Authoring Committees in the series, as well as provide advice and support to the ICCR Dataset Steering Committee on matters relating to the specific anatomical series under development.

The ICCR Dataset Steering Committee will solicit names of potential candidates from representatives on the committee. This will include those authors engaged in the relevant IARC WHO Classification of Tumours “blue book” series. ICCR Dataset Steering Committee members should also consult with relevant organisations and societies during this nomination process. Potential candidate(s) will be circulated to the ICCR Dataset Steering Committee 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, and
- Be authoritative, interactive and consensual in approach.

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

The ICCR Dataset Steering Committee, 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 Dataset Authoring Committee.

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



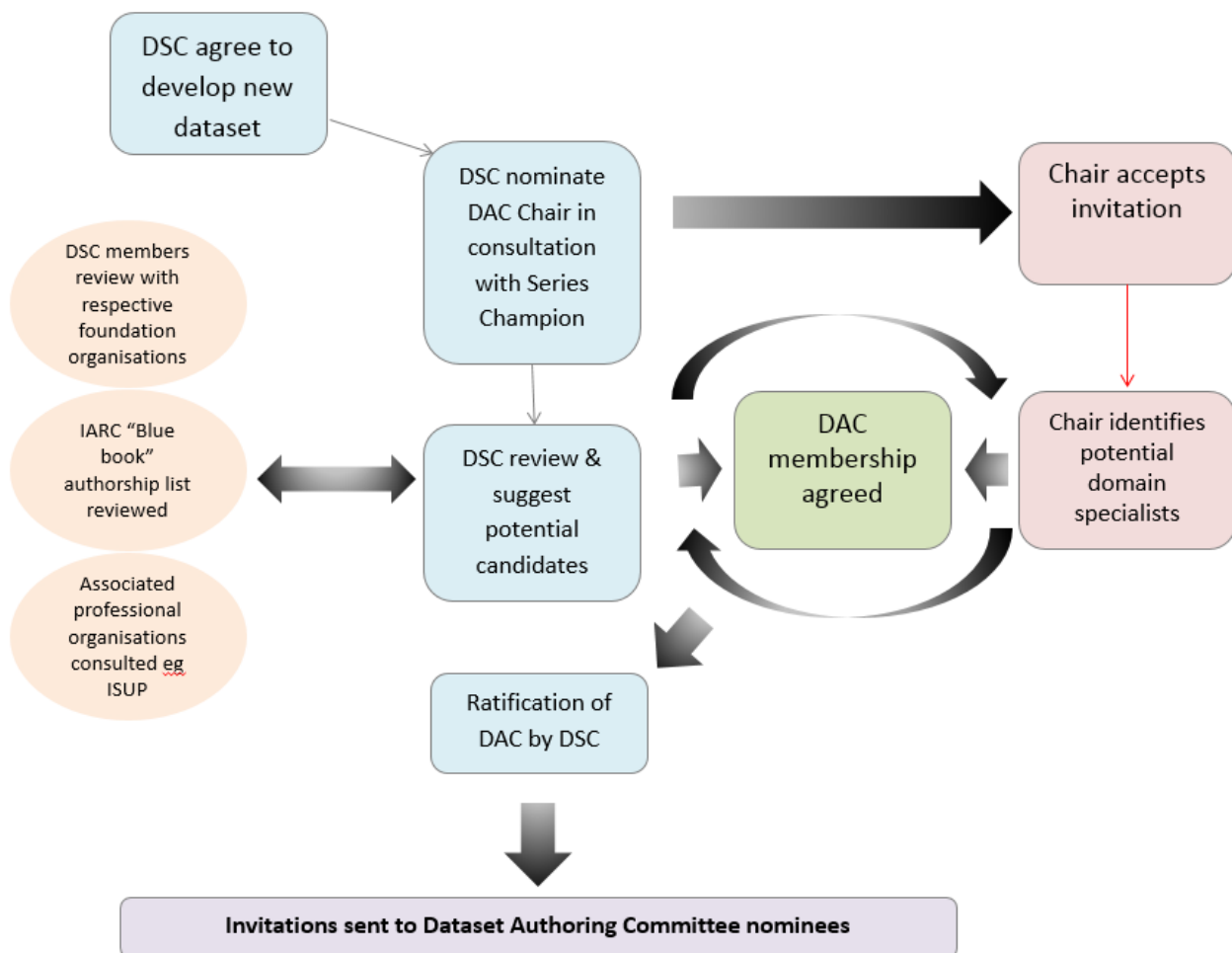
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- be an advocate of structured reporting
- be committed to undertaking elements of writing the dataset as necessary
- be able to manage and lead the development of the dataset
- be able to gain consensus.

Step 3: Selection of the Dataset Authoring Committee members

The Chair of the specific DAC, will identify potential domain specialists in consultation with the Dataset Steering Committee – refer to Figure 1. The Dataset Steering Committee 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 (DAC) formation





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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
- level of expertise *in the specific cancer* such as:
 - experience in writing or reviewing academic papers
 - authorship of relevant World Health Organisation or staging publications
 - previous experience in the development of structured reporting guidelines
 - high volume practical experience ie subspecialisation in the specific area
 - participation in clinical trials and other detailed 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**
- be committed to undertaking research (literature review) and 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 Dataset Steering Committee should include relevant supporting information as to their level of expertise or experience according to the above criteria.

The ICCR Dataset Steering Committee, 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).

** refer to procedure for non-responders.

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. This scan includes review of datasets from existing ICCR members and also of datasets, protocols or checklists published in review articles or other international websites.



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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, Dataset Authoring Committee. 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 eg 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.

The proposed elements and responses are reviewed against the harmonisation guidelines (see ICCR Harmonisation Guidelines) to ensure conformance to standard terminology across all of the ICCR datasets.

Step 6: Committee review of the draft 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 eg active pdf, in which a recipient can enter his/her agreement or any issues or changes they would like to make.

This interactive document is circulated to the Dataset Authoring Committee 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.



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- Whether there are additional elements not described in the interactive document which should be considered by the committee.

The responses from the committee are compiled as follows:

- Those elements upon which there is agreement
- Those elements which require some small changes
- Those elements requiring further detailed discussion in Step 7.

Step 7: Undertake a series of committee discussions to agree and finalise the dataset

The Dataset Authoring Committee will usually require about three or four meetings (by teleconference /web meeting) to produce a final 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 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.

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 cancer dataset document produced in Step 7. Development includes:

- Seeking permissions to include copyright material in the dataset eg Figures, TNM staging, WHO Classification of tumours etc



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- Check for errata of any co-dependent publication such as TNM staging and include the errata publication date in the dataset.
- Review of the elements and responses against the ICCR Harmonisation Guidelines document
- Citing all references

The draft guide is circulated to the Dataset Authoring Committee 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 Editorial/Quality Committee. This is a quality assurance review to ensure that the process has been followed and the resultant dataset meets the standards of the ICCR as determined by the Dataset Steering Committee.

Feedback on the dataset may necessitate amendments.

Step 10: Open consultation of the dataset

Once finalised, 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 Dataset Authoring Committee. Responses are formulated and amendments made to the dataset. All feedback received and responses from the Dataset Authoring Committee 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, will be undertaken and the errata publication date updated in the dataset.

Step 12: Publication of the dataset on the ICCR website



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The datasets are finalized after step 11 and are submitted to the Dataset Steering Committee for ratification and then published on the ICCR website.

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 version of the dataset is provided to an ISO accredited organisation capable of translating the dataset 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 Dataset Authoring Committee to produce an article for publication on the dataset explaining the rationale as to why the key features (core data items) were included. The ICCR Dataset Steering Committee will retain oversight of any article produced from this process.



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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 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 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 for example.

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

1. Dataset revisions

Each revision for a specific dataset 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.



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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 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 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 core element to a non-core element.

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 non-core element to a core element.
2. 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.
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.

The final decision on whether a revision will be categorised as major (requiring open consultation) or minor (not requiring open consultation) will be made by the DSC in consultation with the Chair of the relevant DAC.

For all revisions, generally the original Chair of a Dataset Authoring Committee will be invited to oversee the update with the assistance of a Project Manager. If the original Chair is not available, the Dataset Steering Committee will elect a new Chair, preferably from the existing Dataset Authoring Committee.

Domain specialists from the original Dataset Authoring Committee will be invited to participate. Additional members may be invited by the Chair in consultation with the Dataset Steering Committee if deemed appropriate.

Once the process of dataset revision is completed, the dataset will be approved by the Dataset Steering Committee, and then ratified by the ICCR Editorial/quality committee for publication on the ICCR website. Updates to datasets will be provided to the ISO accredited translation organisation for translation of the updates into other languages. Once approved for publication, these updated datasets are published to the appropriate pages on the ICCR website.



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2. Corrections of 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. 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 dataset e.g. ICCR Lung Cancer Dataset 2.1 denotes an errata update to the 2nd published edition of the lung cancer dataset.

An errata update will be undertaken as needed. The Dataset Steering Committee will appoint a Project Manager to liaise with the original Chair of the Dataset Authoring Committee to oversee the update, and once completed the dataset will be approved for publication by the ICCR Editorial/quality committee and published to the ICCR website.

3. Errata in co-dependent publications

Staging systems are integral to ICCR Datasets. However, staging systems are subject to continued review and publication of errata. To ensure accuracy in ICCR datasets, each dataset which includes a staging system will include the date at which errata has been reviewed and incorporated in to the dataset. A yearly review of staging errata will be undertaken and discussed by the Dataset Steering Committee. Those modifications deemed important to include in the datasets will be identified and updates to affected datasets scheduled.

7. NON RESPONDERS

'Non-responders' are defined as those DAC domain specialists who have accepted the ICCR invitation to participate but with whom no communication on the dataset content is received by the open consultation phase (Step 10).

It is the responsibility of the Project Manager to identify potential non-reponders and to ensure adequate followup and reminders are provided to maximize the opportunities for response. In the event that this is unsuccessful, the DAC Chair will be asked to send an email to each non-responder specifically asking them for feedback /indication of participation before final review prior to open consultation. Once these steps are completed with no response then non-responders will be removed from the DAC and authorship of the dataset.

8. 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 eg medical record number, national identification number etc.
- Request date



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- 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.

9. 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 eg tumour site, margin status and response terms eg '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.

10. 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

11. STAKEHOLDERS

Lead organizations 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 organizations
- Special interest groups



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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



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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.



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- 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.



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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).