Australian Government

Cancer Australia

Framework for Specialist Minimum Data Set Development for Specific Cancers in Clinical Cancer Registration

Technical monograph 1

Framework for Specialist Minimum Dataset Development for Specific Cancers in Clinical Cancer Registration

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1. Introduction

The development and use of a generic minimum data set (MDS) for clinical registration, supplemented by specialist extensions for individual cancer groups, is an optimum approach to the collection of cancer data. Although clinicians and researchers have access to the Clinical Cancer Core Data Set (CCCDS)[1], there is considerable work still to be done in developing nationally recommended modules for specialist registration across the full spectrum of cancers.

The Framework for Specialist Minimum Data Set Development for Specific Cancers in Clinical Cancer Registration has been developed by Professor David Roder on behalf of Cancer Australia. He has been assisted in this work by the National Cancer Data Strategy Advisory Group. This group reflects the diversity of professionals working across the spectrum of cancer data collection, analysis and coordination as well as end users and beneficiaries of cancer data. Members of the group have provided informed and practical input into the development of the document.

The framework provides a starting point for specialists working in clinical cancer registries who wish to develop their own tumour-specific data sets. It will enable them to work through a self directed process where the required specialist data items are not covered by the existing CCCDS. Specialist MDS modules developed in this way should supplement, not replace, CCCDS items.

An 8-step bridging process is outlined in this paper, and recommended for use until nationally agreed modules for specialist registration are developed. Through this self-guided process, data sets are likely to be more homogeneous, ensuring capacity for benchmarking with, and collective applications between, similarly developed sets.

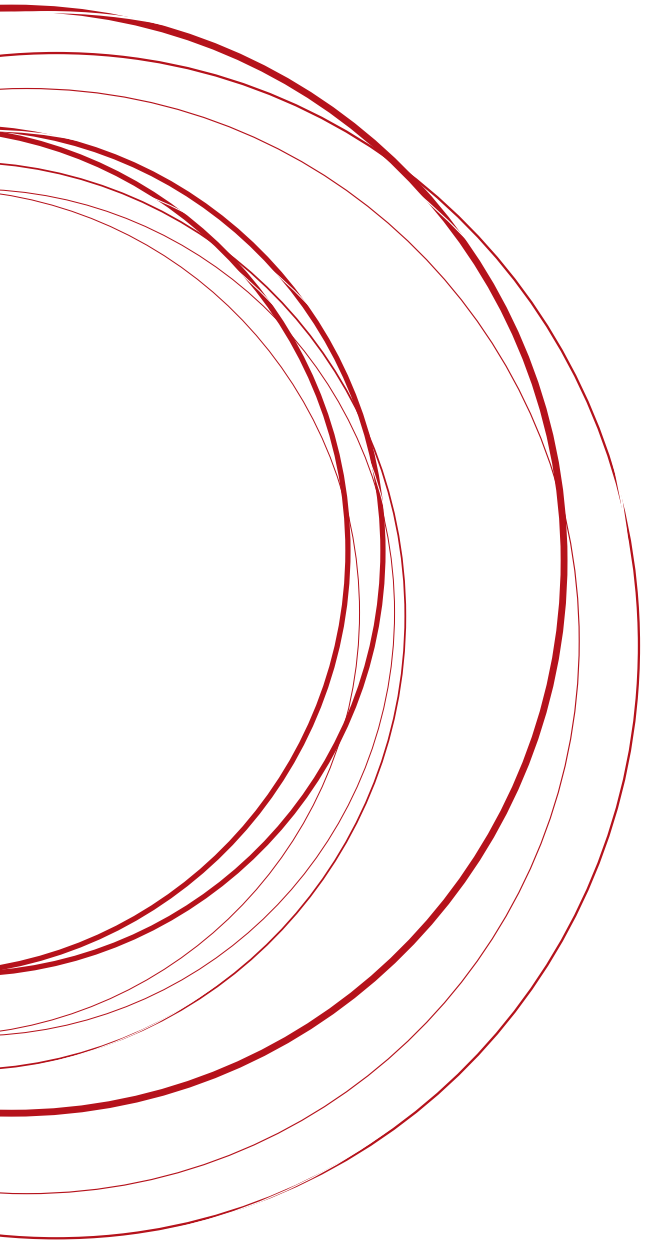
To achieve comparability with data items already in use, a pathway is proposed where data sets would include the CCCDS, plus selected specialist items already in use elsewhere, giving priority to the more authoritative and relevant reference sources and only proceeding to lower level sources when the items required are not found at a higher level.

A range of reference data sets are described, with brief outlines of the data item and topics covered that are mostly expressed as key words. The principal aim is to show the "lie of the land" to support data set development. Data dictionary references are provided, where available. In addition, a cross-section of Australian patterns of care surveys are referenced, since these would assist data set developers when the data items they require are not available through other sources.

1 The Clinical Cancer Core Data Set was originally developed as the national generic minimum data set (MDS) under the aegis of the National Cancer Control Initiative (NCCI). Cancer Australia has subsequently assumed stewardship of this data set to ensure its currency and relevance.

This document does not review incentives for implementing common data sets. The CCCDS has been followed in many settings, simply because it provides opportunity for external comparison. Other incentives could be introduced through accreditation processes, inter-jurisdictional health information agreements, and financial arrangements, although an exploration of these and other options is beyond the scope of this report.

This report is best viewed in the context of the broader national cancer agenda, including A National Cancer Data Strategy for Australia



2. Purpose

The purpose of this document is to support specialists working in clinical cancer registries on the development of specific cancer data sets by:

- proposing a common pathway for developing specialist MDS items to complement the CCCDS, in order to promote similarities in data sets and increase the potential to combine and compare data output from them.
- proposing as reference sources data definitions already used in data collections in Australia, the United Kingdom and North America, to increase the potential for benchmarking and comparison.
- proposing a pathway that gives priority to reference data definitions that have been endorsed by the National E-Health Information Principal Committee, established under the Australian Health Ministers Advisory Council, or where these are unavailable, data definitions used by other national, state or territorial health authorities, or professional colleges.
- proposing that data set developers, where possible, select and define data items using the most authoritative reference sources, and proceed stepwise to less authoritative sources only to the extent that required items are not found at a higher level.
- proposing a hierarchy of reference sources, ranging from the most authoritative (i.e., a specialist module with data dictionary definitions endorsed by the National E-Health Information Principal Committee) to the least authoritative (i.e., a historic pattern of care survey used in a restricted locality).
- showing a range of data used or proposed in Australia by national and state health authorities, and authorities in the USA and United Kingdom, and to list a cross-section of published patterns-of-care studies, to provide reference sources for data set development.
- proposing that the minimum number of data items be used, consistent with achieving data set objectives, with this selection process involving consultation with key stakeholders.

3. Background

Clinical cancer registration covers only a small proportion of cancers in Australia, but there is a strong interest in extending it to obtain data on stage, treatment and other clinical features not otherwise available for service administration, quality assurance, planning and evaluation, and research.

At a government level, clinical registration is mostly a responsibility of states and territories in Australia, with registry models differing in response to legislation, administrative environments, interests and resources. In addition, health agencies often undertake clinical registration independently of government health administrations. To achieve nationally consistent data for benchmarking, research and other purposes, a national generic minimum data set was developed under the aegis of the National Cancer Control Initiative (NCCI) and released in 2004, along with data dictionary definitions.

Generally, data items are distributed across four levels, i.e.:

- Level 1: generic demographic items
- Level 2: generic health items (i.e., facility/provider/etc.)
- Level 3: generic cancer items (i.e., the former NCCI MDS, now CCCDS)
- Level 4: specialist cancer items

The CCCDS relates to Level 3 in covering only a limited range of generic data items. Its purpose has been to support the collection of enough data to be informative for service monitoring, without imposing an unsustainable burden of data collection. A strong emphasis was placed in this MDS initiative on feasibility, sustainability and quality of data. While the CCCDS is not expected to change significantly, it will need to evolve in response to emerging diagnostic and prognostic criteria.

The CCCDS does not address detailed data requirements of specialists for service audits and clinical research, which fall into Level 4. Without supplementary MDS modules for these Level 4 purposes, tumour groups are likely to develop their own, often without unifying guidance. This will increase the potential for heterogeneous data collections that cannot be used collectively for benchmarking and related purposes.

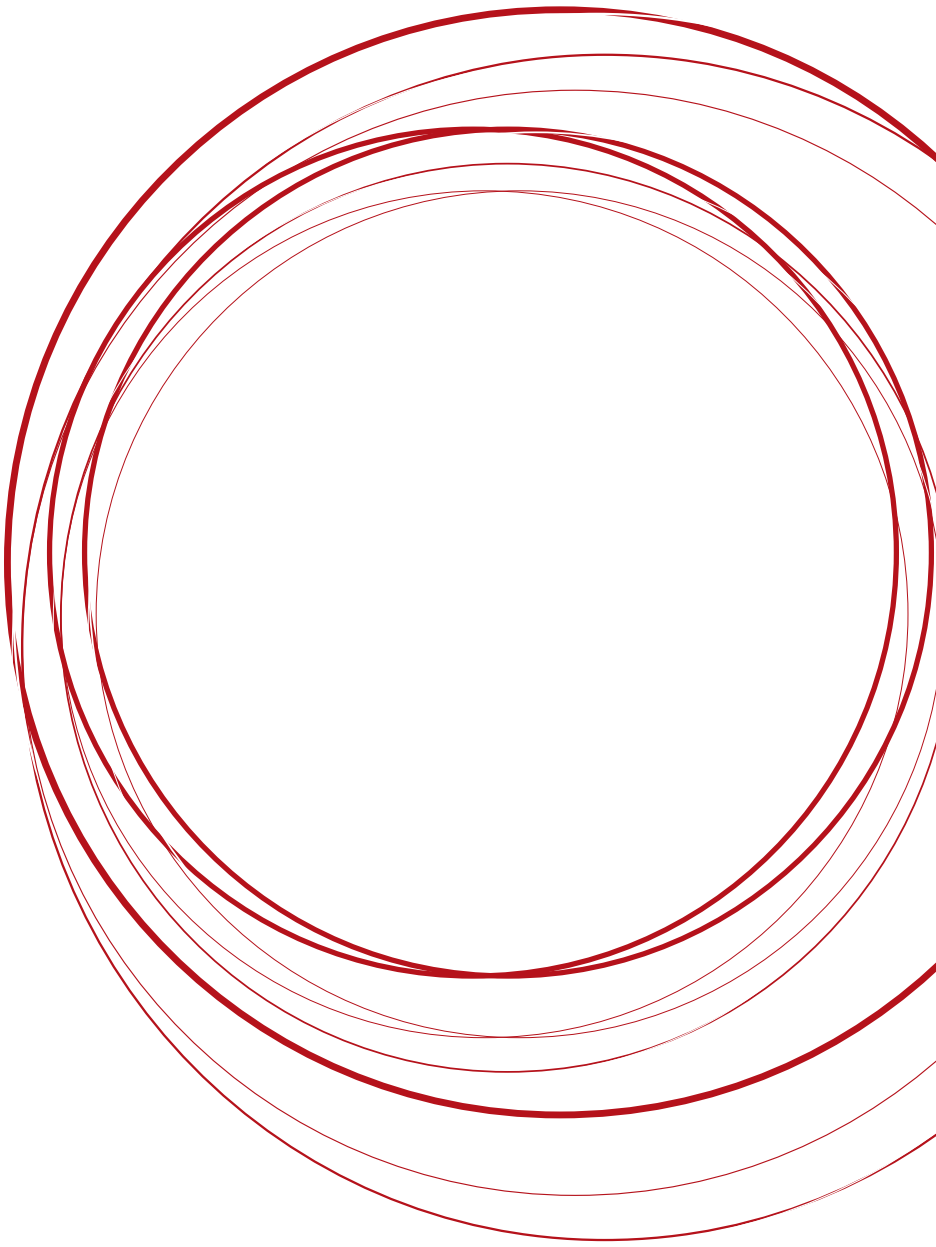
Specialist data sets now existing in Australia include the Royal Australasian College of Surgeons (RACS) National Breast Cancer Audit data set, and in NSW, draft extensions to generic MDS items for gynaecological, haematological, colorectal, and upper gastrointestinal cancers, and melanoma.

The National Breast and Ovarian Cancer Centre (NBOCC) has coordinated the development of a specialist breast-cancer MDS, with data dictionary definitions, to complement generic clinical cancer registration. This has been field-tested in NSW and needs further modification. In addition, the NBOCC and Cancer Australia are collaborating with other stakeholders in the development of a specialist MDS module for gynaecological cancers.

The use of a generic MDS for clinical registration, supplemented by specialist extensions for individual cancer groups, is an approach commonly seen in other countries. For example, in the United Kingdom, the National

Health Service (NHS) Information Authority has a manual for clinical registration comprising a generic core data set covering all cancers, supplemented by draft extensions for sarcomas, haematological malignancies, and cancers of the thyroid, breast, colon/rectum, lung, head & neck, urological sites, gynaecological organs, upper gastrointestinal tract, brain and central nervous system (CNS), and skin. A specialist extension is also being developed for cancers of childhood and adolescence.

It would be desirable for Australia to have specialist MDS modules for major cancer sites, but this would take years to develop, based on experience with other MDS development. While this is being pursued, it would be beneficial to have a common operational framework to assist specialist groups to develop MDS modules along common lines. This would increase the potential for similarities in data collection that would facilitate data linkage and aggregate analysis, even if some mapping were still required to align coding categories.



4. Proposed approach for specialist MDS development

SUPPLEMENT THE CCCDS:

A specialist MDS module should supplement, not replace the CCCDS. Incorporating the CCCDS will ensure that specialist collections have nationally comparable core items that describe patient, provider, cancer, treatment and outcome characteristics. Where existing data sets exclude CCCDS items, these items should be added.

The data items and data dictionary definitions of the CCCDS, as approved by the then National Health Data Standards Committee and endorsed by the then National Health Information Management Principal Committee, are available at: http://www.aihw.gov.au/publications/hwi/dssccnhddv12sup/dssccnhddv12sup.pdf

SELECT SPECIALIST MDS ITEMS:

Where possible, selected specialist items should be the same as those used or advocated in other settings, particularly those in the most authoritative category. Also, they should accord with those provided in synoptic laboratory reports, to facilitate standardised data collection. It is suggested that there be six reference categories graded by authority, with Category 1 providing the most authoritative references and Category 6 the least authoritative, as indicated:

Category 1:

- A nationally recommended specialist MDS module with data dictionary definitions approved by the National Health Information Standards and Statistics Committee and endorsed by the National E-Health Information Principal Committee.

  Comment:

  No module currently meets this requirement in relation to specific cancer types, although some specialist items may exist in other data sets, such as BreastScreen and Cervical Screening data sets, along with their accompanying data dictionary definitions. A list of these data sets is included in the Cancer Australia document: Data Sets for Cancer Control and Research in Australia.

  In addition, there is a national MDS for admitted patient palliative care, developed by the Australian Institute of Health and Welfare (AIHW) with involvement from the Palliative Care Intergovernmental Forum, agreed by the National Health Information Management Group and published by the AIHW (AIHW Cat. No. HWI 50).

Category 2:

- A nationally recommended specialist MDS module with data dictionary definitions that is to be submitted for approval of the National Health Information Standards and Statistics Committee and endorsement by the National E-Health Information Principal Committee.

  Comment:

  A draft NBOCC breast module exists, entitled *Breast Cancer Specific Data Items for Clinical Cancer Registration*, with draft data dictionary definitions.

  Where a nationally recommended specialist MDS module does not exist, and resources permit, steps could be taken to develop one. This MDS development would need to involve a broad cross-section of stakeholders, including specialty colleges and relevant consumer bodies, to gain the necessary legitimacy.

Category 3:

- A specialist MDS with data dictionary definitions in use or proposed for state or territory government health agencies, or approved by a professional college for use by its members.

  Comment:

  Examples include the NSW draft extensions to generic MDS items for gynaecological, haematological, colorectal cancer, and upper gastrointestinal cancers, and melanoma, and the RACS National Breast Cancer Audit data set (*Appendix 1*).

Category 4:

- A specialist MDS module, with data dictionary definitions used or proposed by another country's national health authority.

  Comment:

  Draft extensions to the NHS Information Authority's generic MDS module are an example, as applying to sarcomas, haematological malignancies, and cancers of the thyroid, breast, colon/rectum, lung, head & neck, urological sites, gynaecological organs, upper gastrointestinal tract, brain and CNS, and skin, and the planned extension for cancers of childhood and adolescence (*Appendix 2)*. While the USA Facility Oncology Registry Data Standards (FORDS) manual is directed largely at generic cancer registration, it too includes items that might be relevant for specialist modules in Australia (*Appendix 3*). An advantage of using the FORDS manual would be the opportunities gained to benchmark with data from the USA Commission on Cancer.

Category 5:

- A specialist MDS with data dictionary definitions used in individual Australian hospitals, but not approved for use at a state, territorial or national government level, or by a professional college.

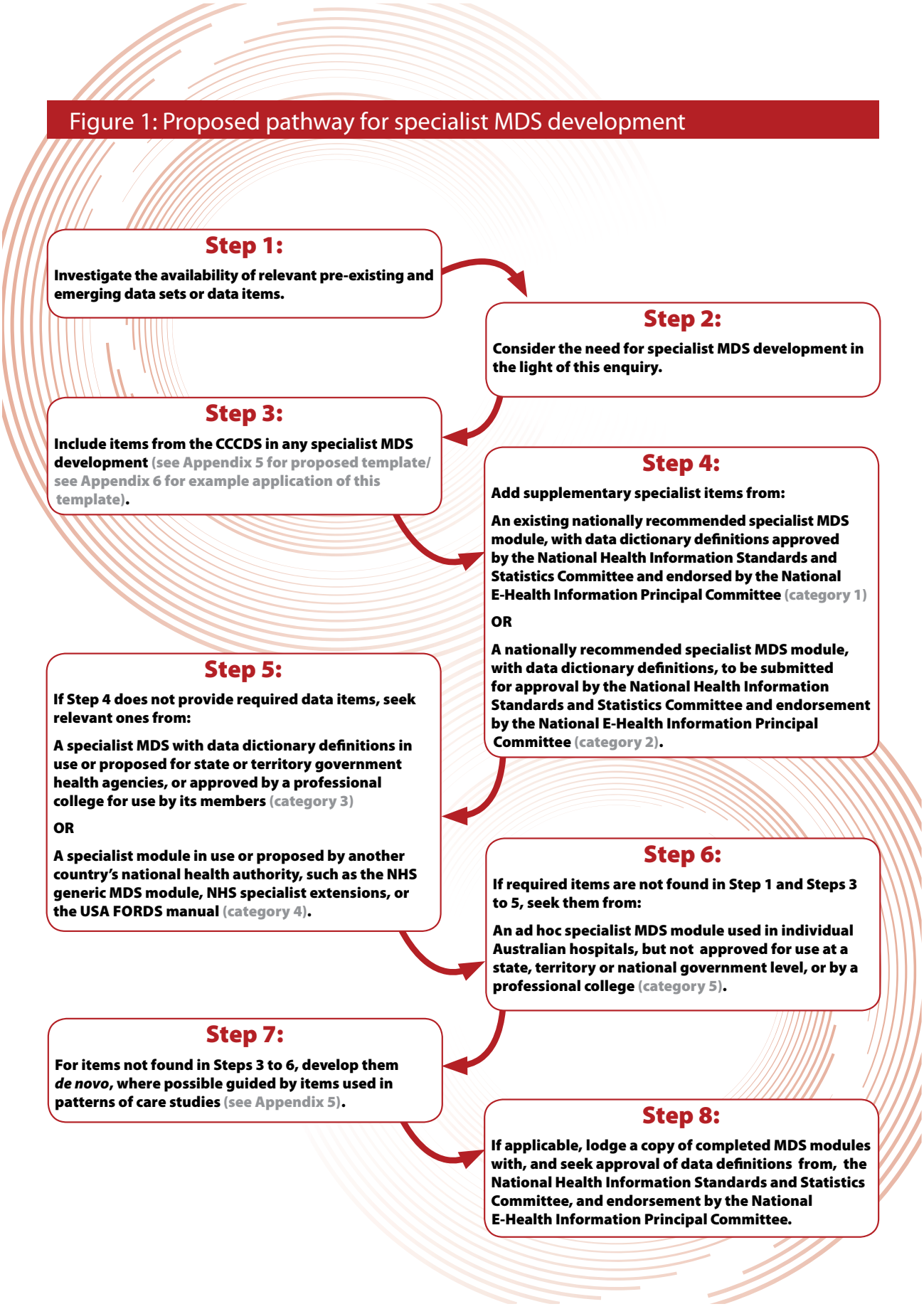
  Comment:

  Many *ad hoc* clinical data collections in Australian leading hospitals would fall into this category.

Category 6:

- When required items are not found in higher categories (i.e., categories1–5), they could be developed as a new initiative. Where there have been relevant patterns of care surveys, local item development could be based on the items used in these surveys to enable comparisons (*Appendix 4*). To optimise benchmarking opportunities, priority should normally be given to national over state surveys, and to those undertaken more recently.

Figure 1: Proposed pathway for specialist MDS development



5. Implementation Issues

This document provides a sound starting point for specialists wishing to develop their own tumour specific data sets.

However, to be credible, MDS development would need to involve a broad cross-section of relevant stakeholders, including specialty colleges and consumer bodies. In general, there would be involvement of surgeons, pathologists, radiologists, medical oncologists, haematologists, and other oncology specialties, tissue-bank administrators, and consumer representatives. Key principles advocated for clinical guideline development by the National Health and Medical Research Council would be applicable, and are available at: http://www.csp.nsw.gov.au/nhmrc/downloads/pdfs/NHMRC%20Clinical%20Practice.pdf

When undertaking specialist data set development, items should be categorised along the lines suggested in *Appendix 5*. CCCDS cancer registration items should be included, plus the selected specialist items (see bracketed examples of possible inclusions *(Appendix 5)*). A hypothetical urology dataset is provided as an example (*Appendix 6*).

It is recommended that a minimalist approach be taken, having regard for feasibility, sustainability and quality of data collection. A compelling rationale should present for proposing data items, given the burden on data providers. If there is uncertainty about inclusion of an item, it may be better to leave it out.

New modules for national application should be submitted for approval of the National Health Information Standards and Statistics Committee and endorsement by the National E-Health Information Principal Committee.

Appendix 1

SPECIALIST MDS MODULES WITH DATA DICTIONARY DEFINITIONS PROPOSED FOR STATE OR TERRITORIAL HEALTH AGENCIES OR BY A PROFESSIONAL COLLEGE FOR USE BY ITS MEMBERS

(This gives examples of specialist modules in Australia and the range of data items and topics covered by them, expressed mostly as key words. Reference documents are cited.)

Jurisdictional—selected examples from NSW:

Specialist MDS items additional to NSW Generic MDS:

NSW Generic MDS data items (adapted from NCCI MDS):

Cancer Institute NSW: NSW clinical cancer registration: minimum data set data dictionary. Version 2.0. Sydney: Cancer Institute NSW, 2006 (draft).

Data items: family name, given name, person identifier on MRN, unique patient identifier (Area UPI), Medicare card number, sex, birth date, country of birth, residential address, Indigenous status, AMO registration number, facility code, diagnosis date, primary site, multiple primaries, cancer type—clinical groupings, best basis for diagnosis, laterality, histopathological grade, morphology, degree of spread, T code, N code, M code, TNM, staging basis, other staging systems/grading and classifications, other stage groupings, treatment modality, admission/discharge dates, surgical procedure, radiotherapy type/dose/fractions/start and completion dates, systemic therapy name/start and completion dates, date referred to cancer specialist, date consulted cancer specialist, date of decision to treat, date of first clinical trial involvement, date of first multidisciplinary team consultation, date of referral for palliative care, performance status at diagnosis, distress thermometer, psycho-social referral by provider type for this care, date of death, cause of death.

NSW Specialist MDS extensions:

1.Cancer Institute NSW. NSW clinical cancer registry: gynaecology oncology. Draft data set, with FIGO extensions for uterine & ovarian cancer. Sydney: Cancer Institute NSW, 2005 (draft).

Data items: date of assessment, metastasis site, response to treatment, tumour size, depth of invasion, associated vulvar lesions, HPV status, regional lymph node site, regional lymph node positive, regional lymph nodes examined, extent of lymph nodes, relapse/recurrence, date of relapse/recurrence, region/site of relapse/recurrence, treatment at relapse/recurrence, date of last contact, last known vital status/status at date of last contact, involved vaginal site, lymphovascular involvement, use of imaging diagnostic tools, size of tumour outside fallopian tube, diameter of residual implants, number of residual

implants, date of second surgical procedure, type of second surgical procedure, status of second surgical procedure, size of tumour outside ovary, risk factors, cytology, FIGO stage, lympho-vascular involvement, histologically-proven lymph node involvement, involvement of lymph nodes, pelvic lymph nodes—number examined/positive, para-aortic lymph nodes—number examined/positive, response to treatment, date of death, cause of death.

2. Cancer Institute NSW. Draft NSW data set extensions for haematological cancer. Sydney: Cancer Institute NSW, n.d. (draft).

Data items: cytogenic molecular marker, haematological cancer group/sub-group, Hodgkin lymphoma—Ann Arbor stage/prognostic score (Hasenclever)/response/date of report, Non-Hodgkin lymphoma—Ann Arbor stage/response/date of report, Follicular lymphoma—International prognostic score, Aggressive Non-Hodgkin lymphoma—International prognostic score, Multiple myeloma—response/prognostic score/date of report, Chronic myeloid leukaemia—stage/prognostic score (Sokal)/response/date of report, Acute leukaemias—response/date of report, Chronic lymphocytic leukaemia—stage (Rai)/response/date of report, Other haematological cancer—type/response/date of report, Myelodysplastic syndrome—type/prognosis score/response/date of report.

3. Cancer Institute NSW. Data dictionary for the NSW colorectal minimum data set extension. Sydney: Cancer Institute NSW, 2007 (draft)

Data items: presentation, method of surgery, level of rectal cancer, radial resection margin (rectal cancers), lymphovascular invasion, number of lymph nodes examined/positive, date of resection of primary cancer, mismatch repair deficiency, first recurrence site/date, perineural invasion (optional).

4. Cancer Institute NSW. Data dictionary for the NSW upper gastrointestinal minimum data set extension. Sydney: Cancer Institute NSW, 2007 (draft)

Data items: intent of treatment, date of first symptoms, duration of symptoms, reason for palliative care referral, complications, nutritional status, pain at presentation, diagnostic tests.

5. Cancer Institute NSW. Data dictionary for the NSW melanoma minimum data set. Sydney: Cancer Institute NSW, 2007 (draft)

Data items: sentinel lymph node biopsy indicator/site(s)/result, lymph node dissection, lymph node dissection extent/site(s)/laterality/intent, thickness (Breslow), narrowest lateral excision margin, excision type, cancer recurrence indicator, recurrence—date of diagnosis/site/laterality/type.

Professional College—example from RACS:

The RACS Breast Cancer Audit Data set

Australian Safety & Efficacy Register of New Intervention Procedures—Surgical: On behalf of the Section of Breast Surgery and the Royal Australasian College of Surgeons. The National Breast Cancer Audit, Data Dictionary. Adelaide: RACS, 2006.

Data items: adjuvant therapy types, axillary surgery, bilateral synchronous cancer, clinical exam, clinic reference, cosmetic result, date of diagnosis, DCIS size, diagnostic procedures/result, dominant pattern, trial enrolment, margin size, sex, histological grade, histological type, hospital/clinic, invasive/in situ, size of invasive lesion, laterality, lymphoedema, mammogram, menopausal status, necrosis present, number of invasive breast cancers, number of nodes examined/positive, number of sentinel nodes histologically positive, patient status for follow up, percentage DCIS in tumour, position of principal tumour, pre-operative scintigraphy—nodes detected by location, private/public, HER 2 status, oestrogen/progesterone receptor status, referral source, refused treatment, scintigraphy (y/n)—date, sentinel node biopsy—nodes detected/position and number positive, surgery date/discharge date/procedure, ultrasound, vascular/lymphatic invasion.

Appendix 2

UNITED KINGDOM MDS FOR CLINICAL CANCER REGISTRATION

(This gives examples of the range of generic data items and topics, and specialist extensions, recommended in the United Kingdom, expressed mostly as key words.)

Source Reference:

NHS Information Authority: Cancer data set pilot. London: National Health Service, 2003.

Generic—essential items

Demographic: eg, NHS number, surname, forenames, residential address, sex, birth date, GP, ethnicity, religion, marital status, next of kin, carer details.

Smoking status: eg, smoking status, date started smoking, referral to stop, date stopped smoking.

Symptoms: eg, symptom type, duration.

Referral option: eg, referral source to GP, referral for secondary care/date/to whom.

Diagnosis: eg, date, primary site, histology, differentiation, staging (eg, Dukes/Ann Arbor/FIGO/Gleason grade/Breslow depth/TNM), metastasis date/site(s).

Stages of patient experience: eg, suspected cancer, confirmed, treatment started, ongoing review, recurrence, final-days pathway, bereavement.

Treatment: eg, intent, date started/completed, start/end dates for radiotherapy/chemotherapy/hormone therapy/ immunotherapy/complementary therapy/gene therapy/specialist palliative care/biological treatment, route of admission of treatment.

Supportive care/palliative care: eg, support information provided, GP out of hours notification, admission to hospice/hospital, referral for specialist palliative care in the community and reason(s)/inpatient/outpatient, syringe driver commenced/discontinued

Death: date of death, place of death, cause of death.

Specialist items or additional codes for generic items

Thyroid cancer:

History: eg, history of thyroid disease, previous irradiation, previous treatment for thyroid related disease, family history of thyroid disease, family history of non-thyroid cancers, genetic screening.

Examination: eg, presentation, cytology results.

Surgery: eg, operative procedure, operative findings, neck dissection procedures, thyroid hormone commencement date.

Pathology: eg, histology, grade, pathological features, undifferentiated component, pathology in adjacent gland, parathyroid gland(s) identified.

Imaging: eg, chest X-ray, CT scan, MRI, PET etc.

Radio-iodine ablation: eg, dose, response, thyroglobulin level, TSH level, thyroid hormone status.

Radiotherapy/chemotherapy: as for generic data set.

Follow-up: eg, marker response/marker level, assay method, imaging result, salivary complications, non-thyroid malignancy, surgical complications, co-morbidity.

Haematological cancers:

Imaging: eg, result, mediastinal mass ratio, cancer disease site, bulk disease, myeloma skeletal survey, myeloma evidence.

Referral details: eg, predisposing conditions, past cancer site/diagnosis year, family history of cancer.

Patient evaluation: eg, spleen size, hepatomegaly, lymphadenopathy site, skin involvement, testicular involvement, neurological involvement, systemic symptoms, pruritis.

Diagnosis tests: eg, haemoglobin, mean corpuscular volume, HCT percentage, WBC total, neutrophils, monocytes, lymphocytes, eosinophils, basophils, blasts, platelets, ESR, viscosity, CRP, coagulation, cancer film appearance, plasma cells, plasma cells percentage, antiglobulin test.

Biochemistry data items: eg, creatinine, albumin, corrected calcium, LDH, B2M, ferritin, urate, IGG, IGM, IGA, serum electrophoresis.

Paraprotein data items: eg, paraprotein type/value, Bence Jones protein type/value, creatinine clearance/clearance value.

Microbiology: eg, HIV test, Hepatitis C test, bone marrow aspirate, aspirate blast cells/plasma cells/lymphoid cells/storage iron/trilineage involvement, bone marrow trephine, trephine blast cells/plasma cells/lymphoid cells/infiltration pattern/reticulin pattern/trilineage involvement, cancer diagnostic source, immunophenotype cells percentage.

Antigen profile data items: eg, type, result, blood cytogenetics result, cytogenetics NHL/CML/ALL/AML, blood cytogenetics MDS, bone marrow cytogenetics result, bone marrow cytogenetics NHL/CML/ALL/AML/MDS, blood molecular diagnostics result/TCR rearrangements present/blood IGH rearrangements present/blood somatic mutations present, blood BCR ABL rearrangement present, blood other abnormality, bone marrow molecular diagnostic result/TCR rearrangements present/IGH rearrangements present/somatic mutations/BCR ABL rearrangements present/other abnormality, red cell mass, arterial oxygen saturation, serum erythropoietin, haemoglobinopathy screen report, haematological cancer secondary cause, tissue diagnosis date.

Diagnosis: CML phase, Ann Arbor symptoms, extra nodal disease, extranodal disease site, lymph node site, International Prognostic Index, Prognostic Hasenclever score/Hasford total score/Sokal score/score Lille/ Sheffield score/Cervantes score.

Clinical trials: clinical trials status.

Breast cancer:

Breast cancer specific codes: eg, specific codes are provided for imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, extended TNM, the Nottingham Prognostic Index, surgical procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, diagnostic route (screening status), breast cancer nurse, menstrual status, LMP date, clinical examination findings, marker lymph node result, endocrine therapy type.

Colorectal cancer:

Colorectal cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, extended TNM, Dukes stage, surgical procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, diagnostic route, colorectal nurse or stoma therapist, colonoscopy result, grade of surgeon, surgical urgency, marker lymph node result, clinical status at follow-up.

Lung cancer:

Lung cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, cancer care plan intent, stage—limited/extensive (small cell), extended TNM, diagnostic procedures, main procedures and sub-procedures, specialised treatments, endobronchial therapies, drug regimens, post-operative complications.

Additional items: eg, smoking status, COPD presence, FEV1.

Head and neck cancer:

Head and neck cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, pre-treatment staging information, extended TNM, surgical procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, history of other cancers, history of head and neck cancer treatment, history of tobacco and alcohol use, quality of life, date symptoms first noted, family history of cancer, nutritional services.

Urological cancer:

Urological cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, extended TNM, procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, serum PSA, pre-treatment stage, drug route of administration.

Gynaecological cancer:

Gynaecological cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, tumour laterality, grade of differentiation, FIGO staging, extended TNM, procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, diagnostic route, oncology accreditation.

Upper gastrointestinal cancer:

Upper gastrointestinal cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, extended TNM, procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, possum score at diagnosis, for pancreas cancer—family history/smoking status/alcohol status/co-morbidity/symptoms, for stomach cancer—symptoms/possum score after surgery.

Brain and CNS cancer:

Brain and CNS cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, extended TNM, procedures and sub-procedures.

Additional items: not applicable.

Skin cancer:

Skin cancer specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, extended TNM, procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, for basal cell carcinoma—dermatologist body site/largest clinical diameter/clinical morphology/new or recurrent, for squamous cell carcinoma—dermatologist body site/largest clinical diameter/clinical excision margin/new or recurrent, for Kaposi's sarcoma—dermatologist body site/largest clinical diameter, for cutaneous lymphoma—dermatologist body site/largest clinical diameter/lymphoma clinical morphology/lesion distribution/T cell clinical variant and surface area, clinical excision marker, immunosuppressive therapy, previous skin cancer, genetically determined skin cancer type, new/recurrent lesions treated, perineural invasion, pathology specimen type, drug route of administration, skin tumour status, surgical margins, investigations.

Sarcoma:

Sarcoma specific codes: eg, imaging modality, anatomical site examined, primary site, histology coding, grade of differentiation, for bone sites—Enneking staging, procedures and sub-procedures, drug regimens, post-operative complications.

Additional items: eg, actual site, largest diameter, condition first seen, predisposing conditions, surgical procedure/margins, pathological features—necrosis/closest margin/relation to deep fascia.

Appendix 3

USA COMMISSION ON CANCER FACILITY ONCOLOGY REGISTRY DATA STANDARDS (FORDS), REVISED FOR 2007

(This gives examples of the range of data items and topics covered by FORDS, expressed mostly as key words.)

Source Reference:

Commission on Cancer (USA): FORDS—Facility Oncology Registry Data Standards Revised for 2007. Chicago: American College of Surgeons, 2002.

Data items:

Patient identification: eg, accession number, last name, first/middle name, residential address, place of birth, date of birth, age at diagnosis, race, sex, co-morbidities and complications, names of treating/follow-up clinicians

Cancer identification: eg, class of case, referral source, where referred, date of first contact, date of initial diagnosis, primary site, laterality, histology, behaviour code, grade/differentiation, date of multiple cancers, multiple cancers reported as one primary cancer, tumour size, regional lymph nodes examined/positive.

Stage at diagnosis: eg surgical diagnostic and staging procedure/date, T/N/M/TNM stage (clinical/pathologic), SEER summary stage.

First course of treatment: eg, date, surgical procedure, surgical margins, regional lymph node surgery, reason if no surgery, radiation—start/end date/location/volume/regional modality/dose/boost treatment modality/boost dose/reason if no radiotherapy, systemic therapy—start date/chemotherapy/hormone therapy/immunotherapy/haematological transplant and endocrine procedures, other treatment, palliative care

Outcomes: eg, first recurrence: date/type, date of last contact, cancer status, date of death, cause of death.

Appendix 4

AUSTRALIAN PATTERN OF CARE STUDIES

(This shows a cross-section of source documents for studies of care that may guide data item development)

National surveys:

Breast:

1. Cuncins-Hearn A, Boult M, Babidge W, Zorbas H, Villanueva E, Evans A, Oliver D, Kollias J, Reeve T, Maddern G. National breast cancer audit: ductal carcinoma in situ management in Australia and New Zealand. ANZ J Surg 2007; 77: 64–68.
2. Cuncins-Hearn A, Boult M, Babidge W, Zorbas H, Villanueva E, Evans A, Oliver D, Kollias J, Reeve T, Maddern G. National breast cancer audit: overview of invasive breast cancer management. ANZ J Surg 2006; 76: 745–750.
3. Drummond R, Power A, Evans A, Luxford K, Blakey D, Delaney G, Rodger A. Changes in practice of breast cancer radiotherapy 1998–2002: an Australasian survey. Australasian Radiology 2005; 49: 44–52.
4. White V, Pruden M, Giles G, Collins J, Jamrozik K, Inglis G, Boyages J, Hill D. The management of early breast carcinoma before and after the introduction of clinical management guidelines. Cancer 2004; 101: 476–485.
5. Pendlebury SC, Ivanov O, Renwick S, Stevens GN. Long-term review of a breast conservation series and patterns of care over 18 years. ANZ J Surg 2003; 73: 577–583.
6. Delaney G, Blakey D, Drummond R, Kenny L, Centre RO. Breast radiotherapy: an Australasian survey of current treatment techniques. Australas Radiol 2001; 45: 170–178.
7. National Breast Cancer Centre. Surgical management of breast cancer in Australia in 1995. Sydney: NHMRC National Breast Cancer Centre, 1999.
8. Hill D, Jamrozik K, White V, Collins J, Boyages J, Shugg D, Pruden M, Giles G, Byrne M. Surgical management of breast cancer in Australia in 1995. Sydney: NHMRC National Breast Cancer Centre, 1999.

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Appendix 5

DRAFT AUSTRALIAN CLINICAL CANCER REGISTRATION TEMPLATE

(Generic MDS in black type/Examples of items to consider for specialist registration in red type)

A. PATIENT:

1. SURNAME: _____

2. GIVEN NAME(S): _____

3. ADDRESS: _____

_____ 4.POSTCODE:_____

5. SEX: _____ 6. BTH DATE: _____ (dd) __ (mm) _____ (yyyy) 6. DTH DATE: _____ (dd) __ (mm) _____ (yyyy)

7: DTH CAUSE: _____8: MEDICARE NO:_____ 9.ID NO:_____

(Electives: eg, Indigenous status (strongly recommended), ethnicity, country of birth, religion, inpatient type (public/private), marital status, smoking status, alcohol intake, menstrual status, place of death)

B. PROVIDER:

1. ESTABLISHMENT NO: _____ (2. Doctor Id No (Dr in charge of case): _____)

(PRESENTATION & HISTORY:

Eg, *Referral details* (eg, date specialist referral, date specialist consult, referral source—GP/A&E/allied health/ screening service, review clinic etc.), *symptoms* (eg, persistent weight loss, fever, night sweats, fatigue, anaemia, headaches, pain, skin change, changed bowel/bladder function, persistent sore, unusual bleeding or discharge, thickening/lump, bloating, persistent indigestion, dysphagia, nagging cough or hoarseness), *co-morbidity* (eg, co-morbidity type, co-morbidity index), *personal/family history of cancer or predisposing conditions* (eg, sunburn, hyperkeratosis, excess body weight, iodine deficiency, asbestosis, chronic irritation/ inflammation, polyps, congenital conditions—eg, FAP, cholesterol gallstones, Barrett oesophagus, undescended testes, Li-Fraumeni Syndrome, HNPCC family group, Ataxia Telangiectasia, multiple endocrine neoplasia, Xeroderma Pigmentosum, Von Hippel-Lindau Syndrome), *nutritional status* (eg, vitamin A/D/C deficiency, low fruit/vegetable/ whole grain food/cereal intake, excess processed meat, deficient/excess dairy food intake, low tea intake, etc.), *low parity, predisposing habits* (eg, smoking, excessive alcohol intake, etc.))

(DIAGNOSTIC PROCEDURES:

Eg, *Surgery* (eg, excision biopsy, lymph node surgery, sentinel node biopsy, exploratory surgery, laparotomy, etc.); *Imaging* (eg, x-rays, radionuclide scans, mammography, CT scan, MRI scan, chest X-rays, PET scan, Brain CAT, ultra sound, sonogram, barium enema, pyelogram, angiogram, lymphangiogram, pyelogram, urogram, hysterosalpingogram, myelogram , bone scan, liver/spleen scans. etc.); *Laboratory tests* (eg, Pap tests, other cytology exams, histopathology, molecular diagnostics, microbiology, thyroid testing, urine/blood counts and tests/PSA, FOBT & other stools testing, liver function tests, tumour marker evaluation—eg, AFP, B2M, Beta-HCG, BTA, CA 15-3, CA 27.29, CA 125, CA 72-4, CA 19-9, Calcitonin, CEA, Cg A, HER2, hCG, Ig A, Ig G, Ig D, Ig M, LASA-P, NSE, NMP22, PSMA, S-100, TA-90, thyroglobulin, TPA, BJ protein, ploidy, etc.; *Genetic tests* (eg, BRAC1, BRAC2, APC, k-ras, p53, etc.); *Endoscopy* (eg, bronchoscopy, colonoscopy, cystoscopy, oesophagoscopy, gastroscopy, laryngoscopy, ophthalmoscopy, otoscopy, panendoscopy, proctoscopy, sigmoidoscopy. etc.); *Physical exam* (digital rectal exam, pelvic examination, skin examination))

C. CANCER:

1. PRIM SITE: _____ 2. DIAG DATE: _____(dd) _____ (mm) _____ (yyyy) 3. MORPHOLOGY: _____

4. DIFFERENTIAT: well ( ), moderate ( ), poor ( ), undiff. ( ), UK ( ) 5: LATERALITY (L/R/Bilat): _____

6. MOST VALID BASIS OF DIAGNOSIS: tick—death certificate ( ), clinical ( ), clin. investig /ultrasound ( ), tumour marker ( ), cytology ( ), histology (metastasis) ( ), histology (primary) ( ), histology (UK) ( ), unknown ( )

7. PERFORM (ECOG): _____ 8. STAGE: _____ (T) _____ (N)_____ (M)_____ (TNM) SCHEM/EDIT: _____

8. SIZE: _____ (mm) 9. MEL THICKNESS: _____ (mm) 10. ER (+/-/?):_____ 11. PR (+/-/?) _____

12. REGIONAL NODES: Number examined _____; Number positive: _____

(Electives: eg, other staging systems (eg, FIGO, Dukes, Ann Arbor, Rai staging , rhabdomyosarcoma I/ II/ III, Durie-Salmon stage, Clark's level, etc.), LVI, depth of invasion, other prognostic markers (eg, necrosis, bulk disease, hormone levels, blood chemistry), metastatic sites, blood/biomarkers, genetic markers, surface receptors (eg, HER-2), mitotic rates, abnormal ploidy (FLOW cytometry), capsular extension, direct extra-organ extension, biochemical tests, microbiology, antigen profiles, spleen size, synchronous cancers)

D. TREATMENT (First round):

1. TYPE: _____ 2. INTENT: _____ 3. SURGERY: Procedure(s): _____ ;
Start date(s): ___ (dd) ___ (mm) _____ (yyyy); Target site(s): _____
4. RADIOTHERAPY: Type: _____; Dose: _____; Target site: _____
5. SYSTEMIC THERAPY: Agent: _____
6. TREATMENT: Start date: ___ (dd) ___ (mm) ____ (yyyy); Finish date: ___ (dd) ___ (mm) _____ (yyyy)
7. TREATMENT OUTCOME: _____ 8. 1st RECURRENCE: Date: _____ (mm/yyyy); Region (L/R/D) _____

(**Electives**: eg, clinical trial enrolment, clinician name, MDT consultation/date, surgeon category, operation category/intent, discharge date/destination, decision/referral date for specialist palliative care, complementary therapies, route of treatment admission, gene therapy, biological treatment, complications during and post treatment, pain control, provision for community/home supportive care, surgical margins, radiotherapy fractions, systemic drugs cycles/doses/venous access devices, treatment compromises (due to medical conditions, patient choice), sites of distant recurrences, dates of detection of distant recurrences, residual disease, diameters of residual implants, other visceral resections, extent of ascites, adherence of primary tumour, rupture of primary tumour, pattern of spread, reconstruction procedures)

REPEAT (??): TREATMENT & TREATMENT OUTCOMES FOR RECURRENCES

LAST KNOWN CONTACT DATE (vital status—alive/dead; cancer status—cancer evident/not evident)

Appendix 6

HYPOTHETICAL AUSTRALIAN CLINICAL UROLOGY CANCER REGISTRATION

(Generic MDS in black type/Hypothetical items selected to illustrate specialist registration in red)

A. PATIENT:

1. SURNAME: _____

2. GIVEN NAME(S):_____

3. ADDRESS: _____

_____ **4.POSTCODE:**_____

5. SEX: ____ **6. BTH DATE:** ____ (dd) __ (mm) _____ (yyyy) **7. DTH DATE:** ____ (dd) __ (mm) _____ (yyyy)

8: DTH CAUSE: _____**9: MEDICARE NO:**_____ **10.ID NO:**_____

11. INDIGENOUS STATUS:_____

B. PROVIDER:

1. ESTABLISHMENT NO: _____

PRESENTATION:

1. REFERRAL SOURCE: tick—GP (), A&E (), allied health (), review clinic (), other () specify_____

2. SYMPTOMS: tick—haematuria (), pain (), voiding dysfunction (), mass (), other() specify _____

3. SMOKING: tick—present smoker () specify___cigs/day, past smoker (), never smoked ()

DIAGNOSTIC PROCEDURES:

tick—biopsy (), cytology (), imaging (), HCG () specify____ mIU/L, AFP () specify____ kU/L, PSA () specify ____ microgms/L, creatinine () ____ mmol/L, other () specify_____

C. CANCER:

1. PRIM SITE: _____ **2. DIAG DATE:** ___ (dd) ___ (mm) _____ (yyyy) **3. MORPHOLOGY:** _____

4. DIFFERENTIAT: well ( ), moderate ( ), poor ( ), undiff. ( ), UK ( ) 5: **LATERALITY** (L/R/Bilat): _____

6. MOST VALID BASIS OF DIAGNOSIS: tick—death certificate ( ), clinical ( ), clin. investig /ultrasound ( ), tumour marker ( ), cytology ( ), histology (metastasis) ( ), histology (primary) ( ), histology (UK) ( ), unknown ( )

7. PERFORM (ECOG): _____ **8. STAGE:** _____ (T) _____ (N)_____ (M)____ (TNM) SCHEM/EDIT: _____

9. SIZE: _____ (mm) 1**0. ER:** (+/-/?) **11.** PR: (+/-/?) **12. REGIONAL NODES:** Number examined _____; Number positive _____ **13. MULTIFOCAL:**_____ **14: IN SITU COMPONENT:** _____
15. GLEASON GRADE: _____ **16. DISTANT MET SITES:** _____

D. TREATMENT (First round):

1. RCT inclusion: _____**2. TYPE:** _____ **3. INTENT:** ___ **4. SURGERY:** Procedure(s):_____;

Start date(s): _____ (dd) _____ (mm) _____ (yyyy); Target site(s):_____ Margins: clearance (mm) _____; involvement (mm) _____ **5. RADIOTHERAPY:** Type: _____; Dose: _____; Target site: _____
6. SYSTEMIC THERAPY: Agent: _____ **7. TREATMENT:** Start date: ___ (dd) ___ (mm) ____

(yyyy); Finish date: _____(dd) _____ (mm) _____ (yyyy) **8. TREATMENT OUTCOME:** _____

9. 1st RECURRENCE: Date: _____ (mm/yyyy); Region (L/R/D) ___; Distant met sites: _____

E. LAST CONTACT:

1. DATE: _____ (dd) _____ (mm)___))) (yyyy) **2. CANCER STATUS:** (tick) none (), local (), regional (), dist ()

3. DISTANT METS: Diagnosis date ___(dd) ___ (mm) ___ (yyyy); Dist met sites: _____