The New South Wales Colorectal Cancer Care Survey 2000
Part 3. Radiotherapy management for rectal cancer

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Summary

The primary aim of the New South Wales (NSW) Colorectal Cancer Care Survey was to determine the proportion of colorectal cancer cases in NSW managed according to recommendations in the initial version of the National Health and Medical Research Council (NHMRC) guidelines (http://www.nhmrc.gov.au/publications/synopses/cp106/cp106syn.htm). These guidelines were released and widely disseminated to practitioners involved in the management of patients with colorectal cancer including surgeons and radiation and medical oncologists in Australia just before this survey began.

Information was sought from primary treating practitioners regarding their management of patients newly diagnosed with colorectal cancer who were notified to the NSW Central Cancer Registry between 1 February 2000 and 31 January 2001; 94% of eligible patients ascertained were diagnosed in 2000, 2% in 1999 and 4% in 2001. This report covers initial radiotherapy treatment for rectal cancer. Previous reports described the surgical [1] and chemotherapy management[2] of these patients as well as patients with colon cancer.

Data on radiotherapy treatment were obtained for 288 (97%) of 296 patients in this survey who received radiotherapy as part of their initial treatment. Assessment of radiotherapy management with reference to the guidelines was limited to 238 patients who had only one primary rectal cancer diagnosed.

Concordance of management with NHMRC guidelines is summarised below for the recommendations relating to radiotherapy management.

NHMRC Guideline	**Management**
Adjuvant therapy for rectal cancer	
When chemotherapy is given postoperatively in combination with radiotherapy, protracted venous infusion of 5-FU chemotherapy may offer further benefits in survival when compared to bolus 5-FU therapy. It is the recommended way of delivering combined modality therapy. (Level II evidence)	When chemotherapy was given post-operatively in combination with radiotherapy, 48% of patients were given infusional 5-FU chemotherapy (Table 21).
Postoperative 5-FU based chemotherapy and radiotherapy (combined modality therapy) is recommended for patients with high-risk rectal cancer. (Level II evidence)	41% of patients with tumours that had penetrated beyond the full thickness of the bowel wall, or involved regional nodes, received combined modality therapy. 18% of high-risk rectal cancer patients received combined modality therapy based on post-operative radiotherapy (Table 8).

Management of locally advanced rectal cancer	
Preoperative radiation therapy, possibly with chemotherapy, is recommended in rectal cancers fixed or tethered within the pelvis if it is felt down-staging will enable successful resection. (Level II evidence)	67% of patients with tumours deemed locally advanced pre-operatively were given pre-operative radiotherapy alone or with chemotherapy (Table 10).
Radiation therapy should be considered in patients with locally advanced rectal cancer not amenable to surgery. (Level III evidence)	Most patients (3 out of 4) with locally advanced rectal cancer not amenable to surgery received radiotherapy (Table 10).
Participation in clinical trials	
Doctors should encourage patients with colorectal cancer to consider participating in appropriate clinical trials for which they are eligible. (Expert opinion)	2% of patients were eligible for a trial. Only 1% of all patients in this survey participated in a trial (Figure 1).
Follow up intentions	
All patients who have undergone surgery for colorectal cancer should have specialist follow up in conjunction with the patient's general practitioner. (Expert opinion)	85% of patients were to be followed-up by a specialist. In 38% of cases treated with radiotherapy, the attending radiation oncologist indicated that he or she intended to participate in the patient's follow-up (Table 23).

Generally, there was poor concordance between use of radiotherapy in practice for rectal cancer in NSW in 2000 and recommendations in NHMRC guidelines pertaining to the use of radiotherapy with or without chemotherapy. Less than half of high-risk rectal cancer patients received chemotherapy in combination with radiotherapy post-operatively. When 5-FU chemotherapy was given post-operatively in combination with radiotherapy, 48% received it via infusion. Two-thirds of patients considered to have locally advanced disease pre-operatively were given radiotherapy alone or in combination with chemotherapy before surgery. The results indicate there is scope for improvement in the management of rectal cancer, especially for patients at high risk of recurrence.

The NHMRC guidelines for the management of colorectal cancer have recently been reviewed and updated. More effective and rapid uptake of evidence into radiotherapy treatment for colorectal cancer should be supported by more organised and active steps of professional organisations, health services and the Cancer Institute NSW to ensure that guidelines are communicated to radiation oncologists in ways that have been shown to influence practice.

Background

Australia has one of the highest incidence rates of colorectal cancer in the world. In 2001 there were 12,844 new cases and 4754 deaths from the disease.[3] Important advances in the last decade such as the use of "adjuvant" post-operative chemotherapy have allowed for significant improvement in its outcomes. [4,5]

Comprehensive guidelines on the management of colorectal cancer were developed by the Clinical Oncological Society of Australia (COSA) in conjunction with the Australian Cancer Network (ACN). The guidelines were then endorsed by the National Health and Medical Research Council (NHMRC) and the initial version was released in late 1999. All surgeons and oncologists in Australia were sent a copy of these guidelines[6] which are available at http://www.nhmrc.gov.au/publications/synopses/cp62syn.htm. They were updated in 2005, however the initial version was used for the standard of care for this survey as it was contemporaneous to the cohort.

Given the evidence indicating significant variation in colorectal cancer treatments and outcomes, together with the availability of a defined standard of care and difficulties with the implementation of clinical management guidelines, it was considered timely to obtain a baseline record of existing management practices and outcomes for this disease in NSW.

Some of the data from the NSW survey contributed to the National Colorectal Cancer Care Survey which was conducted on all newly diagnosed colorectal cancer patients notified to each Australian Cancer Registry between 1 February and 30 April 2000. [7] This survey showed among other things, that there was less than 50% concordance for eight of the 23 NHMRC guidelines analysed. Variations in the types of operation performed, participation in clinical trials, and the use of adjuvant therapy (which varied by patient's age) were also observed. In relation to the National Cancer Institute's recommendation, 76% of patients with Stage C colon cancer were offered chemotherapy, with 64% of patients with Stage C colon cancer receiving it.

Rectal cancer represents almost a third of the colorectal cancers diagnosed in Australia with 4301 new cases and 1359 deaths from the disease in 2001.[3] Local recurrence remains a significant problem in the management of rectal cancer as it may require further surgery and approximately one-third of patients survive a further five-years.[8]

Multiple randomised trials and meta-analyses have provided strong support for the effectiveness of radiotherapy in reducing local recurrence.[5,6] Approximately half of patients present with Dukes stage B and C rectal cancer and according to NHMRC guidelines these patients should be considered for radiotherapy.[6] Studies looking at optimal utilisation of radiotherapy for rectal cancer suggest that nearly 69% of all rectal cancer patients should receive radiotherapy as part of their initial management.[9]

Utilisation of radiotherapy varies widely and there are a multitude of reasons. A US study of 534 patients with stage II and stage III rectal cancers showed that radiotherapy was used less often among older patients, black patients, and those initially treated in low-volume hospitals. Physicians' reasons for not providing

radiotherapy included patient refusal (22%), co-morbid illness (14%) or lack of clinical indication (45%).[10]

In Australia an optimal utilisation rate for radiotherapy was modelled based on treatment guidelines and incidence data. Radiotherapy was indicated in 61% of patients with rectal cancer. The actual radiotherapy utilisation rate for rectal cancer (38%) fell short of the optimal rate. Factors that influence this low rate of radiotherapy utilisation are unknown.[11]

The data collected in the NSW survey in 2000 provides an opportunity to explore further the use of radiotherapy in the management of rectal cancer.

Coverage

This report describes the initial radiotherapy treatment of rectal cancer (excluding carcinoma in-situ) in NSW, Australia, predominantly in the year 2000. Rectal cancers are defined as those tumours located in the upper, middle or lower third of the rectum, excluding rectosigmoid cancers. All detailed analyses are based on patients who had only one primary colorectal cancer treated in the episode of care that was surveyed.

Aims

The aims of the NSW Colorectal Cancer Care Survey were to obtain a comprehensive record of the management and outcomes of patients with newly diagnosed colorectal cancer in NSW in 2000. The survey sought to determine:

1. The proportion of colorectal cancer cases in NSW managed according to recommendations in the NHMRC guidelines.

2. The variables associated with the patient, their cancer and their doctor, that are associated with management that is in accordance with guideline recommendations.

3. The two-year disease free survival and overall survival rates for the patients studied.

4. The level of concordance with the guidelines and how this relates to recurrent disease and cancer-specific and overall survival for this cohort.

This report addresses points 1 and 2 above in relation to radiotherapy for rectal cancer only. At the time of this survey, there were no Australian treatment guidelines relating to radiotherapy for colon cancer; although 43 patients receiving initial treatment for primary colon cancer (out of a total of 2161 surveyed) were reported in the survey to have received radiotherapy (unpublished data).

Methods

Questionnaires were designed to record key aspects of the management of colorectal cancer described in the NHMRC guidelines. Separate questionnaires were used to collect information pertinent to radiotherapy (Appendix 1), surgery (Appendix 2) and chemotherapy. A multidisciplinary Expert Advisory Group of clinicians provided oversight for the development of these questionnaires (Appendix 3). Completion of the questionnaires by practitioners was validated against separate abstraction of information from records in a pilot study.

Patients newly diagnosed with colorectal cancer and notified to the NSW Central Cancer Registry between 1 February 2000 and 31 January 2001 were entered into this survey. Patients were excluded if they only had benign tumours, had a previous primary colorectal cancer, were treated outside NSW or were non-Australian residents.

Practitioners who treated these patients were identified from Cancer Registry notifications and were sent the relevant questionnaires seeking information on treatment received within their speciality. The contact details of other practitioners who treated these patients were also requested, the relevant questionnaires were then sent to these practitioners.

Unreturned questionnaires were followed up with reminder letters and phone calls. Field collection was done to abstract information from patients' medical records if a practitioner requested it. Patients were not contacted for this survey.

Data collected were entered in an Access database then analysed using Statistical Analysis System, Version 8 (SAS). Analysis was restricted to people with rectal cancer for this report.

Approval for the conduct of this survey was obtained from the Ethics Committees of The Cancer Council NSW and the University of Newcastle. Where necessary, ethics clearance was also obtained from Area Health Services or institutions where field collection was performed.

Scope of this Report

This report covers aspects related to the initial radiotherapy management of patients with rectal cancer. Separate reports and publications cover, or will cover, the following aspects of colorectal cancer management and outcomes:

- Histopathology reporting[12]
- Surgery[1]
- Predictors of evidence-based surgical care[13]
- Chemotherapy[2]
- Follow-up investigations and clinical outcomes (in preparation)

Data Quality

Representativeness of the sample

This was a population based survey done with the aim of obtaining data on all eligible cases of colorectal cancer notified to the NSW Central Cancer Registry in the year 2000.

Since 1972, notification of malignant neoplasms to the Cancer Registry has been a statutory requirement in NSW for all public and private hospitals, pathology laboratories, radiation oncology departments, nursing homes and the Registry of Births, Deaths and Marriages. This has led to the keeping of accurate population statistics for most malignancies. In 2000, 94% of colon cancers and 96% of rectal cancer cases had histological verification of the disease. As a rough index of the completeness of notification, the proportion of cases in NSW, where the only source of notification was from a death certificate, was 0.4% for colon and 0.1% for rectal cancers.[14] Therefore the accrual of consecutively notified cases of colorectal cancers for a 12-month period in NSW provided a sample representative of colorectal cancer cases.

Questionnaire response rate

Data were obtained for 288 (97%) of 296 radiotherapy questionnaires sent to radiation oncologists. Of those questionnaires returned, 245 were for patients with rectal cancer. This high return rate ensures that the radiotherapy management recorded in the survey was representative of the management of patients with rectal cancer in NSW.

Validity of radiotherapy questionnaire

Questionnaires used in this survey were designed specifically to record aspects of management covered in the NHMRC guidelines for the management of colorectal cancer. Performance indicators were developed to measure the conformity of practice to each of the major guideline recommendations. Data items required to construct each performance indicator were then identified. Questions were designed to collect information pertinent to the data items required.

The radiotherapy questionnaire sought details of radiotherapy management. Its purpose was not to identify the reasons why patients did not have radiotherapy. Hence data from the surgical questionnaires are also used in this report to supplement the information provided in the radiotherapy questionnaires. This includes information on the factors that influence the use of radiotherapy.

Accuracy of the data collected

A pilot study was performed, before commencement of the main survey, to test and validate the questionnaires for collecting information on the management of colorectal cancer from patients' treating practitioners. Sixty questionnaires were sent to practitioners in metropolitan Sydney who were identified from an earlier batch of first colorectal cancer notifications received at the NSW Central Cancer Registry. The survey's project coordinator validated data provided from the practitioners by checking the completed forms against information held in patients' hospital or clinic medical records.

The discrepancies found between the questionnaire and patient records were minor and did not indicate that any modifications to the questionnaire would be required.

For the main study, a trained field officer abstracted information from patient records when practitioners were unable to fill in the questionnaires but were willing to provide access to patient records.

Coverage of guideline recommendations

This report covers guidelines from the following topics in the NHMRC guidelines:

- Adjuvant therapy for rectal cancer
- Management of recurrent and advanced rectal cancer

Where sections of the report are relevant to the guidelines they have been stated. The levels used in the guidelines to categorise the evidence supporting a particular guideline are listed below. When no level of evidence is given it means that the guideline is based on consensus of expert opinion.

Level I	*Evidence obtained from systematic review of all relevant randomised controlled trials.*
Level II	*Evidence obtained from at least one properly designed randomised controlled trial.*
Level III	*Evidence obtained from a well designed controlled trial without randomisation; or from well designed cohort or case-control analytic studies, preferably from more than one centre or research group; or from multiple time-series with or without the intervention.*

Results

The results presented in this report are based on data collected from both the radiotherapy and the surgical questionnaires for the management of rectal cancer (Table 2).

Accrual into the survey

Details of radiotherapy treatment were available for 97% of the 296 patients for which a radiotherapy questionnaire was sent (Table 1). These details were sought when an attending surgeon or medical oncologist indicated that a patient was given radiotherapy or the NSW Central Cancer Registry had received a notification of the cancer from a radiation oncology facility (referred to below as eligible radiotherapy cases).

Of those questionnaires returned, 245 were for patients with rectal cancer, of which 238 had one primary tumour.

Table 1. Accrual into the survey of all cases (both colon and rectal cancer cases)

		n	
New cases of colorectal cancer notified from NSW Central Cancer Registry 1/2/2000 – 31/1/2001		3443	
Cases excluded:		66	
Practitioner indicated that the patient did not have a diagnosis of colorectal cancer	*36*		
Treatment was administered outside NSW	*9*		
Patient had a previous colorectal cancer notification	*21*		
Eligible surgical cases		3377	(100%)
Surgical questionnaires returned		**3095**	**(92%)**
Rectal		**934**	**(30%)**
Rectosigmoid		**327**	**(10%)**
Colon		**1834**	**(60%)**
Eligible chemotherapy cases		920	
Eligible radiotherapy cases		**296**	**(100%)**
Radiotherapy questionnaires returned		**288**	**(97%)**
Rectal		**245**	**(85%)**
Colon		**43**	**(15%)**

Table 2 describes the patient groups used in the analyses for this report and the source of the data analysed.

Table 2. Description of patient groups used in analysis

Patient description*	Questionnaire	n
All resected rectal cancers	Surgical	**821**
Resected rectal cancers that had radiotherapy	Surgical	**258**
High-risk rectal cancers that had curative surgery	Surgical	**389**
Rectal cancers without metastases deemed locally advanced pre-operatively	Surgical	**73**
Locally advanced rectal cancers without metastases	Surgical	**69**
Rectal cancers	Radiotherapy	**238**

**Only patients with one primary tumour were included in the analyses*

Use of radiotherapy for rectal cancer

Rectal cancers are defined as those tumours located in the upper, middle or lower third of the rectum, excluding rectosigmoid cancers. The results refer to patients who had only one primary cancer in the rectum. That is, patients with multiple synchronous primary cancers were excluded from the analyses.

The broad reasons for which radiotherapy was given to rectal cancer patients, as recorded in the radiotherapy questionnaires, are summarised in Table 3. In more than 90% of cases it was given in association with surgical treatment for the primary cancer.

Table 3. Indications for receiving radiotherapy for rectal cancer

Indications for radiotherapy	Total	
	n	%
Pre-operative treatment for initially resectable rectal cancer	**95**	**40**
Adjuvant post-operative treatment for rectal cancer	**75**	**32**
Pre-operative treatment for initially unresectable rectal cancer	**45**	**19**
Palliation of locally advanced or metastatic disease	**19**	**8**
Only treatment for primary cancer	**4**	**2**
Total	**238**	**100**

All surgically treated rectal cancers

Based on responses to the surgical questionnaires, 258 (31%) of the 821 patients with surgically treated rectal cancer were also treated with radiotherapy during the primary treatment phase (Table 4). Details of radiotherapy treatment were received for 238 patients.

There are many factors, apart from stage, that influence the use of radiotherapy. These include patient factors such as age, sex and remoteness of residence (measured by the ARIA - Accessibility/Remoteness Index of Australia), tumour factors such as type of presentation, treatment factors such as type of surgery, location and surgeon factors. The impacts of these on radiotherapy use for the 821 resected rectal cancers are shown in Table 4.

Younger age and a lower location of the tumour were patient or disease factors associated with the use of radiotherapy for rectal cancer. Accessibility of residence, presentation as an emergency and surgeon caseload did not appear to greatly influence radiotherapy use (Table 4).

Table 4. Factors related to the use of radiotherapy for resected rectal cancer

Factor	Resected rectal cancers	Use of radiotherapy	
	n	n	%
Age (years)			
0-59	232	94	**41***
60-69	222	82	**37**
70-79	266	74	**28**
80+	101	8	**8**
Sex			
Male	558	188	**34**
Female	263	70	**27**
†ARIA category			
Highly accessible	673	205	**30**
Accessible	123	44	**36**
Moderately accessible	17	6	**35**
Remote/Very remote	8	3	**38**
Cancer site			
Upper third	179	28	**16**
Middle third	283	77	**27**
Lower third	359	153	**43**
Presentation			
Elective	801	249	**31**
Emergency	20	9	**45**
Surgery			
Abdomino-perineal resection	201	96	**48**
Anterior resection	534	133	**25**
Hartmann's procedure	42	18	**43**
Other	44	11	**25**
Surgeon caseload			
<10	87	24	**28**
10-19	135	45	**33**
20-29	147	55	**37**
30-39	110	37	**34**
40-49	76	31	**41**
>=50	266	66	**25**
Chemotherapy given			
Yes	285	197	**69**
No	536	61	**11**
Total (%)	**821**	**258**	**31**

** Percentages in this table are row percentages*

*†ARIA defines **five categories** of remoteness based on road distance to service centres.*
The five categories are:

1. ***Highly accessible** (ARIA score 0 - 1.84) - relatively unrestricted accessibility to a wide range of goods and services and opportunities for social interaction*
2. ***Accessible** (ARIA score >1.84 - 3.51) - some restrictions to accessibility of some goods, services and opportunities for social interaction*
3. ***Moderately accessible** (ARIA score >3.51 -5.80) - significantly restricted accessibility of goods, services and opportunities for social interaction*
4. ***Remote** (ARIA score >5.80 - 9.08) - very restricted accessibility of goods, services and opportunities for social interaction*
5. ***Very remote** (ARIA score >9.08 - 12) - very little accessibility of goods, services and opportunities for social interaction*
   (http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pubs-hfsocc-ocpanew14a.htm/$FILE/ocpanew14.pdf)

Surgical technique did not appear to play a major role in influencing radiotherapy use though patients having total mesorectal excision (TME) were somewhat more likely to receive adjuvant radiotherapy (36% versus 15%) (Table 5).

Table 5. Relation between radiotherapy use and surgical technique for resected rectal cancer

Surgical technique	Radiotherapy use				
	None	Pre-operative	Post-operative	Total	
	n=563	n=160	n=98		
	%	%	%	n	%
Extra fascial dissection					
Yes	69*	20	11	**724**	**88**
No	69	15	15	**59**	**7**
Uncertain	60	22	19	**38**	**5**
Total mesorectal excision (TME)					
Yes	64	23	14	**590**	**72**
No	85	9	6	**181**	**22**
Uncertain	65	21	15	**49**	**6**
Type of stoma created					
None	83	6	11	**294**	**36**
Temporary	67	22	12	**284**	**35**
Permanent	54	33	13	**243**	**30**
Colonic pouch construction					
Yes	71	22	7	**184**	**22**
No	68	18	13	**569**	**69**
Not applicable	63	22	15	**68**	**8**
Total (%)	**69**	**20**	**12**	**821**	**100**

* *Percentages in this table are row percentages*

Patients having pre-operative radiotherapy were more likely to have a temporary or permanent stoma (Table 6). Having pre-operative therapy was not associated with a lower rate of permanent stoma formation.

Table 6. Stoma formation by rectal cancer site and adjuvant therapy timing

Type of stoma created	Adjuvant therapy timing							
	Surgery +/- post-operative radiotherapy				Pre-operative radiotherapy or chemotherapy/radiotherapy			
	Upper/Mid	Lower	Total		Upper/Mid	Lower	Total	
	n=415	n=246			n=47	n=113		
	%	%	n	%	%	%	n	%
None	55	20	**277**	**42**	26	4	**17**	**11**
Temporary	36	30	**222**	**34**	60	30	**62**	**39**
Permanent	9	50	**162**	**25**	15	66	**81**	**51**
Total (%)	**63**	**37**	**661**	**100**	**29**	**71**	**160**	**100**

Seventy-two percent of the 821 patients with resected rectal cancer did not have a surgically related complication (Table 7). Surgical complication rates were higher in patients who had pre-operative radiotherapy (36%) as compared with those who subsequently received post-operative radiotherapy (22%) or had no radiotherapy (27%).

Table 7. Complications of surgery for rectal cancer that required admission by timing of radiotherapy

Complication	Radiotherapy timing				
	No radiotherapy	**Pre-operative**	**Post-operative#**	**Total**	
	n=563	n=160	n=98		
	%	%	%	n	%
No complication	73	64	78	**590**	**72**
Wound infection	4	7	7	**39**	**5**
†Minor anastomotic leak	1	4	1	**16**	**2**
†Major anastomotic leak	2	2	0	**14**	**2**
Deep venous thrombosis	1	1	0	**5**	**1**
Pulmonary embolus	1	3	0	**12**	**2**
Death	1	1	0	**10**	**1**
Multiple complications	1	1	1	**7**	**1**
*Other	15	18	13	**128**	**16**
Total (%)	**69**	**19**	**12**	**821**	**100**

 # Surgical complications occurred prior to receiving radiotherapy
† Re-operation or death distinguishes a major anastomotic leak from a minor one
** The most common 'other' complication is wound complications. Others include ileus or bowel obstruction, renal or urological complications, infection and cardiac complications.*

High-risk rectal cancer patients

Guideline
"Postoperative 5-FU based chemotherapy and radiotherapy (combined modality therapy) is recommended for patients with high-risk rectal cancer." (Level II evidence)

High-risk rectal cancers were defined as all rectal cancers (excluding rectosigmoid) that had penetrated through the bowel wall and/or involved lymph nodes. In this subgroup of 389 patients, 41% of patients received adjuvant radiotherapy combined with chemotherapy (Table 8). Only 18% of patients with high-risk rectal cancer received the combined modality post-operatively as recommended by the NHMRC guidelines at the time of the survey. Current (2005) NHMRC guidelines state that both pre-operative and post-operative radiotherapy are acceptable adjuvant therapy approaches for resectable rectal cancer deemed at high risk of local recurrence. However since this time, a randomised trial has demonstrated the superiority of pre-operative irradiation over the post-operative approach.[15]

Although there didn't appear to be any difference in radiotherapy utilisation between metropolitan, other urban and rural regions, there was marked variation amongst different Area Health Services in the treatment offered for high-risk rectal cancers (Table 9). Areas such as South Western Sydney and Central Coast had more than 60% of high-risk rectal cancer receiving radiotherapy versus less than 25% in areas such as Northern Sydney and Illawarra.

Table 8. Radiotherapy and chemotherapy given in relation to potentially curative surgery for high-risk rectal cancer patients

	n	%
No adjuvant therapy	164	42
Pre-operative radiotherapy or chemoradiotherapy alone	53	14
Pre-operative chemoradiotherapy and post-operative chemotherapy	35	9
Post-operative radiotherapy or chemoradiotherapy	70	18
Chemotherapy alone	67	17
Total	**389**	**100**

Table 9. Radiotherapy and chemotherapy given in relation to potentially curative surgery for high-risk rectal cancer patients by Area Health Service

Area Health Service	Adjuvant therapy						
	None	Pre-op RT or chemo/RT	Pre-op RT and post-op chemo	Post-op chemo/RT	Chemo alone	Total	
	n=164 %	n=53 %	n=35 %	n=70 %	n=67 %	n	%
Metropolitan	**52***	**19**	**7**	**14**	**17**	**203**	**52**
South Eastern Sydney	39	26	10	10	16	**62**	**16**
Central Sydney	43	18	11	7	21	**28**	**7**
South Western Sydney	27	24	12	30	6	**33**	**8**
Western Sydney	43	10	0	23	23	**30**	**8**
Wentworth	71	0	14	14	0	**7**	**2**
Northern Sydney	53	14	2	7	23	**43**	**11**
Other urban	**44**	**10**	**8**	**19**	**19**	**89**	**23**
Central Coast	29	23	10	29	10	**31**	**8**
Hunter	53	6	6	18	18	**34**	**9**
Illawarra	50	0	8	8	33	**24**	**6**
Rural	**41**	**6**	**13**	**25**	**15**	**95**	**2**
Far West	33	33	0	33	0	**3**	**1**
Greater Murray	36	0	7	50	7	**14**	**4**
Macquarie	60	0	40	0	0	**5**	**1**
Mid North Coast	46	4	7	21	21	**28**	**7**
Mid Western	39	23	31	0	8	**13**	**3**
New England	25	13	0	38	25	**8**	**2**
Northern Rivers	50	0	13	31	6	**16**	**4**
Southern	25	0	13	25	38	**8**	**2**
Unknown	0	0	50	0	50	**2**	**<1**
Total (%)	**42**	**14**	**9**	**18**	**17**	**389**	**100**

** Percentages in this table are row percentages*

Locally advanced rectal cancer without metastases

Guideline
"Preoperative radiation therapy, possibly with chemotherapy, is recommended in rectal cancers fixed or tethered within the pelvis if it is felt down-staging will enable successful resection." (Level II evidence)

Radiation therapy should be considered in patients with locally advanced rectal cancer not amenable to surgery." (Level III evidence)

Only 67% of rectal cancers deemed locally advanced pre-operatively were given pre-operative radiotherapy alone or with chemotherapy as recommended in the NHMRC guidelines. Treatment approaches and pathologic outcome are given in Table 10.

A total of 69 patients were found to have locally advanced disease at the time of surgery but this was not recognised pre-operatively in 58% of patients (Table 11). Only 36% of patients found to have locally advanced disease at the time of surgery had pre-operative radiotherapy alone or with chemotherapy as recommended by the NHMRC guidelines.

Three out of four such patients not amenable to surgery received radiotherapy as recommended by the NHMRC guidelines (Table 10).

Table 10. Surgical treatment outcome for rectal cancers deemed locally advanced pre-operatively without metastases

Treatment modality	Outcome				
	Complete resection	**Incomplete resection**	**No resection**		**Total**
	n=56 %	n=13 %	n=4 %	n	%
Surgery alone	83*	17	0	**13**	**18**
Pre-op radiotherapy or chemoradiotherapy	84	16	0	**49**	**67**
Post-op radiotherapy or chemoradiotherapy	50	50	0	**6**	**8**
Surgery plus chemotherapy	100	0	0	**2**	**3**
Radiotherapy or chemoradiotherapy only	0	0	100	**3**	**4**
Chemotherapy only	0	0	0	**0**	**0**
Unknown	0	0	100	**1**	**0**
Total rectal cancers deemed locally advanced pre-operatively(%)	**77**	**18**	**5**	**73**	**100**

** Percentages in this table are row percentages*

Table 11. Treatment of locally advanced rectal cancers without metastases by pre-operative findings

Treatment modality	Pre-operative findings			
	Deemed locally advanced pre-operatively	**Not deemed locally advanced pre-operatively**	**Total**	
	n=29 %	n=40 %	n	%
Surgery alone	24	33	**21**	**30**
Pre-operative radiotherapy or chemoradiotherapy	59	21	**25**	**36**
Post-operative radiotherapy or chemoradiotherapy	14	36	**18**	**26**
Surgery plus chemotherapy	4	8	**4**	**6**
Radiotherapy or chemoradiotherapy alone	0	0	**0**	**0**
Chemotherapy alone	0	0	**0**	**0**
Unknown	0	3	**1**	**1**
***Total rectal cancers deemed locally advanced at time of surgery (%)**	**42**	**58**	**69**	**100**

** Surgeon found there was operative invasion of adjacent structures or presence of microscopic or macroscopic margins*

Characteristics of patients' cancer

For simplicity and clarity of presentation in this report, all subsequent analyses are based on responses to the radiotherapy questionnaire for patients who had only one primary rectal cancer (n=238). This is the sample size for the remainder of this report unless stated otherwise.

Cancer site

The distributions of the cancer site by patients' age and sex are shown in Table 12. There is no difference in location of the tumour in the rectum by patients' age or sex.

Table 12. Distribution of rectal cancer site by patients' sex and age

	Rectal cancer site				
	Upper third	**Middle third**	**Lower third**	**Total**	
	n=26	n=80	n=132		
	%	%	%	n	%
Sex					
Male	77	74	70	**172**	**72**
Female	23	26	30	**66**	**28**
Age (years)					
0-59	38	38	36	**88**	**37**
60-69	31	31	24	**65**	**27**
70-79	31	29	30	**70**	**29**
80+	0	3	10	**15**	**6**
Total (%)	**11**	**34**	**55**	**238**	**100**

Extent of cancer

For simplicity, we have presented cancer "stage" in terms of the extent of the cancer at diagnosis rather than in categories of any of the staging schemes (see Appendix 4). The question used to elicit disease extent requested the respondent to "use the most accurate clinical or pathological staging information available". For ease of reference we refer to "extent of cancer" as "stage" hereafter.

Table 13. Distribution of cancer stage by rectal cancer site

	Rectal cancer site				
	Upper third	**Middle third**	**Lower third**	**Total**	
	n=26	n=80	n=132		
	%	%	%	n	%
Cancer stage					
Submucosa/muscularis	8*	31	62	**26**	**11**
Beyond bowel wall	14	39	47	**59**	**25**
Regional nodes	12	39	49	**90**	**38**
Distant metastases	12	30	58	**33**	**14**
Missing or unknown	3	13	83	**30**	**13**
Total (%)	**11**	**34**	**55**	**238**	**100**

** Percentages in this table are row percentages*

Table 14. Distribution of rectal cancer stage by sex, age and remoteness of residence

	Cancer stage					
	Submucosa / muscularis	**Beyond bowel wall**	**Regional nodes**	**Distant metastases**	**Missing/ unknown**	**Total**
	n=26	n=59	n=90	n=33	n=30	
	%	%	%	%	%	n %
Sex						
Male	10*	29	36	13	12	**172** **72**
Female	10	15	41	18	15	**76** **28**
Age (years)						
0-59	9	26	37	13	15	**88** **37**
60-69	9	25	40	13	12	**65** **29**
70-79	10	23	41	19	7	**70** **28**
80+	20	27	13	7	33	**15** **6**
ARIA category						
Highly accessible	10	24	37	16	14	**196** **82**
Accessible	9	31	43	6	11	**33** **14**
Moderately accessible	25	38	25	13	0	**7** **3**
Remote/Very remote	0	33	67	0	0	**2** **1**
Total (%)	**10**	**25**	**38**	**14**	**13**	**238** **100**

** Percentages in this table are row percentages*

Caseloads of surveyed radiation oncologists

Thirty five percent of patients received their radiotherapy under the supervision of a radiation oncologist who treated only 1-6 rectal cancer patients during the survey period (Table 15). Most (70%) of the radiation oncologists who provided information for the survey treated only 1-6 patients with rectal cancer during the study period (Table 15). Patients in "other urban" and rural settings were significantly less likely to be treated by a radiation oncologist with a high caseload than their metropolitan counterparts (Table 16). This pattern was similar to that for surgical treatment by surgeons' caseload.[1] No such trend was seen for medical oncology with rural and other urban patients equally likely to see a medical oncologist with a high colorectal caseload compared to those in metropolitan areas.[2]

Table 15. Distribution of patients and radiation oncologists by radiation oncologists' rectal cancer caseload

Radiation oncologist caseload*	Patients		Radiation oncologists	
	n	%	n	%
1-6	83	35	24	70
7-16	72	30	6	18
>=17	83	35	4	12
Total	**238**	**100**	**34**	**100**

** Number of patients radiation oncologist had in the survey*

Table 16. Distribution of cases of rectal cancer by radiation oncologists' rectal cancer caseload and Area Health Service of patients' residence

Area Health Service	Radiation oncologists' caseload				
	1-6	7-16	>=17	Total	
	n=83	n=72	n=83		
	%	%	%	n	%
Metropolitan	**26***	**19**	**55**	**139**	**58**
South Eastern Sydney	28	8	64	**39**	**16**
Central Sydney	19	31	50	**16**	**7**
South Western Sydney	34	4	62	**29**	**12**
Western Sydney	16	16	68	**19**	**8**
Wentworth	60	0	40	**5**	**2**
Northern Sydney	19	45	36	**31**	**13**
Other urban	**44**	**52**	**4**	**54**	**23**
Central Coast	14	79	7	**29**	**12**
Hunter	62	38	0	**13**	**5**
Illawarra	100	0	0	**12**	**5**
Rural	**51**	**40**	**9**	**45**	**19**
Far West	100	0	0	**1**	**<1**
Greater Murray	100	0	0	**10**	**4**
Macquarie	0	100	0	**3**	**1**
Mid North Coast	36	36	27	**11**	**5**
Mid Western	17	83	0	**12**	**5**
New England	80	0	20	**5**	**2**
Northern Rivers	100	0	0	**1**	**<1**
Southern	50	50	0	**2**	**1**
Total (%)	**35**	**30**	**35**	**238**	**100**

** Percentages in this table are row percentages*

Table 17. Distribution of specialist caseload by Area Health Service of rectal cancer patients' residence

Area Health Service	Specialist caseload							
	Radiation oncologist		Medical oncologist *		Surgeon #			
	<=10	>10	<=10	>10	<=30	>30	Total	
	n=100 %	n=138 %	n=15 %	n=145 %	n=117 %	n=106 %	n	%
Metropolitan	**32**†	**68**	**8**	**92**	**38**	**62**	**139**	**58**
South Eastern Sydney	28	72	5	95	29	71	**39**	**16**
Central Sydney	25	75	0	100	60	40	**16**	**7**
South Western Sydney	34	66	20	80	48	52	**29**	**12**
Western Sydney	26	74	6	94	24	76	**19**	**8**
Wentworth	60	40	0	100	60	40	**5**	**2**
Northern Sydney	35	65	11	89	31	69	**31**	**13**
Other urban	**56**	**44**	**9**	**91**	**65**	**35**	**54**	**23**
Central Coast	17	83	20	80	85	15	**29**	**12**
Hunter	100	0	0	100	62	38	**13**	**5**
Illawarra	100	0	0	100	20	80	**12**	**5**
Rural	**58**	**42**	**12**	**88**	**82**	**18**	**45**	**19**
Far West	100	0	0	100	91	9	**1**	**<1**
Greater Murray	100	0	44	56	83	17	**10**	**4**
Macquarie	0	100	0	100	60	40	**3**	**1**
Mid North Coast	63	36	0	100	0	100	**11**	**5**
Mid Western	17	83	0	100	50	50	**12**	**5**
New England	80	20	0	100	38	62	**5**	**2**
Northern Rivers	100	0	0	100	65	35	**1**	**<1**
Southern	50	50	50	50	82	18	**2**	**1**
Total (%)	**42**	**58**	**9**	**91**	**52**	**48**	**238**	**100**

† *Percentages in this table are row percentages*
\# *15 cases did not have surgery*
* *78 cases did not have chemotherapy*

Patients of higher volume surgeons and radiation oncologists were more likely to receive pre-operative radiotherapy for resectable disease (Table 18).

Table 18. Type of radiotherapy for rectal cancer by surgeon and radiation oncologists' caseload

Caseload	Indications for radiotherapy						
	Pre-op resectable	Adjuvant post-op	Pre-op unresectable	Palliation	Only treatment	Total	
	n=93	n=70	n=44	n=14	n=2		
	%	%	%	%	%	n	%
Surgeon caseload							
<10	20*	67	13	0	0	**15**	**7**
10-19	30	38	18	15	0	**40**	**18**
20-29	43	31	18	6	2	**49**	**22**
30-39	38	41	14	7	0	**29**	**13**
40-49	52	13	29	3	3	**31**	**14**
>=50	51	24	22	3	0	**59**	**26**
Total	**42**	**32**	**20**	**6**	**1**	**223**	**100**
Radiation oncologist caseload							
	n=95	n=75	n=45	n=19	n=4		
1-6	23	40	24	12	1	**83**	**35**
7-16	36	29	25	8	1	**72**	**30**
>=17	60	25	8	4	2	**83**	**35**
Total (%)	**40**	**32**	**19**	**8**	**2**	**238**	**100**

** Percentages in this table are row percentages*

Types and doses of radiotherapy and associated chemotherapy

Tumours in the lower third of the rectum were much more likely to receive pre-operative radiotherapy (Table 19).

Table 19. Type of radiotherapy for rectal cancer by site, stage and remoteness of residence

	Indications for radiotherapy						
	Pre-op resectable	**Adjuvant post-op**	**Pre-op unresectable**	**Palliation**	**Only treatment**	**Total**	
	n=95	n=75	n=45	n=19	n=4		
	%	%	%	%	%	n	%
Cancer site							
Upper third	8*	62	19	12	0	**26**	**11**
Middle third	35	38	21	5	1	**80**	**34**
Lower third	49	22	17	9	2	**132**	**55**
Cancer stage							
Submucosa/muscularis	58	27	12	0	4	**26**	**10**
Beyond bowel wall	31	22	42	5	0	**59**	**25**
Regional nodes	33	59	8	0	0	**90**	**38**
Distant metastases	24	6	21	46	3	**33**	**14**
Missing or unknown	80	0	10	3	7	**30**	**13**
ARIA category							
Highly accessible	40	31	18	9	2	**196**	**82**
Accessible to Very remote	38	33	24	5	0	**42**	**18**
Total (%)	**40**	**32**	**19**	**8**	**2**	**238**	**100**

** Percentages in this table are row percentages*

Radiotherapy techniques used are shown in Table 20. Sixteen percent of patients (n=37) received short course hypofractionated radiotherapy (25Gy/5#), which was used almost entirely in the pre-operative setting for resectable rectal cancer. The great majority of other doses used for both pre-operative and post-operative adjuvant therapy were between 45 and 50.4 Gy.

In all cases with a curative approach, multi-field arrangements were used with a slight favouring towards the three-field technique. Shielding was used in two-thirds of patients though small bowel contrast was only used to aid shielding in a third of cases.

Table 20. Radiation technique used for rectal cancer

	Indications for radiotherapy					
	Pre-operative resectable	**Adjuvant post-operative**	**Pre-operative unresectable**	**Other**	**Total**	
	n=95	n=75	n=45	n=23	n	%
Average dose						
25Gy/5#	97*	0	3	0	**37**	**16**
45Gy/25#	41	43	13	3	**88**	**37**
50 Gy/25#	19	50	31	0	**16**	**7**
50.4Gy/28#	28	36	32	4	**53**	**22**
54Gy/30#	0	75	25	0	**4**	**2**
≥60Gy	0	50	0	50	**2**	**1**
Other	14	17	29	40	**35**	**15**
Unknown	0	0	0	100	**3**	**1**
Field arrangement						
AP:PA	0	0	30	70	**10**	**4**
3 Field	46	33	18	3	**129**	**54**
4 Field	38	33	20	9	**96**	**40**
Unknown	0	0	0	100	**3**	**1**
Small bowel shielding techniques						
Small bowel contrast simulation	53	26	16	4	**68**	**29**
Shielding	47	31	16	6	**157**	**66**
Intestinal mesh/sling	100	0	0	0	**1**	**0**
Immobilisation moulds	100	0	0	0	**1**	**0**
Bladder distension	21	46	20	13	**80**	**34**
Belly board	40	33	23	3	**60**	**25**
Other	29	33	29	10	**21**	**9**
Total (%)	**40**	**32**	**19**	**10**	**238**	**100**

** Percentages in this table are row percentages*

Guideline
"When chemotherapy is given postoperatively in combination with radiotherapy, protracted venous infusion of 5-FU chemotherapy may offer further benefits in survival when compared to bolus 5-FU therapy. It is the recommended way of delivering combined modality therapy." (Level II evidence)

Three quarters of patients received chemotherapy with radiotherapy (Table 21), of which 37% were given this combination post-operatively. When chemotherapy was given post-operatively in combination with radiotherapy, 48% of patients were given 5-FU by infusion as recommended by the guideline.

Table 21. Use of 5-FU chemotherapy with radiotherapy for rectal cancer

Chemotherapy use with radiotherapy	Indications for radiotherapy					
	Pre-operative resectable	Adjuvant post-operative	Pre-operative unresctable	Other	Total	
	n=95 %	n=75 %	n=45 %	n=23 %	n	%
Proportion of patients given chemotherapy with radiotherapy	65	85	84	48	**175**	**74**
5-FU Scheduling during radiation	n=62 %	n=64 %	n=38 %	n=11 %		
Bolus	23	27	32	18	**45**	**26**
Infusion	39	48	58	45	**82**	**47**
Unknown	39	25	11	36	**48**	**27**
Total (%)	**35**	**37**	**22**	**6**	**175**	**100**

Radiotherapy complications

The reported rate of complications of radiotherapy was low (8%) (Table 22).

Table 22. Complications of radiotherapy for rectal cancer that required admission by timing of radiotherapy

Complication	Radiotherapy timing			
	Pre-operative	**Post-operative**	**Total**	
	n=140	n=75		
	%	%	n	%
No complication	91	93	**197**	**92**
Enteritis	1	3	**3**	**1**
Proctitis	0	0	**0**	**0**
Bowel obstruction/perforation	2	0	**4**	**2**
Febrile neutropenia	1	1	**3**	**1**
Other†	4	4	**9**	**4**
***Total (%)**	**65**	**35**	**215**	**100**

* *Total excludes 23 patients who did not have surgery*

† *Other included:*

Pre-operative - perineal pain, perineal sinus, pulmonary embolus, wound breakdown, DVT & PE

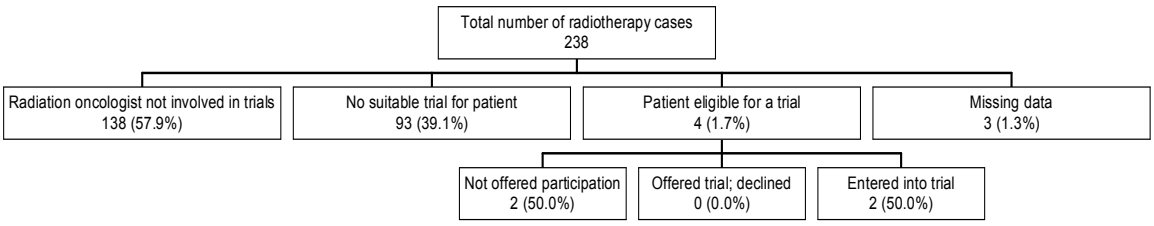
Post-operative - sepsis, odd turn, dehydration, UTI, constipation

Participation in clinical trials

Guideline
"Doctors should encourage patients with colorectal cancer to consider participating in appropriate clinical trials for which they are eligible." (Expert opinion)

For 58% of patients, their radiation oncologist did not participate in any clinical trials. For 2% of patients, their radiation oncologist considered them to be eligible for a clinical trial. Of this group, 50% were recorded as having been entered into a clinical trial. Thus the actual proportion of patients participating in a clinical trial was 1%.

Figure 1. Participation of radiotherapy patients in clinical trials



Follow-up intentions

Guideline
"All patients who have undergone surgery for colorectal cancer should have specialist follow up in conjunction with the patient's general practitioner." (Expert opinion)

In 38% of cases, the attending radiation oncologist indicated that they intended to participate in the follow-up of the patients' cancer (Table 23). The radiation oncologist intended to follow-up 29% of patients who had chemotherapy and radiotherapy for potentially curable rectal cancer (Table 24). Overall 85% of patients were intended to be followed-up by a specialist. Collection of follow-up management practices, investigations and outcomes was undertaken in 2002/03, and the data will be published in a comprehensive report specifically addressing these aspects of colorectal cancer management.

Table 23. Radiation oncologists' follow-up intentions for patients treated with radiotherapy for rectal cancer by characteristics of patients and cancer

Indications for radiotherapy	Follow-up intentions				
	Yes	No	Missing	Total	
	n=83	n=114	n=22		
	%	%	%	n	%
Pre-operative treatment for initially resectable rectal cancer	25[†]	68	7	**91**	**42**
Adjuvant post-operative treatment for rectal cancer	52	32	16	**71**	**32**
Pre-operative treatment for initially unresectable rectal cancer	44	46	10	**41**	**19**
Palliation of locally advanced or metastatic disease	28	64	7	**14**	**6**
Only treatment for primary cancer	50	50	0	**2**	**1**
***Total (%)**	**38**	**52**	**10**	**219**	**100**

** Excludes 19 cases that are deceased or their vital status is unknown*
[†] Percentages in this table are row percentages

Table 24. Intended follow-up practice for all patients receiving chemotherapy and radiotherapy for potentially curable rectal cancer

Patient followed up by	n	%
Surgeon only	**60**	**35**
Surgeon plus Medical Oncologist	**24**	**14**
Surgeon plus Radiation Oncologist	**22**	**13**
Surgeon plus Medical and Radiation Oncologist	**20**	**12**
Medical Oncologist only	**11**	**6**
Radiation Oncologist only	**4**	**2**
Medical and Radiation Oncologist	**3**	**2**
Missing or unknown	**26**	**15**
Total (%)	**170**	**100**

Further analyses proposed

The data collected for this survey are intended for further analyses and publications. These include the following:

Reports from other data collected in this survey

Follow-up data on patient outcomes were collected in 2003 and will be covered in a separate report.

Further analysis and dissemination of data collected on surgical management

Economic analysis will be undertaken to estimate the direct health costs incurred in NSW for the surgical management of colorectal cancer. These data will be submitted for consideration of publication in major peer-reviewed medical journals.

In addition, third parties may request the data collected in suitably de-identified form for further analyses. Proposals should be made in writing and are subject to the approval of the survey's Expert Advisory Group and any necessary ethical clearances. Such proposals can be discussed beforehand by contacting either:

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Director of Research, Sydney Cancer Centre
Gloucester House
Royal Prince Alfred Hospital
Camperdown NSW 2050, Australia
E-mail: brucea@health.usyd.edu.au
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or

Associate Professor Dianne O'Connell
Cancer Epidemiology Research Unit
Research Division
The Cancer Council NSW
PO Box 572
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E-mail: dianneo@nswcc.org.au
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Appendices

Appendix 1 Radiotherapy Questionnaire

Form No: NR

Details of tumour

1. Site(s) of primary tumour:
   - 1☐ caecum
   - 2☐ ascending colon
   - 3☐ hepatic flexure
   - 4☐ transverse colon
   - 5☐ splenic flexure
   - 6☐ descending colon
   - 7☐ sigmoid colon
   - 8☐ rectosigmoid
   - 9☐ rectum, upper third
   - 10☐ rectum, middle third
   - 11☐ rectum, lower third
2. Number of primary tumours: _____
3. (a) Local tumour stage *(use the most accurate clinical or pathological staging information available; for >1 primary, select most advanced)*:
   - a1☐ unknown
   - a2☐ carcinoma *in situ*
   - a3☐ submucosal involvement
   - a4☐ involvement of muscularis
   - a5☐ subserosa (or perirectal tissues)
   - a6☐ serosal involvement
   - a7☐ adjacent organ invasion

   (b) Spread to lymph nodes (any combination)
   - b1☐ unknown
   - b2☐ not involved
   - b3☐ epi-, para-, retro-colic or mesenteric
   - b4☐ apical
   - b5☐ distant: _____ (name chain)

   (c) Distant spread: (any combination)
   - c1☐ none known
   - c2☐ non-adjacent peritoneum
   - c3☐ liver
   - c4☐ lung
   - c5☐ other(s): _____
4. Was a cancer diagnosis confirmed *histologically* before any cancer treatment (e.g. radiotherapy) commenced?
   1☐ no 2☐ yes 3☐ uncertain

Radiotherapy treatment details

5. Did this patient receive radiotherapy?
   - a2☐ Yes → ***go to next question (6)***
   - a1☐ No → Reason (tick one):
     - b1☐ offered but declined
     - b2☐ not indicated
     - b3☐ other: _____

     → ***Skip to question 12***
6. Radiotherapy indication (tick one):
   - 1☐ definitive treatment
   - 2☐ pre-operative treatment for initially resectable rectal cancer
   - 3☐ pre-operative treatment for initially *un*resectable rectal cancer
   - 4☐ adjuvant post-operative treatment for rectal cancer
   - 5☐ palliation of locally advanced or metastatic disease
7. Treatment delivery (any combination):
   1☐ interstitial 2☐ external beam
8. Details of **pelvic field** (if applicable):
   - Total dose planned: _____ .__ Gy(a)
   - Number of fractions planned: __ (b)
   - Start date: _____/_____/_____ (c)
   - Finish date: _____/_____/_____ (d)
   - Total dose received: _____ .__ Gy(e)
   - Point at which prescribed:
     f1☐ ICRU f2☐ covering isodose
   - Fields used:
     g1☐ AP/PA g2☐ 3-field g3☐ 4-field
   - Upper limit of field:
     - h1☐ pelvic brim
     - h2☐ L5/S1
     - h3☐ above L5/S1
   - Use of lateral fields? i1☐ no i2☐ yes
   - Use of boost field?
     - j1☐ no
     - j2☐ yes → dose: _____Gy
   - Site(s) of boost (if applicable):
     - k1☐ sacral hollow
     - k2☐ tumour bed
   - Select technique(s) used to minimise small bowel irradiation:
     - L1☐ small bowel contrast simulation
     - L2☐ shielding
     - L3☐ intestinal mesh/sling
     - L4☐ immobilisation moulds
     - L5☐ bladder distension
     - L6☐ bellyboard
     - L7☐ other: _____
9. Other treatment fields (if applicable):

   (a) _____

   (b) _____

Form No:

10. Is this patient eligible for any clinical trial you may be involved in?
    - a1☐ I am not involved in any trials
    - a2☐ patient was not eligible
    - a3☐ patient was eligible for a trial →

      a. Was this patient entered?
      - b1☐ Yes
      - b2☐ Offered but declined
      - b3☐ Not offered

      b. Study type:
      - c1☐ randomised
      - c2☐ non-randomised

11. Did this patient *require hospitalisation* for any treatment complications?
    - a1☐ No
    - a2☐ Yes (any combination):
      - b1☐ enteritis; start date: __/___ /___
      - b2☐ proctitis; start date: __/___ /___
      - b3☐ bowel obstruction/perforation
      - b4☐ febrile neutropenia
      - b5☐ other: _____

12. Did this patient undergo surgery?
    - a1☐ No
    - a2☐ Yes: Date: __ / ____ / _____

      Operation performed:
      - b1☐ colectomy (any type)
      - b2☐ colostomy only
      - b3☐ anterior resection
      - b4☐ abdomino-perineal resection
      - b5☐ other: _____

13. Did this patient receive chemotherapy?
    - a1☐ No → go to next question (14)
    - a2☐ Yes → Timing (choose one):
      - b1☐ only *with radiotherapy*
      - b2☐ *completely* separate from radiotherapy
      - b3☐ combination of the above

      Drugs used (any combination):
      - c1☐ 5-Fluorouracil
      - c2☐ leucovorin
      - c3☐ levamisole
      - c4☐ other(s): _____

      5FU scheduling during radiation (if applicable)
      - d1☐ bolus
      - d2☐ infusional

Follow-up information

14. Has this patient's tumour recurred or progressed since treatment started?
    - a1☐ No → go to next question (15)
    - a2☐ Yes → Date of relapse or progression:____ / ___ / ___

      Sites involved (any combination)
      - b1☐ primary site
      - b2☐ liver
      - b3☐ lung
      - b4☐ other: _____

      Evidence available (any combination)
      - c1☐ pathology
      - c2☐ radiology
      - c3☐ rise in serum CEA
      - c4☐ endoscopy
      - c5☐ clinical

      Has this patient been referred to a palliative care service?
      - d1☐ yes
      - d2☐ offered but patient declined
      - d3☐ not indicated
      - d4☐ this service is not available

15. As far as you know, is this patient alive?
    - a1☐ **No** →Date of death: __/___ / ___

      Cause of death: (tick one)
      - b1☐ colorectal cancer
      - b2☐ treatment complication (state: _____)
      - b3☐ other cause: _____
      - b4☐ unknown

    - a2☐ **Yes** →Date last known to be alive: ___ / ___ / ___

      Will this patient be returning to see you for follow-up visits?
      - c1☐ no
      - c2☐ yes

16. We may wish to obtain further details of surgery and chemotherapy. Please provide names and addresses, if applicable, for these practitioners:

    Attending surgeon:

    _____

    _____

    _____

    Attending medical oncologist:

    _____

    _____

    _____

THANK YOU FOR YOUR VALUABLE ASSISTANCE **Page 2**

Appendix 2 Surgical Questionnaire

A: Presenting symptoms

1. Date of patient's first presentation *to you:* _____/_____/ _____

2. How did this patient present (any combination)?
   - 1_ population screening
   - 2_ screening, strong family history
   - 3_ screening, other risk factors
   - 4_ change in bowel habit
   - 5_ *acute* bowel obstruction
   - 6_ anaemia
   - 7_ PR bleeding
   - 8_ *massive* PR haemorrhage
   - 9_ rectal symptoms (pain, tenesmus)
   - 10_ abdominal pain/discomfort
   - 11_ symptoms from metastases
   - 12_ bowel perforation
   - 13_ other: _____

B: Details of tumour

3. Site(*s*) of primary tumour:
   - 1_ caecum
   - 2_ ascending colon
   - 3_ hepatic flexure
   - 4_ transverse colon
   - 5_ splenic flexure
   - 6_ descending colon
   - 7_ sigmoid colon
   - 8_ rectosigmoid
   - 9_ rectum, upper third
   - 10_ rectum, middle third
   - 11_ rectum, lower third

4. Number of primary tumours:_____

5. (a) Local tumour stage *(use the most accurate clinical or pathological staging information available; for > 1 primary, select most advanced)*:
   - a1_ unknown
   - a2_ carcinoma *in situ* (severe dysplasia)
   - a3_ submucosal involvement
   - a4_ involvement of muscularis propria
   - a5_ subserosa (or perirectal tissues)
   - a6_ serosal involvement
   - a7_ adjacent organ invasion

   (b) Spread to lymph nodes (any combination):
   - b1_ unknown
   - b2_ not involved
   - b3_ epi-, para-, retro-colic or mesenteric
   - b4_ apical
   - b5_ distant:_____ (name chain)

   (c) Sites of distant spread: (any combination)
   - c1_ none known
   - c2_ non-adjacent peritoneum
   - c3_ liver
   - c4_ lung
   - c5_ other(s): _____

C: Investigations

6. Investigations performed *before* commencement of treatment (any combination):
   - 1_ colonoscopy (pre-operative)
   - 2_ colonoscopy (intra-operative)
   - 3_ barium enema
   - 4_ sigmoidoscopy
   - 5_ abdomino-pelvic ultrasound
   - 6_ abdomino-pelvic CT scan
   - 7_ abdomino-pelvic MRI scan
   - 8_ endo-rectal ultrasound
   - 9_ chest X-ray
   - 10_ other(s): _____
   - 11_ none

7. Was there any *pre-operative* evidence of invasion of adjacent structures by the tumour?
   - a1 no
   - a2_ yes Evidence:
     - b1_ clinical – tethering
     - b2_ clinical – fixation
     - b3_ imaging

     Was it considered resectable at *pre-operative* assessment?
     c1_ no c2_ yes

8. Was a cancer diagnosis confirmed *histologically* before any cancer treatment (e.g. surgery) commenced?
   1_ no 2_ yes

D: Pre-operative management

9. Did the patient have surgery?
   - a2_ Yes date: ____ / _____/ _____
     continue to the next question (10)
   - a1_ No. The reason is:
     - b1_ patient unfit for surgery
     - b2_ patient had incurable disease
     - b3_ patient refused
     - b4 other:

     skip to question 30

10. Did any of these health practitioners other than you counsel the patient *pre-operatively?* (any combination)
    - 1_ no
    - 2_ professional counsellor
    - 3_ social worker
    - 4_ stomal therapist
    - 5_ team registrar/resident
    - 6_ unit nurse
    - 7_ GP (i.e. a *specific* appointment was made for counselling)
    - 8_ other: _____

11. Was the patient seen by a stomal therapist *before* surgery? (tick one)
    - a1_ yes
    - a2_ no, not indicated
    - a3_ no, not available
    - _ no, emergency surgery

      if so, was the stoma sited pre-operatively?

      u_ *no* u_ *yes*

E: Surgical procedure

12. Operation performed (any combination)
    - 1_ transanal endoscopic microsurgery (TEM)
    - 2_ sigmoid colectomy
    - 3_ segmental resection
    - 4_ right hemicolectomy
    - 5_ extended right hemicolectomy
    - 6_ left hemicolectomy
    - 7_ extended left hemicolectomy
    - 8_ subtotal colectomy
    - 9_ total colectomy with ileorectal anastomosis

(Question 12 – continued)

- 10_ total proctocolectomy +/- ileoanal reservoir
- 11_ Hartmann's procedure
- 12_ high anterior resection
- 13_ low anterior resection
- 14_ ultra low anterior resection
- 15_ abdomino-perineal resection
- 16_ liver resection
- 17_ insertion of hepatic arterial catheter
- 18_ pelvic exenteration
- 19_ defunctioning stoma *only*
- 20_ laparotomy/laparoscopy only
- 21_ other: _____

13. Method for surgical access:
    1_ open 2_ laparoscopic

14. *Post-operative* assessment of the intent of surgery:
    - a1 curative
    - a2_ palliative reason(s):
      - b1_ resection not done/incomplete
      - b2 presence of distant metastases
      - b3_ other: _____

15. What methods of *pre*-operative bowel preparation were used?
    - 1_ none 3_ oral preparation
    - 2_ enema 4_ other: _____

16. What methods for DVT prophylaxis were used?
    - 1_ none
    - 2_ unfractionated heparin
    - 3_ low molecular weight heparin
    - 4_ graduated (TED) stockings
    - 5_ intermittent intra-operative calf compression or stimulation
    - 6_ other: _____

17. What agents were used for *pre-operative* antibiotic prophylaxis:
    - a1_ none
    - a2_ a cephalosporin
    - a3_ metronidazole
    - a4_ gentamicin/other aminoglycoside
    - a5_ other: _____

Duration of antibiotic ***prophylaxis:***

b1_ single dose b2_ >1 dose

18. *Type* of stoma created:
a1_ none a2_ temporary a3_ permanent

Site of stoma (if applicable):
b1_ colostomy b2_ ileostomy

19. Was there *operative* evidence of tumour invasion of adjacent structures?
a1_ No
a2_ Yes (a) Method of resection:
b1 removed *en bloc*
b2 removed separately
b3 incomplete resection
b4 no resection
(b)Was frozen section performed?
c1_ no c2_ yes

20. Presence of residual tumour following procedure (tick one box only):
1_ none
2_ microscopic only (e.g. positive resection margin)
3_ macroscopic

21. Is this patient eligible for any clinical trial you may be involved in?
a1_ I am not involved in any trials
a2_ patient was not eligible
a3_ patient was eligible for a trial
Was the patient entered?
b1_ Yes
b2_ Offered but declined
b3_ Not offered
Study type:
c1_ randomised
c2_ non-randomised

22. Did the patient experience any post-operative complications (any combination)?
a1 no
a2_ Yes Please tick (any combination):
b1_ wound infection
b2 anastomotic leak not requiring re-operation
b3_ anastomotic leak requiring re-operation
b4_ deep venous thrombosis
b5_ pulmonary embolus
b6_ other:_____

23. (for females): Did the patient have an oophorectomy? (tick one box only)
1_ no
2_ yes, prophylactic oophorectomy
3_ yes, therapeutic (for *macro*scopic involvement)

F: for Rectal cancer only:
(*If the patient does not have a rectal tumour, skip to question 30*)

24. Distance of tumour from anal verge:
a1_ not assessed
a2_ assessed
Distance = b1_____ cm
Method(s) used:
c1_ PR examination
c2_ *rigid* sigmoidoscopy
c3_ *flexible* sigmoidoscopy

25. Was an anatomical (extrafascial) dissection performed?
1_ no 2_ yes 3_ uncertain

26. Was the mesorectum completely excised?
1_ no 2_ yes 3_ uncertain

27. What techniques were used to isolate small bowel from the pelvis? (any combination)
1_ none
2_ omental sling
3_ mesh
4_ other: _____

28. Was a colonic pouch constructed?
1_ no
2_ yes (length: ____cm)
3_ not applicable

29. Did the patient have sphincter conservation (any combination)?
1_ yes
2_ no, inadequate sphincter function
3_ no, unable to clear distal tumour margin ǂ 2cm
4_ no, resection margin will involve sphincter
5_ no, difficult surgical access to pelvis
6_ no, lateral tumour spread was too extensive
7_ no, other reason: _____

G: Other treatment modalities

30. Has this patient received radiotherapy? (tick one)
- 1_ yes, pre-operatively
- 2_ yes, post-operatively
- 3_ yes, without any surgery
- 4_ referred but not treated
- 5_ patient declined referral
- 6_ not indicated

31. Has the patient received chemotherapy? (tick one)
- 1_ yes, pre-operatively
- 2_ yes, post-operatively
- 3_ yes, pre- and post-operatively
- 4_ yes, without any surgery
- 5_ referred but not treated
- 6_ patient declined referral
- 7_ not indicated

H: Follow-up

32. Has the patient's tumour recurred or progressed since treatment started?
- a1_ no go to next question (33)
- a2_ yes Date of relapse or progression: ____ / ___/____

Sites involved (any combination):
- b1_ primary site
- b2_ liver
- b3_ lung
- b4_ other: _____

Evidence available (any combination):
- c1 pathology
- c2_ radiology
- c3_ endoscopy
- c4_ clinical
- c5_ rise in serum CEA

Has the patient been referred to a palliative care service?
- d1_ yes
- d2_ offered but patient declined
- d3_ not indicated
- d4_ this service is not available

33. As far ass you know, is this patient still alive?
- a1_ **No** Date of death: __ / ___ /____

Cause of death: (tick one)
- b1_ colorectal cancer
- b2_ treatment complication (state: _____)
- b3_ other cause:_____
- b4_ unknown

- a2_ **Yes** Date last known to be alive: /____/ ____

Will the patient be returning to see you for follow-up visits?
- c1_ no
- c2 yes we may wish to send you a brief follow-up questionnaire in 12 months. If this patient will be followed-up at a different practice address, please give the address below:

_____

34. We wish to obtain further details of chemotherapy and radiotherapy. Please provide names and addresses if applicable, for these practitioners:

Attending medical oncologist:

_____

_____

_____

Attending radiation oncologist:

_____

_____

_____

THANK YOU FOR YOUR VALUABLE ASSISTANCE

Appendix 3 Membership of the Expert Advisory Group

- Dr Stephen Ackland, Department of Medical Oncology, Newcastle Mater Hospital
- Professor Bruce Armstrong*, Director of Research, Sydney Cancer Centre; Professor, School of Public Health and Medical Foundation Fellow, University of Sydney
- Associate Professor Pierre Chapuis, Department of Surgery, Concord Hospital
- Dr Andrew Kneebone, Department of Radiation Oncology, Liverpool Hospital
- Dr David Leong*, Medical Oncologist, John James Medical Centre
- Associate Professor Dianne O'Connell, Senior Epidemiologist, Cancer Epidemiology Research Unit, The Cancer Council NSW
- Professor Michael Solomon, Department of Surgery, Royal Prince Alfred Hospital
- Professor Allan Spigelman*, Director of Cancer Services, St Vincent's Mater Health; Head, Department of Surgery, St Vincent's Hospital; Professor of Surgery, St Vincent's Clinical School, University of New South Wales

** chief investigators*

Appendix 4 Cancer stage assignment using questionnaire responses

For reference, the radiotherapy questionnaire is in Appendix 1.

Questionnaire response			Cancer stage		
Local spread:	**Spread to nodes:**	**Distant spread:**	**ACP Stage**	**Dukes' Stage**	**TNM Stage**
Carcinoma in-situ	Not involved	No distant spread	A0	¢-	0 (T1sN0M0)
Submucosa	Not involved	No distant spread	A	¥A	I (T1N0M0)
Muscularis propria	Not involved	No distant spread	A	A	I (T2N0M0)
Subserosa Serosal	Not involved	No distant spread	B	£B	II (T3N0M0)
Adjacent organ(s)	Not involved	No distant spread	B	B	II (T4N0M0)
Any except line of resection	Epi-, para-, retro-colic or mesenteric	No distant spread	C	C	III (Any T, N1M0)
Any except line of resection	Apical node(s)	No distant spread	C	C	III (Any T, N2M0)
Line of resection	Yes or No	No distant spread	D	Not* defined	IV (Any T, Any N, M0)
Any	Yes or No	Non-adjacent peritoneum Liver Lung Other	D	Not* defined	IV (Any T, Any N, M1)

¢ This would be classified as "A" under the Astler & Coller modification of Dukes' staging

¥ This would be classified as "B1" under the Astler & Coller modification of Dukes' staging

£ This would be classified as "B2" under the Astler & Coller modification of Dukes' staging

* Not defined in classical Dukes classification

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