International Collaboration on Cancer Reporting

Roles and Responsibilities for the ICCR Dataset Development Process

TABLE OF CONTENTS

Document history

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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
WHO	World Health Organization
COI	Conflict of interest
UICC	International Union Against Cancer
AJCC	American Joint Committee on Cancer

1. PURPOSE

International Collaboration on Cancer Reporting (ICCR) dataset development involves commitment to a quality process. The *Guidelines for the Development of ICCR Datasets* document outlines the steps to be undertaken:

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 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
13. Publication of an academic review in peer reviewed journal.

This document outlines the roles and responsibilities of the following participants in the dataset development process:

- ICCR Dataset Series Champion
- Chair, DAC
- ICCR Dataset Steering Committee (DSC) member
- Domain specialists, DAC.

An ICCR Project Manager is also included as part of every DAC.

Refer to Organisational Chart (Appendix B).

Each of these roles and their responsibilities is discussed in detail below.

2. ICCR Dataset Steering Committee (DSC)

The ICCR DSC will:

- Select an appropriately qualified Dataset Series Champion if a suite of datasets is to be developed synchronously for a single anatomical area e.g., Genitourinary, Breast, Bone and soft tissue, Head and Neck, Endocrine etc.
- Select the Chair(s) of the DACs.
- Ratify the Domain specialist nominations. The ICCR DSC will resolve any jurisdictional issues (perceived or real) within the Domain specialists in conjunction with the Chair.
- Nominate one of their membership to participate on each ICCR DAC.
- Review and endorse the final dataset prior to open consultation and publication.
- Review and resolve any conflicts of interest (COI) that arise.

3. ICCR Dataset Series Champion

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 engage with all of the ICCR DACs in the series.

The ICCR Dataset Series Champion will have the following responsibilities:

- Sign a COI document and maintain an awareness of any potential conflict of interest in relation to the project, and immediately notify the ICCR Project Manager of any potential or perceived conflict of interest.
- Provide advice and support to the ICCR DSC on the choice of DAC Chairs.
- Provide advice and support to the Chairs of the DACs within their specific anatomical series to ensure harmonisation across the datasets under development.
- Assist the Chairs of the DACs in the identification and nomination of domain specialists.
- Provide a conduit of communication between DACs within the series and with the ICCR DSC.
- Treat all individuals in the process with respect and professionalism.
- Be positive and supportive of the ICCR process in all communications external to the ICCR.
- Be available and place high priority on the ICCR development process in order to meet the agreed timeframes.
- Assist the Chairs of the DACs in any conflict resolution including dealing with non-responders on the committee.
- Work closely with the ICCR DSC member and ICCR Project Manager throughout the development of the dataset(s) to ensure adherence to the ICCR process.

4. Chair, Dataset Authoring Committee (DAC)

The ICCR DSC, having selected a specific cancer dataset or dataset series for development, will invite appropriately qualified expert pathologist(s) 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(s) of the DAC is required to:

- Sign a COI document and maintain an awareness of any potential conflict of interest in relation to the project, and immediately notify the ICCR Project Manager of any potential or perceived conflict of interest. For continued participation in the DAC, the signed COI must be returned prior to the first meeting of the DAC to the ICCR Project Manager.
- Sign 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). For continued participation in the DAC, the signed copyright licence must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Nominate on average 8-12 domain specialists (comprising expert pathologists, and where applicable 1 or more clinicians) for review and endorsement by the ICCR DSC. These nominations should, where possible:
    - represent international expertise in this cancer field
    - be geographically and linguistically diverse
    - include reasonable gender distribution
    - include both seasoned experts and up and coming pathologists in the field
    - work effectively as part of a team
    - support structured pathology reporting of cancer
    - be committed to deliver a quality outcome.
- Lead the DAC seeking the best input from all participants.
- Treat all individuals in the process with respect and professionalism.
- Be positive and supportive of the ICCR process in all communications external to the ICCR.
- Be able to author/edit sections of the dataset as required.
- Be available and place high priority on the ICCR development process in order to meet the agreed timeframes. 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 DSC.
- Respond in a timely manner to all communications.
- Act as the arbitrator amongst the group and seek consensus.
- Adhere to the definitions of core/non-core elements – ensuring adequate evidence is cited in support of core elements.
- Work closely with the ICCR DSC member and ICCR Project Manager to ensure adherence to the ICCR process.
- Support the ICCR process of harmonisation of element and value names.
- Lead the authorship of an academic article on the ICCR dataset for submission to a peer-reviewed journal or propose a suitable DAC member to undertake this role if they are not able to.

- Manage participation of committee members; addressing matters of non-responsiveness or dispute at their discretion and with the assistance and advice of the ICCR Series Champion and ICCR DSC member.

The role of Chair is vital to the success of ICCR dataset development. The ICCR DSC maintains the right to remove a Chair who is not able to commit to the above responsibilities, or fails to meet the above expectations during the development process. A Chair will be asked to step down from the role in the event that the Chair:

- Is unavailable for a period of time which delays development for more than 3 months past the agreed timeframe;
- Does not respond in a timely manner to others on the DAC, the ICCR Project Manager or Series Champion;
- Has a conflict of interest which the ICCR DSC deems irreconcilable with the development process; and/or;
- Engages in unprofessional conduct as determined by the ICCR DSC.

5. ICCR Dataset Steering Committee (DSC) member

The ICCR DSC will elect a representative to participate on its behalf, on an ICCR DAC in the event of a single dataset development or to a dataset series if a suite of datasets in a specific anatomical area are to be developed synchronously.

The ICCR DSC member is not chosen specifically for their expertise or interest in a specific cancer area however, this will be taken into consideration.

The ICCR DSC member will:

- Act as a liaison between the DSC and DAC. This is important because the Dataset Series Champion and/or Chair(s) of the DAC are not necessarily members of the DSC. DSC members can assist the development process by bring an understanding of the purpose and goals of the ICCR, its standards, and development directives and expectations regarding committee participation.
- Provide guidance and support to the Dataset Series Champion and/or Chair(s) of the DAC as applicable, regarding ICCR standards and authoring committee participation.
- Represent the DAC on issues that have been referred to the DSC for consideration and decision.
- Undertake a quality assurance role, overseeing the process specifically around the nomination of core/non-core elements and evidentiary review.
- Work closely with the ICCR Project Manager throughout the process to resolve any issues.

6. Domain Specialists, DAC

Domain specialists, on the DAC are required to:

- Sign a COI document to ensure an impartial participation in the development process. For continued participation in the DAC the signed COI must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Sign 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). For continued participation in the DAC the signed copyright licence must be returned to the ICCR Project Manager prior to the first meeting of the DAC.
- Be supportive of the objectives of the ICCR and its goal to encourage structured pathology reporting of cancer.
- Be available and place high priority on the ICCR dataset development process, including the journal article, in order to meet the agreed timeframes. DAC members are required to provide written approval for the draft dataset to be sent for open consultation and publication and for the journal article to be submitted for publication.
- Provide feedback in a timely manner. Feedback must be provided via email or attendance at the first DAC meeting to meet ICCR DAC contribution criteria. If a member fails to meet the contribution criteria they are deemed to have retired and will be removed from the committee (refer to Section 8 Non responders). Note that substitutions are not permitted to the DAC. If a DAC member is not able to attend a meeting then they should send in comments via email.
- Work cooperatively as part of a team.
- Treat all individuals in the process with respect and professionalism.
- Be able to work in a culturally diverse team.
- As the work of the DAC is in English, a good command of the English language is needed.
- Be able to author/edit sections of the dataset or article for publication as required.
- Where applicable, eligibility for retired professionals to join the DAC should be limited to within one year since retirement.
- Keep the work of the ICCR DAC confidential until such time as public comment is invited. Though DAC members may be members of other key stakeholder groups, they are invited to the ICCR DAC as an individual representing themselves. Other stakeholder groups will be invited to comment on the draft dataset at the open consultation phase.
- Be familiar with the definitions of core/non-core elements.
- Work closely with the ICCR Project Manager and Chair throughout the process.

7. World Health Organisation (WHO)/International Agency for Research on Cancer (IARC) Volume Editor

World Health Organization (WHO)/International Agency for Research on Cancer (IARC) may nominate an appropriate representative to liaise with the DAC(s) and advise on synchronisation with IARC publications if deemed appropriate by the DSC.

8. 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 up to and including the first meeting in the development or update process.

It is the responsibility of the ICCR Project Manager to identify potential non-responders and to ensure adequate follow-up and reminders are provided to maximise the opportunities for response, including escalation to the DAC Chair, Series Champion and Chair of the DSC. In the event that this is unsuccessful, the DAC Chair or Series Champion, will be asked to send an email to the non-responder advising them they have failed to meet the contribution criteria for DAC members and they are deemed to have retired and are removed from the DAC and authorship of the dataset.

9. Dataset Authoring Committee (DAC) tasks

A DAC is responsible for the development of a cancer dataset. The goal of the DAC is to create a practical dataset that can be used for a broad audience, including lower and middle income countries.

Each dataset will contain the following components:

1. **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[1] 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 by the DAC.

   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, 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.

2. **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.

3. **Commentary**

   Commentary is based on a review of the current literature and comprises explanatory text, diagrams or tables that clarify core and non-core elements. It is used to:

   - define the way an element should be reported, to ensure clarity and conformity
   - explain why an element 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 essential for core elements and optional for non-core elements.

   Commentary is designed to provide contextual guidance to the reporting pathologist. It is implemented in the ICCR guides as contextual help linked to each element to assist the reporting pathologist. For this reason, consideration should be given as much as possible to diagrammatic images wherever these might assist.

4. **References for cited evidence**

Evidence

The DAC must apply levels of evidence wherever possible. A review of evidence in the latest peer-reviewed literature is necessary to ensure that the dataset is up to date with the most current evidence-based information.

Core elements based on consensus alone should be avoided unless they are essential for staging, management or prognosis.

Citations of published literature must be included where applicable.

The extended NHMRC levels of evidence published by Merlin T, Weston A, et al. 2009 provides a guide for authors (Appendix A). Where no reference is provided, the authority is the consensus of the DAC.

Third party Copyright

During the writing process, care should be taken to note where permission needs to be sought for the use of diagrams, tables, or blocks of text from copyrighted material which is to be included in the dataset e.g., the International Union Against Cancer (UICC), the American Joint Committee on Cancer (AJCC) and cancer staging definitions. It is essential that copyrighted material be identified during the process because permission needs to be sought to use the material prior to publication of the dataset.

Authoring notes

- The rendering, formatting and informatics relating to the developed cancer datasets are outside the scope of the DAC.
- Similarly, patient-specific details, demographics and clinical content will not be considered as inclusion of these items in datasets varies in different countries.
- The naming conventions for elements and value lists will be subject to a harmonisation process so that the specific style or spelling need not be considered, e.g., tumor versus tumour, lymphovascular invasion versus lymph-vascular invasion. ICCR follows the *WHO Style Guide 2nd edition* for spelling.

Process steps

- Each DAC will be supplied with:
    a. Relevant cancer specific published datasets from a variety of jurisdictions.
    b. A Proposed Dataset document. This document puts forward proposed elements following review and consideration of the key/core elements from the various submitted cancer datasets and how they have approached a particular topic e.g., extent of invasion. The proposal aims to incorporate the best of each of the available/published protocols/proformas in as simple a manner as possible. Each proposed element will also include proposed responses and to assist in decision making, evidentiary support for elements where possible.
- Each DAC will be asked to review the proposed elements in the Proposed Dataset document and to provide feedback. This will include:
    - Whether or not each committee member agrees to the element name response type and values for the proposed element with the opportunity to propose alternate or amended responses.
    - Whether the element should be core or non-core. Evidentiary support (at Level III-2 evidence or greater) provided for any core element should be reviewed and expanded on where possible.
    - Any commentary deemed essential for explanation of the element. This is particularly important to ensure conformity in measurement or meaning of the element.
    - Whether there are additional elements not described in the draft dataset document which should be considered by the committee.
- The DAC member will be asked to respond within a specific period of time and the responses will be compiled and circulated to the committee.

- A series of web/conference calls (usually three), will then be organised for the DAC to discuss the feedback provided.
- A final draft document will be circulated and will include:
    - Core and non-core elements
    - Response type and value lists for each element
    - Evidentiary support for core elements at a minimum
    - Commentary where necessary to ensure clarity and conformity.
- The information will then be reformatted into the structure of ICCR guides.

  Once the guides are finalised they will undergo a quality review process followed by a period of international public consultation. After the open review period, the DAC will formally review the comments in conjunction with the ICCR Project Manager and changes will be made as deemed appropriate by the DAC. Following this, all submissions from the public consultation period will be anonymised and published on the ICCR website together with the responses from the DAC.

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

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*.

APPENDIX B ORGANISATIONAL CHART