

**NSW Oncology Group
Colorectal
Minimum Data Set Extension
Data Dictionary**

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1. Document Version Control

| Version | Date Issued | Change Description |
|---------|----------------|---|
| 0.1 | 01/02/2007 | First draft developed by CI NSW based on work by Dr Andrew Kneebone (SSWAHS) and Dr Sian Munro (UNSW) |
| 0.2 | February 2007 | Revised by Dr Sian Munro and Ms Isa Dinh based on review with NSWOG Colorectal |
| 0.3 | 28 March 2007 | Main differences are in the following areas: <ul style="list-style-type: none">▪ Presentation▪ No of nodes examined▪ No of nodes involved▪ Recurrence |
| 1.0 | 15 August 2007 | Revised by Dr Sian Munro based on Guidelines for Colorectal Cancer Reporting, written by Dr Jill Farmer Main differences present in the following area: <ul style="list-style-type: none">▪ Presentation▪ Non-peritonealised circumferential margin |

2. Introduction

Population-based cancer registries in each Australian state and jurisdiction provide comprehensive information on cancer incidence. By matching, verifying and registering each case, incidence of each cancer type can be mapped by area of residence, age, sex and country of birth. Death notifications (and cause of death) are also matched and provide the definitive mortality and survival rates for cancer in NSW.

To enhance this epidemiological information, *clinical cancer registries* are designed to add the dimensions of stage, treatment and quality of care, allowing analyses of patterns of cancer care against best-practice guidelines. The Institute is funding Area-based clinical cancer registries in six Area Health Services.

By describing cancer stage and actual surgical, radiation and chemotherapeutic interventions, Areas and tumour streams can monitor access and quality of care. However, specific quality of care indicators for each cancer type requires collection of a more specific subset of data items. For instance, for breast cancer the receptor status (oestrogen, progesterone and HER2), together with disease stage dictates the appropriate drug treatment options. Other data items will support better monitoring of supportive care or enhance the prognostic value of the core dataset.

The NSW Oncology Group (NSWOG) was established by the Cancer Institute NSW and comprises cancer specialist doctors and nurses, consumers and patients. The aim of NSWOG includes the identification of best practice care guidelines, and of the data needed to monitor and improve cancer outcomes in NSW. NSWOGs also promote sub specialised training and education for each type of cancer, and clinical trials.

The NSW Minimum Dataset for Clinical Cancer Registration is being collected in many public hospitals in NSW. The *core cancer dataset* describes cancer type, stage, treatment and quality of care for each cancer patient. Concurrently, NSW Oncology Group is working to identify succinct *dataset extensions* as statewide standards, to complement the core dataset with additional measures and indicators specific to tumour streams.

Specifically this data dictionary will have relevance to:

- Clinicians (Colorectal)
- Clinical Cancer Registry Staff
- Analysts of Clinical Cancer Registry data

Only data elements specific to colorectal cancer are presented in this data dictionary. Additional data elements for all cancers are covered by the NSW Cancer Registry Data Dictionary and the NSW Clinical Cancer Data Dictionary.

The review of the data dictionary will be conducted after the collection has been piloted for a period of time so that the decisions concerning changes to the dataset can be based on feasibility, usability and experience. It is intended that this data dictionary defines the disease-specific dataset and will be used by a variety of NSW Clinical Cancer Registry stakeholders.

The Data Set Specification, Cancer (Clinical): National Health Data Dictionary Version 12 Supplement published by the Australian Institute of Health and Welfare (AIHW) and the NSW Clinical Cancer Data Collection for Outcomes and Quality Data Dictionary published by the NSW Health Department were both reviewed prior to producing this publication.

This Data Dictionary has been developed in consultation with the NSWOG Colorectal Committee and the Colorectal Cancer Research Consortium and the specific additional data items will be collected as a pilot project in South Eastern Sydney and Illawarra Area Health Service.

This document was written by Dr Sian Munro and Ms Isa Dinh based on the work by Dr Andrew Kneebone and the Colorectal NSW Oncology Group (NSWOG).

3. Colorectal Cancers

The table below shows the Primary Site of Cancer ICD10AM 5th Edition codes that trigger the reporting of the Colorectal Minimum Data Set.

- C18.0 Malignant neoplasm of caecum
- C18.1 Malignant neoplasm of appendix
- C18.2 Malignant neoplasm of ascending colon
- C18.3 Malignant neoplasm of hepatic flexure
- C18.4 Malignant neoplasm of transverse colon
- C18.5 Malignant neoplasm of splenic flexure
- C18.6 Malignant neoplasm of descending colon
- C18.7 Malignant neoplasm of sigmoid colon
- C18.8 Overlapping malignant lesion of colon
- C18.9 Malignant neoplasm of colon, unspecified part
- C19 Malignant neoplasm rectosigmoid junction
- C20 Malignant neoplasm of the rectum

4. Data Dictionary Format Guide

Each data item is described in terms of its defining characteristics and its physical representation. In addition to this, certain administrative information is provided to inform users of the sources and the currency of the version of the individual item. The components included under these section headings are based on the NHDD standard, as described below:

| Heading | Description |
|----------------------------|---|
| Defining Attributes | |
| Definition | A statement that expresses the essential nature of a data element and its differentiation from all other data elements. |
| Coverage | A description of the circumstances under which the data item should be collected and reported. |
| Guide for Use | |
| Data Domain | The set of possible values for the data item. This may take the form of a code set, or a description of the possible values. Domain values are only specified where size of the code set is small enough to be reasonably reproduced in the document. In other instances the domain may be indicated by reference to a source document. |
| Domain Definitions | The definitions of each domain category within the classification, where such definitions are warranted – that is more information that the domain descriptor is required to fully understand what is captured with the domain value. |
| Clarifying Points | These are comments designed to assist in further defining aspects of the data domain. |
| Collection Methods | This provides important comments concerning the actual capture of data for the particular data element. |
| Screen Prompts | This is suggested terminology to use in computer applications. |
| Validation Rules | These are included to assist in reducing input error. Where validation rules are known to exist, they have been included to assist with the programming. |
| Justification | The reason for collecting this data element. |
| Representation | |
| Data Element Type | <p>There are four types of data elements, and this describes which of the element is. Definitions of each type are provided below.</p> <p><i>Data Concept</i> - a concept which can be represented in the form of a data element, described independently of any particular representation. For example, hospital 'admission' is a process, which does not have any particular representation of its own, except through data elements such as 'Date of Admission', 'mode of admission' etc.</p> <p><i>Data Element</i> – a unit of data for which the definition, identification, representation and permissible values are specified by means of a set of attributes.</p> |

| Heading | Description |
|-----------------------------------|---|
| | <p><i>Derived Data Element</i> – a data element whose values are derived by calculation from the values of other data elements. For example the data element 'length of stay' is derived by calculating the number of days from the 'Date of Admission' to the 'Date of Separation' less the number of 'total leave days'.</p> <p><i>Composite Data Element</i> – a data element whose values represent the grouping of the values of other data elements in a specified order.</p> |
| Data Type | The type of symbol or character, or other designation used to represent the data element. For example numeric, alphanumeric, alphabetic or integer. |
| Form | Describes whether the valid values for the data item take the form of a code set, free text. If the form is described as "Code" the relevant code set or sets will be specified in the Domain section. |
| Minimum Size | The minimum number of characters allowable to represent the data element. |
| Maximum Size | The maximum number of characters allowable to represent the data element. |
| Layout | A generic example of what the data element should look like in the unit record. For example, dates should be represented in the format of DDMMYYYY where DD represents, the day, MM represents the month, and YYYY represents the four-digit numeric for the year. "N" is used to represent numeric values and "A" is used to represent alphabetic and alphanumeric values (the Data Type indicates whether it is alphabetic or alphanumeric). |
| Administrative Information | |
| Version | This is the version number of the individual data element as it exists in the New South Wales Health Data Dictionary only. The version number may differ from the version number of the NSW HDD publication, as data elements may be revised independently of the periodic review of the document. |
| Effective Date | The date from which this version of the data element is to be used for reporting. |
| References | |
| Related Elements | Data elements that have some direct relationship with the data element being described. |
| References | Documents listed here have been used as references when designing the specified item. The item as it is presented in the NSW HDD is not necessarily identical to the item in the source document. The name of the organisation(s) that developed the source document(s) or provided advice on the data item. |

5. Data Items

The data items below are described in this data dictionary and are candidates for the NSW Colorectal Minimum Data Set.

1. Presentation
2. Method of Surgery
3. Level of Rectal Cancer
4. Completeness of Resection
5. Radial Resection Margin (Rectal Cancers)
6. Lymphovascular Invasion
7. Number of Lymph Nodes Examined
8. Number of Lymph Nodes Involved
9. Date of Resection of Primary Tumour
10. Mismatch Repair Deficiency (MMRD)
11. Site of First Recurrence
12. Date of First Recurrence

Presentation

Defining Attributes

Definition: The presentation of the patient who has been admitted for a scheduled appointment/ surgery/ screening for bowel cancer.

Coverage: This item should be reported for:

- Cases where Primary Site of Cancer is Colorectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|---|
| 0 | Asymptomatic Screening (FOBT) |
| 1 | Symptoms |
| 2 | Emergency due to obstruction, perforation (with abscess/peritonitis), excessive bleeding or in conjunction with resuscitation |
| 9 | Unknown |

Domain Definitions: The data domain definitions for this data element are shown in the table below.

| Code | Definition |
|------|---|
| 0 | Faecal Occult Blood Test for screening bowel cancer |
| 1 | Patient presented with symptoms of bowel cancer |
| 2 | Emergency due to obstruction, perforation (with abscess/peritonitis), excessive bleeding or in conjunction with resuscitation |
| 9 | It is unknown how the patient presented |

Clarifying Points: Emergency surgery is a prognostic factor in determining postoperative mortality and long-term survival. It is important to note that many patients who have an emergency admission do not have emergency surgery and their risk of dying from surgery approximates to that of an elective case. The term emergency therefore refers to surgery rather than the mode of admission. Patient presentation at surgery should be determined by the surgeon.

Collection Methods: Presentation should be present in the patient's physical or electronic medical record, specifically in the surgical report or detailed on the pathology request.

Validation Rules: Must = 0, 1, 2 or 9

Justification: The presentation of the patient at time of surgery is an important item for data collection as patients who present in emergency with bowel obstructions or perforation, have a worse prognosis than patients who have been admitted for a scheduled appointment/surgery/screening. With the implementation of the Federal Government's bowel screening program initiated in 2006, it will also be useful to determine how many patients are detected through the Faecal Occult Blood Test screening program. This item will be captured by the surgical request form.

Representation

Data Element Type: Data Element
Data Type: Numeric
Form: Code
Minimum Size: 1
Maximum Size: 1
Layout: N(1)

Administrative Information

Version: 1
Effective date: 1 Mar 2007

Related Information

Related Data: Not Applicable

References:

Method of Surgery

Defining Attributes

Definition: The method of surgery performed.

Coverage: This item should be reported for:

Cases where Primary Site of Cancer is Colorectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|--------------------------------------|
| 0 | Open |
| 1 | Laparoscopic / Laparoscopic assisted |
| 2 | Laparoscopic converted to open |
| 3 | Local Excision (e.g. TEMS) |
| 8 | Other method of surgery |
| 9 | No surgery |

Domain Definitions:

| Code | Definition |
|------|--|
| 0 | Open surgery |
| 1 | Laparoscopic and laparoscopic assisted |
| 2 | Laparoscopy used and then converted to open |
| 3 | Local excision e.g. Transanal endoscopic microsurgery (TEMS) |
| 8 | Other method of surgery used not elsewhere classified |
| 9 | No surgery |

Clarifying Points: Method of the surgery is used to excise the tumour, or sections of the tumour and/or to determine the whether cancer has spread (metastasised).

Collection Methods: Surgery method should be present in the patient's physical or electronic medical record. The theatre records or surgical report should be used to identify what method of surgery was used.

Validation Rules: Must = 0, 1, 2, 3 or 8

Justification: Laparoscopic surgical techniques are becoming increasingly utilised in modern surgery. It is thought that although the morbidity and mortality rates are similar to those seen for other surgical methods, the bed days of the patients in hospital and patient recovery time for laparoscopic surgery are reduced [1]. The collection of this data will also inform on practice patterns, which will help direct medical teaching and the need for expertise in specialised surgical

techniques [2].

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | N(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Data: Not Applicable

- References:**
1. Veldkamp, R., et al., *Laparoscopic surgery versus open surgery for colon cancer: short-term outcomes of a randomised trial*. *Lancet Oncology*, 2005. **6**(7): p. 477-84.
 2. Schoetz, D.J., Jr., *Evolving practice patterns in colon and rectal surgery*. *Journal of the American College of Surgeons*, 2006. **203**(3): p. 322-7.

Level of Rectal Cancer

Defining Attributes

Definition: Level of rectal cancer from in centimetres from anal verge.

Coverage: This item should be reported for:
 Cases where Primary Site of Cancer is Rectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|-------------|
| NN | Number |

Domain Definitions: The data domain definitions for this data element are shown in the table below.

| Code | Definition |
|------|--|
| NN | User to enter measurement in centimetres |

Clarifying Points: The clinician enters the measurement in centimetres from best available information (digital rectal examination, rigid sigmoidoscopy, colonoscopy, operative findings)

Collection Methods: The measurement should be present in the patient's physical or electronic medical record.

Validation Rules: Must = integer

Justification: The anatomical site of tumours is captured by the ICD-10 codes. However, there is a need for more precise anatomical localisation of rectal tumours. Rectal cancers tend to have a less favourable prognosis than colon cancers [1-3]. In addition, rectal cancers positioned lower down in the rectum are associated with an increased recurrence rate, compared to cancers positioned in the mid- or upper regions of the rectum [4, 5]. This poor prognosis may be due to an increased risk of having an involved margin [6-8] and a reduced space for tumour spread. The phrasing of this item is based on the 6th Edition of the UICC Staging Manual, which states that a rectal cancer is defined as one that is situated ≤ 12 cm from the anal verge by rigid proctoscopy [9]. The anatomical site is defined by the surgeon and this information would be captured on the surgical request form.

Representation

| | |
|---------------------------|--------------------------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Numeric with one decimal place |
| Minimum Size: | 4 |
| Maximum Size: | 4 |
| Layout: | N (4) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

| | |
|----------------------|----------------|
| Related Data: | Not Applicable |
|----------------------|----------------|

- References:**
1. Halvorsen, T.B. and E. Seim, *Tumour site: a prognostic factor in colorectal cancer? A multivariate analysis*. Scandinavian Journal of Gastroenterology, 1987. **22**(1): p. 124-8.
 2. Wolmark, N., et al., *The prognostic significance of tumor location and bowel obstruction in Dukes B and C colorectal cancer. Findings from the NSABP clinical trials*. Annals of Surgery, 1983. **198**(6): p. 743-52.
 3. Wolters, U., et al., *Colorectal cancer--a multivariate analysis of prognostic factors*. European Journal of Surgical Oncology, 1996. **22**(6): p. 592-7.
 4. Bentzen, S.M., et al., *Time to loco-regional recurrence after resection of Dukes' B and C colorectal cancer with or without adjuvant postoperative radiotherapy. A multivariate regression analysis*. British Journal of Cancer, 1992. **65**(1): p. 102-7.
 5. Pilipshen, S.J., et al., *Patterns of pelvic recurrence following definitive resections of rectal cancer*. Cancer, 1984. **53**(6): p. 1354-62.
 6. Quirke, P. and M.F. Dixon, *The prediction of local recurrence in rectal adenocarcinoma by histopathological examination*. International Journal of Colorectal Disease, 1988. **3**(2): p. 127-31.
 7. Quirke, P., et al., *Local recurrence of rectal adenocarcinoma due to inadequate surgical resection. Histopathological study of lateral tumour spread and surgical excision*. Lancet, 1986. **2**(8514): p. 996-9.
 8. Nagtegaal, I.D., et al., *Circumferential margin involvement is still an important predictor of local recurrence in rectal carcinoma: not one millimetre but two millimetres is the limit*. American Journal of Surgical Pathology, 2002. **26**(3): p. 350-7.
 9. Greene, F.L., et al., eds. *AJCC Cancer Staging Manual*. 6th ed. 2002, Springer: New York.

Residual Tumour Status

Defining Attributes

Definition: This item pertains to the overall completeness of the resection of the tumour.

Coverage: This item should be reported for:

- Cases where Primary Site of Cancer is Colorectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|-------------|
| 0 | R0 |
| 1 | R1 |
| 2 | R2 |
| 9 | RX |

Domain Definitions: The data domain definitions for this data element are shown in the table below.

| Code | Definition |
|------|---------------------------------|
| 0 | R0 – No residual tumour |
| 1 | R1 – Microscopic residual |
| 2 | R2 – Macroscopic residual |
| 9 | RX – Residual status is unknown |

Clarifying Points: This information is required to adequately stage the cancer. To be determined by pathologist using clinical information provided by the surgeon and by histopathological assessment.

Collection Methods: If a resection was performed the pathology results of the resection should be present in the patient's physical or electronic medical record. The pathology report should thus be used to determine the result.

Validation Rules: Must = 0, 1, 2 or 9

Justification: The residual tumour status (R stage) is described as in the 6th Edition AJCC/UICC guidelines. This item pertains to the overall completeness of resection of the tumour, including evidence of residual disease at surgical margins (distal, proximal, radial) or within regions in which resection has not been attempted.

As prognosis is strongly influenced by the completeness of resection,

it is essential that residual tumour status is consistently applied. The following points are therefore clarified in the 6th Edition AJCC/UICC guidelines [1]:

- a) R0 classification may include M1 cases if both the primary tumour and the distant metastasis are completely resected by curative surgery.
- b) “Tumour cells in lymph or blood vessels at the resection margin without contact with the endothelium or invasion of the vessel wall” are classified as R0 [2].

Regarding the application of the R status to surgical margins, it is agreed that R1 classification indicates microscopic evidence that the tumour is transected by the surgical margin. While rectal tumours that are ≤ 1 mm from the resection margin may be considered to have an “involved” margin, they should be classified as R0 unless they are transected by the margin,

With regard to presence of residual disease in areas which have not been resected (e.g. involvement of other organs by trans-cavitary spread), it is the responsibility of the surgeon to recognise and report these deposits so that the histopathology report is accurate.

It should be noted that the reporting of R status does not in itself identify the margin (if any) that is involved. Thus with the exception of radial margin in rectal tumours, the location of margin involvement will not be captured within the minimum dataset, although it is likely to be provided in the full report. In the case of rectal cancers, it has been shown that involvement of the distal margin may be a significant risk factor for local recurrence [3], although this was not the case in earlier studies [4, 5]. All studies however, agreed that involvement of the distal margin in rectal cancer was not a significant factor for overall survival. It was therefore agreed that it is not necessary to include the location of the incomplete resection margin as a specific element within the MDS.

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | N(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Data: Not Applicable

- References:**
1. Greene, F.L., et al., eds. *AJCC Cancer Staging Manual*. 6th ed. 2002, Springer: New York.
 2. Wittekind, C., et al., *TNM residual tumor classification revisited*. *Cancer*, 2002. **94**(9): p. 2511-6.
 3. Law, W.L. and K.W. Chu, *Anterior resection for rectal cancer with mesorectal excision: a prospective evaluation of 622 patients*. *Annals of Surgery*, 2004. **240**(2): p. 260-8.
 4. Cawthorn, S.J., et al., *Extent of mesorectal spread and involvement of lateral resection margin as prognostic factors after surgery for rectal cancer.[see comment]*. *Lancet*, 1990. **335**(8697): p. 1055-9.
 5. 15. Adam, I.J., et al., *Role of circumferential margin involvement in the local recurrence of rectal cancer. [See comment]*. *Lancet*, 1994. **344**(8924): p. 707-11.

Non-peritonealised Circumferential Margin in Rectal Tumours

Defining Attributes

Definition: Refers to the completeness of resection at the non-peritonealised circumferential resection margin.

Coverage: This item should be reported for:

- Cases where Primary Site of Cancer is Rectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|-----------------------|
| NNN | Number in millimetres |

Domain Definitions:

| Code | Definition |
|------|--|
| NNN | User to enter measurement in millimetres |

Clarifying Points:

- Important indicator of quality of surgery and prognosis for local recurrence.
- Tumour is defined as any tumour deposit (primary/lymph/vessel/micrometastases etc).

Collection Methods: If a resection was performed the pathology results of the resection should be present in the patient's physical or electronic medical record. The pathology report should thus be used to determine the margins.

Validation Rules: Must = number in millimetres

Justification: This item is specific for rectal cancer and refers to the completeness of resection at the non-peritonealised circumferential resection margin. There are many terms that describe this margin, including mesorectal margin and radial margin, *inter alia*. These terms are used herein synonymously with the non-peritonealised circumferential resection margin. The term margin is used here to refer to true surgical resection margins and does not include naturally occurring surfaces such as serosa. Involvement of the latter is captured in the T stage.

Involvement of the non-peritonealised circumferential resection margin has been shown to be a significant prognostic factor for local and distant recurrence and overall survival in rectal cancer [1-5], which validates this item's inclusion in the MDS.

Involvement of the non-peritonealised circumferential resection margin by tumour is defined as tumour present at or within 1 mm of the margin. This may mean that a rectal tumour has an involved radial margin (within 1 mm), but is classified as R0, as the margin does not actually transect the tumour.

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Numeric |
| Minimum Size: | 1 |
| Maximum Size: | 3 |
| Layout: | N(3) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Data: Not Applicable

References:

1. Quirke, P., et al., *Local recurrence of rectal adenocarcinoma due to inadequate surgical resection. Histopathological study of lateral tumour spread and surgical excision*. Lancet, 1986. **2**(8514): p. 996-9.
2. Cawthorn, S.J., et al., *Extent of mesorectal spread and involvement of lateral resection margin as prognostic factors after surgery for rectal cancer.[see comment]*. Lancet, 1990. **335**(8697): p. 1055-9.
3. Adam, I.J., et al., *Role of circumferential margin involvement in the local recurrence of rectal cancer. [See comment]*. Lancet, 1994. **344**(8924): p. 707-11.
4. Ng, I.O., et al., *Surgical lateral clearance in resected rectal carcinomas. A multivariate analysis of clinicopathologic features. [See comment]*. Cancer, 1993. **71**(6): p. 1972-6.
5. 17. Wibe, A., et al., *Prognostic significance of the circumferential resection margin following total mesorectal excision for rectal cancer. [See comment]*. British Journal of Surgery, 2002. **89**(3): p. 327-34.

Lymphovascular Invasion

Defining Attributes

Definition: The identification of tumour within an endothelial lined channel.

Coverage: This item should be reported for:

- Cases where Primary Site of Cancer is Colorectal and lymphovascular invasion was tested

Guide for Use

Data Domain: The valid domains and their descriptions are described in the table below.

| Code | Description |
|------|-------------|
| 0 | No |
| 1 | Yes |
| 9 | Unknown |

Domain Definitions: The domain definitions are provided in the table below.

| Code | Definition |
|------|---|
| 0 | No: Lymphovascular invasion was absent |
| 1 | Yes: Lymphovascular invasion was present |
| 9 | Unknown: It is unknown whether lymphovascular invasion was present or absent |

Clarifying Points:

- Often seen as an indicator to receive adjuvant chemotherapy in Stage II tumours.
- Defined as the identification of tumour within an endothelial lined channel.
- Haematoxylin and eosin staining is considered standard. The use of other staining methods should be noted.

Collection Methods: This information should be obtained from a pathology report or system, and/or the patient's medical record and recorded on the hospital's patient administration system.

Validation Rules: Must = 0, 1 or 9

Justification: The identification of lymphovascular invasion in fixed tissue specimens can be complicated by tumour-induced fibrosis and fixation artefact. Even following the recognition of vascular spaces, it can be difficult to differentiate between venous and lymphatic vessels [1, 2]. For these and other reasons, agreement among pathologists in identification of lymphovascular invasion, is often poor [3, 4].

It is debatable whether special techniques, such as histochemical and immunohistochemical stains, to identify elastic tissue or endothelium increase the ease or accuracy of evaluation. Because these techniques are also labour intensive and time consuming they are not performed routinely. Accordingly, special stains are not recommended. The number of blocks reviewed and the type and cut of the tissue examined have also been shown to impact on the probability of studies identifying venous invasion [5].

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | N(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Elements: Not applicable

References:

1. Nakamura, Y., et al., *Importance of lymph vessels in gastric cancer: a prognostic indicator in general and a predictor for lymph node metastasis in early stage cancer*. Journal of Clinical Pathology, 2006. **59**(1): p. 77-82.
2. Van den Eynden, G.G., et al., *Distinguishing blood and lymph vessel invasion in breast cancer: a prospective immunohistochemical study*. British Journal of Cancer, 2006. **94**(11): p. 1643-9.
3. Cooper, H.S., et al., *Endoscopically removed malignant colorectal polyps: clinicopathologic correlations*. Gastroenterology, 1995. **108**(6): p. 1657-65.
4. Komuta, K., et al., *Interobserver variability in the pathological assessment of malignant colorectal polyps*. British Journal of Surgery, 2004. **91**(11): p. 1479-84.
5. 22. Sternberg, A., et al., *Detection of venous invasion in surgical specimens of colorectal carcinoma: the efficacy of various types of tissue blocks*. Journal of Clinical Pathology, 2006. **59**(2): p. 207-10.

Number of Lymph Nodes Examined

Defining Attributes

Definition: The total number of lymph nodes examined.

Coverage: This item should be reported for:
 Cases where Primary Site of Cancer is Colorectal

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|-------------|
| NN | Integer |

Domain Definitions: The data domain definitions for this data element are shown in the table below as per the ROADS Manual, 1998 [1].

| Code | Definition |
|------|---|
| NN | Number of lymph nodes examined |
| 00 | No regional lymph nodes removed |
| 01 | One regional lymph node removed |
| 02 | Two regional lymph nodes removed |
| ... | |
| 90 | Ninety or more regional lymph nodes removed |
| 95 | No regional lymph nodes removed but aspiration of nodes was performed |
| 96 | Regional lymph node removal documented as a sampling and number of lymph nodes unknown/not stated |
| 97 | Regional lymph node removal documented as a dissection and number of lymph nodes unknown/not stated |
| 98 | Regional lymph nodes surgically removed but number of nodes unknown/not stated and not documented as sampling or dissection |

Clarifying Points: Influences N Stage.

The result of the pathology results indicate the extent to which the cancer has spread into the lymph nodes/ lymphatic system.

Collection Methods: If a lymph node examination has been performed the Pathology Reports should document this.

Validation Rules: Must = Integer

Justification:

It is agreed that the number of nodes examined is important to the prognosis of the patient. The 6th Edition of the AJCC/UICC guidelines for staging of CRC recommends that a minimum of 7-14 nodes are required for accurate prognostication based on N stage [2]. It is also recommended that this number should be seen as a minimum and not as a maximum number of nodes to be counted i.e. if more nodes are available then these should also be examined. It is noted that this definition is not universally agreed upon (reviewed in [3]), and that the previous UICC version (5th Edition) listed 12 nodes as a minimum requirement.

The minimum number of lymph nodes to be assessed is a much debated topic, with proposed numbers ranging from 6-17 (reviewed in [3]). An increase in the number of lymph nodes that are assessed will improve the statistical chance of finding a positive node, which will impact on the staging of the tumour and possibly the treatment that the patient will receive. [4]. It is agreed that the UICC recommendation of 7-14 nodes should be followed where possible. It is recognised that in some cases, such as where the patient has undergone a palliative resection or has received pre-operative treatment, lesser numbers of lymph nodes may be retrieved.

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Integer |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | I(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

| | |
|----------------------|-------------|
| Related Data: | Data Item 8 |
|----------------------|-------------|

References:

1. Commission on Cancer. *Registry Operations and Data Standards (ROADS)*, Volume II of the Standards of the Commission on Cancer, three-volume set. Chicago, IL: American College of Surgeons, 1998.
2. Greene, F.L., et al., eds. *AJCC Cancer Staging Manual*. 6th ed. 2002, Springer: New York.
3. Cserni, G., *Nodal staging of colorectal carcinomas and sentinel nodes*. [See comment]. *Journal of Clinical Pathology*, 2003. **56**(5): p. 327-35.
4. Goldstein, N.S., Lymph node recoveries from 2427 pT3 colorectal resection specimens spanning 45 years: recommendations for a minimum number of recovered lymph nodes based on predictive probabilities. [See comment]. *American Journal of Surgical Pathology*, 2002. **26**(2): p. 179-89.

Number of Lymph Nodes Involved

Defining Attributes

Definition: The total number of regional lymph nodes examined by the pathologist and reported as containing malignant tumour.

Coverage: This item should be reported for:

- Cases where Primary Site of Cancer is Colorectal and a lymph node dissection has been performed.

Guide for Use

Data Domain: The data domains for this data element are shown in the table below.

| Code | Description |
|------|-------------|
| NNN | Integer |

Domain Definitions: The data domains for this data element are shown in the table below as per the ROADS manual (1998) [1].

| Code | Description |
|------|---|
| NNN | Number of lymph nodes involved |
| 00 | All nodes examined negative |
| 01 | One positive lymph node |
| 02 | Two positive lymph nodes |
| ... | |
| 10 | Ten positive lymph nodes |
| 96 | 96 positive lymph nodes |
| 97 | Positive nodes but number not specified |
| 98 | No nodes examined |
| 99 | Unknown is nodes are positive or negative |

Clarifying Points: Influences N Stage.

The result of the pathology results indicate the extent to which the cancer has spread (metastasised).

Collection Methods: A lymph node must be excised to determine the number of lymph node involvements. This would be sent to Pathology; therefore the Pathology reports should document this.

Validation Rules: Must = Integer

Justification:

In the 6th Edition of the AJCC/UICC [2] the following clarifications have been made to this item:

- Deposits of tumour adipose tissue are classified as lymph nodes if their form is consistent with a lymph nodes origin and they have a smooth contour. Deposits with a rough or non-smooth contour should be classified as a discontinuous T3 adenocarcinoma and also classified as venous invasion. In the previous 5th Edition this clarification depended upon the size of the deposit (< 3 mm) and not on its form or contour.
- The identification or involvement of an apical node is no longer reported (designated N3 in the previous 5th Edition).

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Integer |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | I(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Data: Data Item 7

References:

1. Commission on Cancer. *Registry Operations and Data Standards (ROADS)*, Volume II of the Standards of the Commission on Cancer, three-volume set. Chicago, IL: American College of Surgeons, 1998.
2. Greene, F.L., et al., eds. *AJCC Cancer Staging Manual*. 6th ed. 2002, Springer: New York.

Date of Resection of Primary Tumour

Defining Attributes

Definition: The date a resection was performed to remove the primary tumour.

Coverage: This item should be reported for:
 Cases where Primary Site of Cancer is Colorectal

Guide for Use

Data Domain: Standard date format (ddmmyyyy).

| Code | Description |
|------|--|
| DD | Day of month (use leading zeros for 1 to 9 e.g. "01", "02") |
| MM | Month of the year (use leading zeros for 1 to 9 e.g. "01", "02") |
| YYYY | Year (use 4 digit format e.g. "2005", "2006") |

Domain Definitions: ddmmyyyy

Clarifying Points: Date that the definitive surgical procedure was carried out to treat the primary cancer

Collection Methods: This information should be obtained from a pathology report or system, and/or the patient's medical record and recorded on the hospital's patient administration system.

Validation Rules: Must = a valid date
Must be = or > date of birth
Must be < date of separation

Justification: The date of resection of the primary tumour is an important data point, which can be used to calculate the following: 30 day surgical mortality, length of stay in hospital (from day of operation), time from diagnosis to surgery, time from neo-adjuvant therapy to surgery, complication data (e.g. re-admission or re-operation rates within 30 days of surgery) and time to start adjuvant therapy after surgery. Many survival curves are also generated from date of operation. This item will be captured by the surgical request form

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data element |
| Data Type: | Numeric Date |
| Form: | Date |
| Minimum Size: | 8 |
| Maximum Size: | 8 |
| Layout: | (ddmmyyyy) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

| | |
|----------------------|----------------|
| Related Data: | Not Applicable |
| References: | Not Applicable |

Mismatch Repair Deficiency (MMRD)

Defining Attributes

Definition: Detection of Mismatch Repair Deficiency found is relevant to genes

Coverage: This item should be reported for:
 Cases where Primary Site of Cancer is Colorectal.

Guide for Use

Data Domain: The domain values for this data element are shown in the table below.

| Code | Description |
|------|-------------|
| 0 | No Staining |
| 1 | Staining |
| 2 | Not Done |

Domain Definitions:

| Code | Definition |
|------|------------------------|
| 0 | No Staining (abnormal) |
| 1 | Staining (normal) |
| 2 | Not Done |

Clarifying Points: Indicator of underlying germline predisposition to colorectal cancer in some cases.
Prognostic and predictive factor for colorectal cancer.

Collection Methods: This would be found in the patient's physical or electronic medical record. Specifically on the histopathology report

Validation Rules: Must = 0, 1 or 2

Justification: A mutation in mismatch repair genes (mainly MLH1, PMS2, MSH2 and MSH6) can cause an accumulation of DNA mutations that result in the initiation of cancer. Mismatch repair deficient (MMRD) cancers occur either sporadically (~12%) or less commonly (~2%) because the individual suffers from hereditary non-polyposis colorectal cancer (HNPCC). Tumours which show loss of MMR proteins by immunohistochemistry are almost always characterised by microsatellite instability (MSI), which is determined by analysis of tumour DNA.

Immunohistochemical (IHC) analysis of mismatch repair proteins is used to detect MMRD in colorectal cancer, with an absence of one or more of the mismatch repair proteins considered an abnormal result.

MMRD can also be determined by microsatellite analysis, which is the amplification and analysis of selected microsatellite loci within the genome of the tumour cells. However, this later technique is not used routinely in diagnostic pathology settings. MMR testing is currently recommended for all cases of colorectal cancer arising in individuals less than 50 years of age, although this cut off is arbitrary.

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric |
| Form: | Code |
| Minimum Size: | 1 |
| Maximum Size: | 1 |
| Layout: | N(1) |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

| | |
|----------------------|----------------|
| Related Data: | Not Applicable |
| References: | Not Applicable |

Site of First Recurrence

Defining Attributes

Definition: The term recurrence refers to the return or reappearance of a primary cancer after a disease-free intermission or remission. The cancer may recur in more than one site (e.g. both locally or as distant metastases).

The anatomical position of the tumour expressed as a diagnosis at first recurrence.

Coverage: This item should be reported for:

Cases where Primary Site of Cancer is Colorectal and patient had local or distant cancer recurrence

Guide for Use

Data Domain: The domain values for this data element are shown in the table below.

| Code | Description |
|------|--------------------------------|
| 0 | None |
| 1 | Local |
| 2 | Distant |
| 3 | Both local and distant |
| 7 | Patient was never disease-free |
| 8 | Recurred but site unknown |
| 9 | Unknown if recurred |

Domain Definitions:

| Code | Definition |
|------|--------------------------------|
| 0 | None |
| 1 | Local |
| 2 | Distant |
| 3 | Both local and distant |
| 7 | Patient was never disease-free |
| 8 | Recurred but site unknown |
| 9 | Unknown if recurred |

Clarifying Points:

- For colorectal cancers local recurrence is defined as clinically or histopathologically verified recurrent disease at the site of the bowel anastomosis or in adjacent soft tissue, but excluding lymph node involvement.
- With regard to rectal cancer only, local recurrence is defined as clinically or histopathologically verified recurrent disease in the pelvis, including the site of the bowel anastomosis and the perineal wound [1]. This definition applies irrespective of whether

new distant metastases are present or absent.

- All other recurrences, including any lymph node involvement, are considered distant.

Collection Methods: This would be found in the patient's physical or electronic medical record.

Validation Rules: Must = 0, 1, 2, 3, 7, 8 or 9

Justification: This item allows for recognition of patterns of disease recurrence.

Representation

Data Element Type: Data Element

Data Type: Numeric

Form: Code

Minimum Size: 1

Maximum Size: 1

Layout: N(1)

Administrative Information

Version: 1

Effective date: 1 Mar 2007

Related Information

Related Data: Data Item 12

References:

1. Hansen, M.H., et al., *Impact of radiotherapy on local recurrence of rectal cancer in Norway*. British Journal of Surgery, 2007. **94**(1): p. 113-8.

Date of First Recurrence

Defining Attributes

Definition: The date the medical practitioner confirms the diagnosis of a recurrent or metastatic cancer of the same histology.

Coverage: This item should be reported for:

Cases where Primary Site of Cancer is Colorectal and patient has a local or distant cancer recurrence

Guide for Use

Data Domain: Standard date format (ddmmyyyy).

| Code | Description |
|------|--|
| DD | Day of month (use leading zeros for 1 to 9 e.g. "01", "02") |
| MM | Month of the year (use leading zeros for 1 to 9 e.g. "01", "02") |
| YYYY | Year (use 4 digit format e.g. "2005", "2006") |

Domain Definitions: ddmmyyyy

Clarifying Points: Date of diagnosis of recurrence.

Collection Methods: This would be found in the patient's physical or electronic medical record.

Validation Rules:

- Must = a valid date
- Must be = or > date of birth
- Must be < date of separation
- Must be > date of diagnosis of cancer

Justification: This data is required for assessment of recurrence free survival. Potential biases in the collection of this data, including differences in follow-up protocols and definitions of recurrence need to be recognised.

Representation

| | |
|---------------------------|--------------|
| Data Element Type: | Data Element |
| Data Type: | Numeric date |
| Form: | ddmmyyyy |
| Minimum Size: | 8 |
| Maximum Size: | 8 |
| Layout: | ddmmyyyy |

Administrative Information

| | |
|------------------------|------------|
| Version: | 1 |
| Effective date: | 1 Mar 2007 |

Related Information

Related Data: Data Item 11

References: AIHW. *Data Set Specification Cancer (Clinical) National Health Data Dictionary version 12 Supplement*. Canberra: 2004.

8. List of Abbreviations

| | |
|-----------|---|
| AJCC | American Joint Committee for Cancer |
| CAP | College of American Pathologists |
| cm | centimetre |
| CRC | colorectal cancer |
| DNA | deoxyribose nucleic acid |
| HNPCC | hereditary non-polyposis colorectal cancer |
| hpf | high power field |
| ICD-10 | International Statistical Classification of Diseases for Oncology and Related Health Problems, Tenth Revision |
| IHC | immunohistochemistry |
| MDS | minimum data set |
| mm | millimetre |
| MMRD | mismatch repair deficiency |
| MSI | microsatellite instability |
| MSS | microsatellite stability |
| CINNSW | New South Wales Cancer Institute |
| NSWOG | New South Wales Oncology Group |
| NSWOG-CRC | New South Wales Oncology Group – Colorectal Cancer Group |
| UK | United Kingdom |