

# The First 1000 Patients on an Internet-based Colorectal Neoplasia Database Across Private and Public Medicine in Australia: Development of a Binational Model for the Colorectal Surgical Society of Australia and New Zealand

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**BACKGROUND:** Collection of multi-institutional data pertaining to the treatment of bowel cancer has been hindered by poor clinician compliance with data entry and the lack of incentive to participate.

**OBJECTIVE:** This study aimed to establish if a novel browser-based model of data collection results in complete data capture.

**DESIGN:** A Web-based data collection interface was custom written, offering automated reporting modules for clinical outcome to participants and an automated reporting system for outstanding data fields, and summary reporting of surgical quality outcomes. The software was combined with a clinical feedback system incorporating fortnightly data review meetings, at the time of clinical multidisciplinary meetings.

**PATIENTS AND SETTING:** Selected were 932 consecutive patients with opt-out consent from 3 hospital sites, including public and private medicine.

**MAIN OUTCOME MEASURES:** The primary outcomes measured were the analysis of data completeness and accuracy and ensuring that the highest-quality data were used for clinical audit of the surgical practices of

Australian colorectal surgeons for the purpose of quality assurance.

**RESULTS:** A total of 932 men and women, 22 to 94 years of age, treated for colorectal neoplasia were evaluated. We obtained 100% completion (>27,000 data points) of perioperative data registered by 8 specialist colorectal surgeons and a full-time database manager.

**CONCLUSIONS:** Data completeness and validity are essential for clinical databases to serve the purpose of quality assurance, benchmarking, and research. The results confirm the safety and efficacy of colorectal cancer surgery in both the public and private sector in Australia. The combination of a simple multiuser interface, defined data points, automated result-reporting modules, and data-deficiency reminder module resulted in 100% data compliance in nearly 1000 clinical episodes. The unprecedented success of this model has led to the Colorectal Surgical Society of Australia and New Zealand adopting this model for data collection for Australia and New Zealand as the binational database.

**KEYWORDS:** Colorectal; Neoplasia; Database; Registry; Audit; Cancer.

**Financial Disclosure:** None reported.

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Dis Colon Rectum 2014; 57: 167–173  
 DOI: 10.1097/DCR.0000000000000041  
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A clinical data management system should be the centerpiece of any contemporary cancer treatment center. Clinical data collection relating to bowel cancer has been undertaken through a variety of sources, including local and hospital audits, through to national registries.<sup>1–5</sup> Reported outcomes usually pertain to clinical and quality assurance parameters. To maximize

the value of systematic data collection, we need to ensure that the data are complete and accurate.<sup>6,7</sup> If the level of data completeness is suboptimal, the extent to which these data repositories can be relied upon to report meaningful results is indeterminate.

To ensure optimal data accuracy, the data collection system should be structured to allow:

1. Removal of barriers to data entry.
2. Encouragement of clinician participation through provision of result feedback.
3. Creation of an agreed and appropriate distribution of responsibility for data entry for specific fields with specific responsibilities for surgeons.
4. Creation of "failsafe" systems to ensure the accuracy of data entry.

## MATERIALS AND METHODS

Planning for the Cabrini Monash Colorectal Database (CMCD) commenced in 2006. The data management system was created along the following lines.

### Removal of Barriers to Data Entry

The database was written by using a browser-based front end, allowing access from any Internet-connected device, and avoiding the cost of hardware installation. Data are stored on centralized servers. Data fields were created by using agreed upon definitions, and presented as pulldown lists to avoid coding errors. On-screen balloon prompts are available for fields to clarify data definitions where required during data entry.

### Encouragement of Clinician Participation

After sign-in, clinicians have 24 hour/7 day-a-week real-time access to a standardized reporting module. This contains individualized, and hospital-specific outcome reporting, in comparison with mean and total results for the entire patient cohort. Individualized login for clinicians ensures that individual's results are accessible only by the clinicians themselves. No clinician can review the outcome data of other clinicians. The outcome parameters reported are contained in Table 1. Participation in an approved audit process is a prerequisite of continuing membership of many learned bodies, colleges, and professional organizations; hence, there is strong primary motivation to participate if possible. The reporting modules contained in this system offer real-time evidence of participation in this audit process.

### Agreed and Appropriate Distribution of Responsibility for Data Entry for Specific Participants

The model of task distribution is represented in Figure 1, and summarized below.

**TABLE 1.** The Comparison report allows a consultant to compare their own patient demographic data (totals and averages) against their hospital and the total database. The outcomes report provides surgical and medical postoperative outcome data on all database patients who have a postoperative data record.

<i>Comparison report</i>	<i>Outcomes report</i>
Patient count	Surgical outcomes
Patient age (both average and range)	Medical outcomes
Diagnoses count	Returned to theater
Patient sex	Inpatient death
Cancer type	Readmitted within 30 days postsurgery
Operative urgency	Average hospital stay period (days)
ASA status	
Operation type	
Cancer resection	
Curability	
TNM stage	

1. At the time of initial consultation, the surgeon forwards a copy of the consultation letter to the unit data manager, prompting initial registration of patient details.
2. The patient is contacted by the data manager seeking opt-out consent, then basic demographic information, details of preoperative staging, patient comorbidities, and details of neoadjuvant therapy are entered by the data manager.
3. At the time of surgery, and during the postoperative stay, specific fields of operative details and clinical outcome are the responsibility of the surgeon. Data entry by trainee and resident staff is not permitted.
4. Postoperative pathology details and adjuvant therapy are entered by the data manager.
5. Ongoing patient follow-up details are entered by the surgeon at the time of subsequent consultations through a standardized set of fields.

### Failsafe Measures to Ensure Data Integrity, Timeliness, and Accuracy

1. Upon login, the surgeon is greeted by a "dashboard" module that provides a summary list of any and all outstanding data points for which they are responsible. Hyperlinks on this page direct to the field in question.
2. A summary email is sent monthly by the data manager to all surgeons highlighting any data deficiencies.
3. Cross-referencing of hospital pathology reports occurs.
4. Fortnightly unit meetings follow a standardized report generated by the software, listing all patients who have undergone surgery in the audit fortnight and any residual inpatients. Deficient audit data are completed at this meeting, and any dispute regarding the presence or absence of adverse outcomes is arbitrated.

During the period of time February 2010 until October 2012, all consecutive patients undergoing abdominal surgery for colorectal neoplasia (with no exclusions) by members of the Colorectal Surgical Society of Australia and New Zealand,

Colorectal cancer database data and process flow all sites. Note that some sites will use a medical fellow in the role of data manager or surgeon or a combination of both.

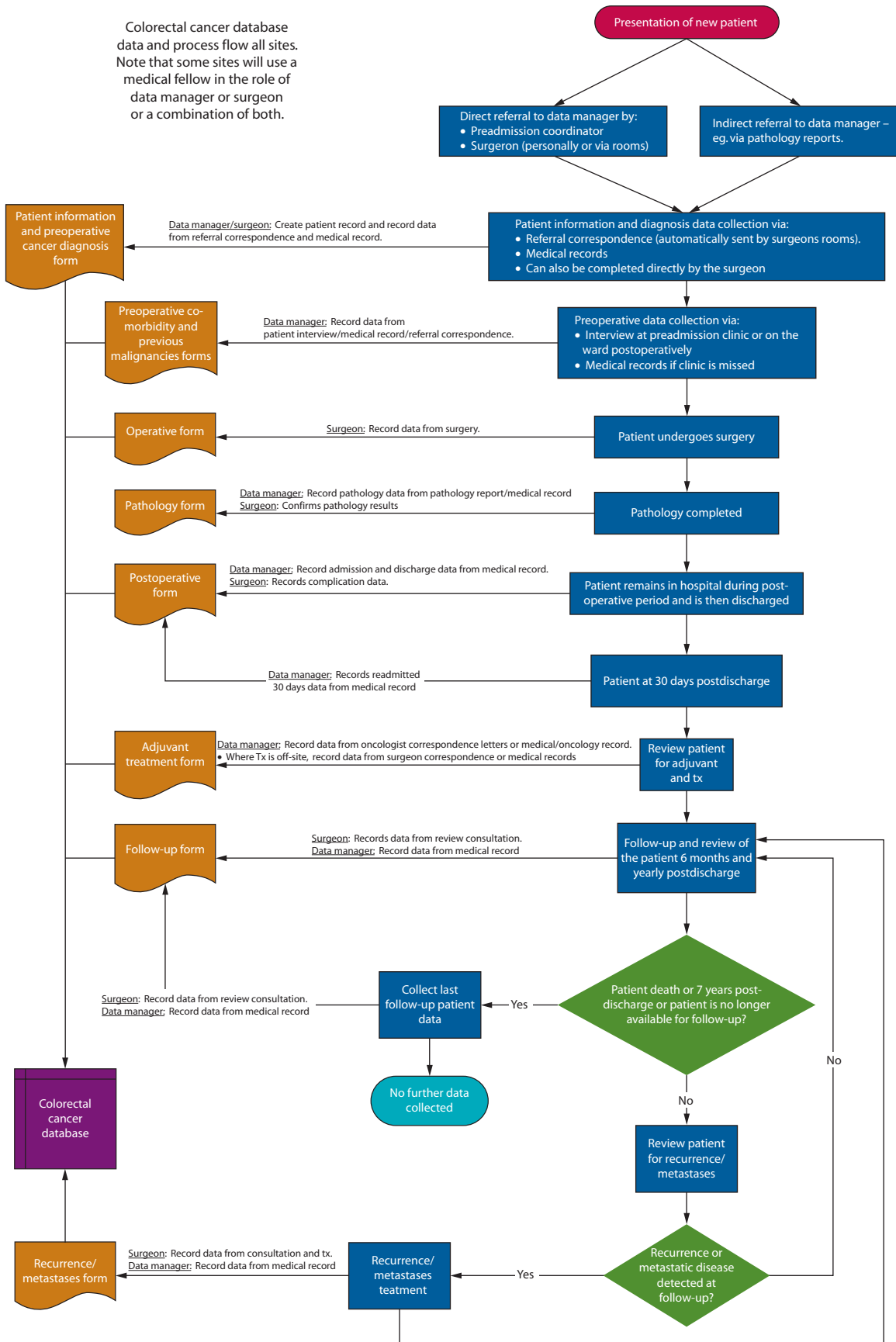


FIGURE 1. Data and process flow. Tx = treatment.

at the 3 participating hospitals (Cabrini Hospital, Alfred Hospital, and The Avenue Hospital, Melbourne, Australia), were included. Agreement was reached that the analysis of results, including completeness of clinician lead data entry and routine clinical outcomes, would occur at the time of entry of the 1000th patient onto the database. This occurred in October 2012. At completion of the recruitment of the 1000th patient, a "grace" period of 2 weeks was defined to allow all surgeons to complete all data points outstanding, as defined by their "dashboard" readout. Analysis of data completeness included patients on whom recruitment had occurred, surgery undertaken, and then a 45-day period had passed (therefore including 30-day postsurgical follow-up and a grace period of 15 days to allow for completion of all data). This study analyzed 932 completed cases.

### **Principles of Development of the Database (CMCD)**

The database was developed under the guiding principles of the Australian Code for the Responsible Conduct of research (the Code)<sup>8</sup> stating that all individuals and institutions have a responsibility to establish good governance, identify ownership, and guarantee security and confidentiality of research data.

### **Confidentiality, Privacy, and Legal Liability**

Collection of data adheres to the "Guidelines on Privacy in the Private Health Sector"<sup>9</sup> whereby all participants are made aware that personal data are being collected. All participants receive a detailed patient information leaflet. An "opt-out" consent process occurred with all patients. Every patient chose to contribute data, thereby, 100% participation rate was realized. All CMCD research staff are trained appropriately and sign confidentiality agreements.

### **Ethics Approval and Governance**

Approval was granted by the Cabrini Human Research Ethics Committee Reference #02-10-04-06 and The Alfred Ethics Committee Certificate of Approval 57/10. The Cabrini Monash University Department of Surgery and the Cabrini Institute own CMCD and control access to the data and its release, in consultation with a Database Management Committee directed by an executive committee, the database manager, participating consultants, and oncologists.

### **Database Infrastructure**

The system is composed of a front-end Web-based application developed in the "Ruby" Web-programming language, using the "Ruby on Rails" application framework hosted on a virtual server at the Monash University Clayton campus. The back-end database is a Microsoft SQL Server 2008 database hosted on a virtual server at the Monash University Department of Epidemiology and Preventive Medicine. The front-end application connects to the back-end database via SQL Server Authentication. Web site security is provided

by an SSL (Secure Sockets Layer Internet data encryption) Certificate, hosted by Thawte Inc (Fig. 2).

### **Audit Trails**

Hospital separations data provide information on services provided to patients admitted to the hospital. We cross-checked patients with a principal diagnosis of cancer according to specific cancer sites in keeping with World Health Organization *International Statistical Classification of Diseases and Related Health Problems*, 10th Revision<sup>10</sup> with those already entered on the database, including C18 "malignant neoplasm of colon" (C18.0–C18.9), C19 "malignant neoplasm of rectosigmoid junction," C20 "malignant neoplasm of rectum," and C21–C21.8 "malignant neoplasm of anus and anal canal." Procedural codes (*Australian Classification of Health Interventions*, 6th edition)<sup>11</sup> were also used to enable specific operative codes to be included in the separation. In addition to this, hard-copy pathology reports ensure that any missing patients are entered on the database. All patients and episodes of care are discussed at multidisciplinary meetings on a fortnightly basis at both the Alfred and Cabrini Hospitals with any data updates entered in real time.

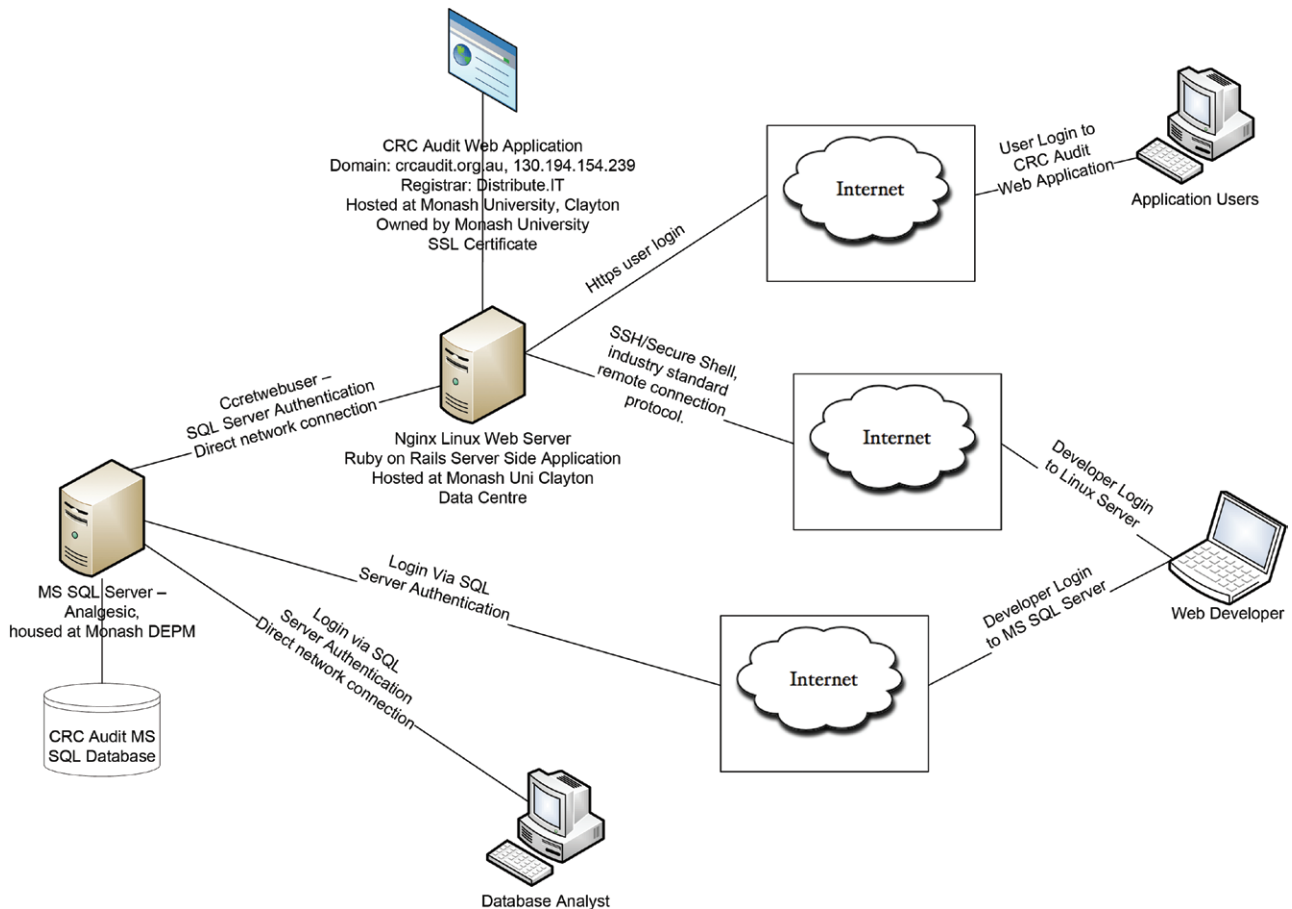
### **Data Sources**

A patient interview is conducted at preadmission clinic or while an inpatient, and data are cross-checked with the patient's health questionnaire. Additional sources are consultant's patient files and correspondence, digital storage in consultants GENIE management system, Medical Records from Hospital Information System, Cabrini and Alfred Patient Inpatient Systems (PAS and CERNER), Oncology Management Information System (CHARM), and pathology Web sites.

### **Data Collection**

The patient management process (Fig. 1) is recorded from the time of presentation and includes details of diagnosis, surgery, pathology, treatment, and follow-up.

Within the treatment episode, there is provision for 13 specific surgical complications and 4 medical complications, return to theater, inpatient death, and readmission within 30 days postsurgery. Pathology data entry includes type, differentiation grade, T, N, and M stage with overall TNM stage calculated, lymph node harvest and number of positive nodes, lymphovascular invasion presence, circumferential margin and distal margin distance, together with any relevant testing for immunohistochemistry, microsatellite instability, and familial adenomatous polyposis. Adjuvant therapy, if offered, outlines drug type and duration of chemotherapy, dose of radiotherapy, as well as 7 possible reasons for cessation of treatment. There is also provision for follow-up data on the patient at 6 months postdischarge and then yearly for 7 years, until the patient is discharged, nominated



**FIGURE 2.** Network connections. CRC = colorectal carcinoma.

as lost to follow-up, or deceased. Follow-up data cover patient status, complications, relevant test results, recurrence, and the development of metastases. Both previous colorectal malignancies and other malignancies are recorded.

## RESULTS

### Data Completion

A total count of 1012 diagnoses from 1000 patients were recorded on the database as of October 2012 with 765 (Cabrini), 228 (Alfred), and 19 (Avenue). Given that there are more fields for patients with rectal cancer than colonic cancer (with greater detail of operative technique recorded) for 1000 patients, there were greater than 27,000 data fields that were specifically expected to be recorded by the treating surgeon. At the time of requested completion of clinician-entered data fields, only 20 were missing and were able to be retrieved from data records within 24 hours. Clinician lead data entry was therefore essentially 100%.

### Clinical Outcomes

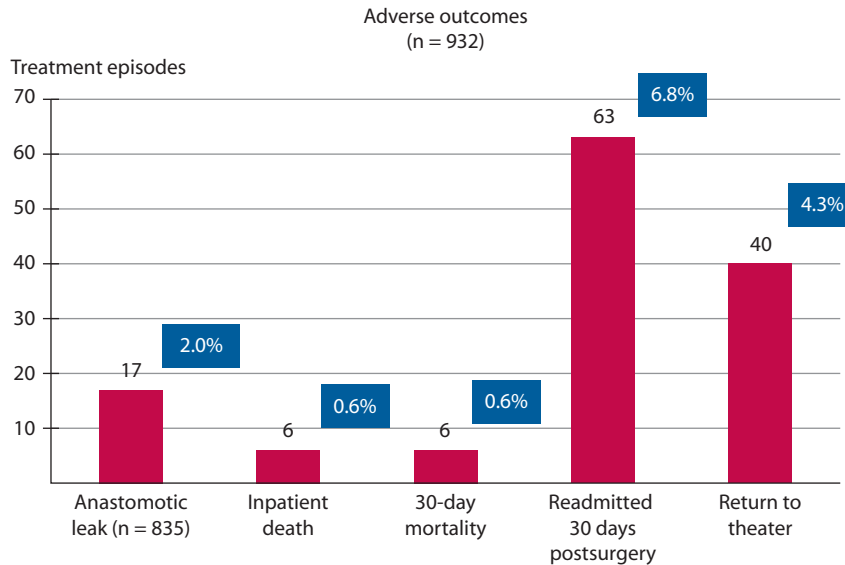
The average patient age over the 3 hospital sites was 68 years with a range of 22 to 94 years. Sex proportions were

very similar with 516 men accounting for 51.6% of all diagnoses compared with 484 women. The proportion of patients with colon cancer was 66.1%; the remainder was rectal cancer. Basaloid anal cancer and other GI neoplasms were not included. The majority of patients (65.2%) presented at operation with an ASA score of either ASA I or II, but almost 5% had a score of ASA IV. The most common types of operation were right hemicolectomies and high anterior resections. Cancers were not resected in 3.9% of all cases; however, 88% of all resections performed were deemed curative. TNM staging distribution was 12.7% stage 0, 21.5% stage I, 27.8% stage II, 25.3% stage III, and 10.8% stage IV. The most common adverse surgical outcome was prolonged ileus, whereas cardiac and "other" complications contribute to the majority of medical outcomes. Forty patients were returned to theater, 63 patients were readmitted within 30 days postsurgery, and 6 patients died while an inpatient (Fig. 3).

## DISCUSSION

In 2013, the rate of most major adverse outcomes after colon and rectal cancer surgery is less than 10% in centers of





**FIGURE 3.** Adverse outcomes.

excellence. If meaningful comparison between centers is to be made, or risk stratification profiling to occur, sample size of several hundred patients will be required at a minimum, assuming completeness of data entry and accuracy. It is therefore imperative that any clinical cancer database approaches 100% data completeness and uses a clinical loop to ensure data accuracy. Skeet,<sup>12</sup> in his definitive review, outlines the importance of all registries being able to quote some objective measure (of data ascertainment). In this particular series, we report 100% completion of those data items entered by clinicians, including operative details and clinical/oncological outcome fields. Bray and Parkin<sup>13</sup> emphasize the importance of the techniques of ensuring data validity. In this series, we have used diagnostic criteria methods including histopathological verification and reference against hospital administrative databases. In addition, objectivity and accuracy of data entry regarding adverse outcome in our series was ensured by subjecting each case, with open presentation of data points, to a departmental meeting for discussion, with input from ward and trainee staff who contribute to reporting of adverse outcome. Data presented at this meeting include triggers for the presence of complications, such as increased length of stay, or return to theater, and the data are secondarily cross-referenced against hospital administrative records relating to theater episodes and pathology specimens.

Many reports of data collection models, both as national registries and local clinical databases, have reported variable results in relation to data completeness and accuracy. The report of a South Australian colorectal cancer database<sup>14</sup> discloses data completeness of approximately 80%. Warsi et al<sup>6</sup> report a regional British series in which data are incomplete in 21% of colorectal cancer cases. The ACPGIB/NBOCAP annual report of 2005 (www.

nbocap.org.uk) reports incomplete data in fields that can be regarded as essential to the assessment of oncological outcome, and for risk stratification (Dukes staging and operative urgency) as being incomplete in between 0% and 80% of data contributed from individual centers. Moreover, Sehgal and Davies,<sup>15</sup> in reporting the roll-out of a regional database indicate that a significant proportion of centers are variable from year to year.

The rate of adverse outcomes reported in this series (Fig. 3) compares favorably with other published series. The anastomotic leakage rate (2.0%), 30-day mortality (0.6% for all cases including palliative and emergency resections), 30-day readmission (6.8% for all causes), and return to theater (4.3% for all causes) compare favorably with Australian and other international audit data.

In series of Due et al,<sup>14</sup> a decision was made to remove the process of data entry from the hands of contributing surgeons and have the duty performed by senior trainees, arguing that this would improve the objective nature of data reporting. Conversely, we would propose that specific details of operative data entry (for example, the height of anastomosis, details of anastomotic technique, etc) require the accurate input of a consultant surgeon rather than a trainee who may or may not be present at the time of surgery, particularly in the private sector, where a substantial proportion of colon and rectal surgery occurs in many developed countries.

The placement of the database in a university department of epidemiology ensures that issues of data "ownership" are not the source of interhospital rivalry, enhancing the appeal of the model to multiple centers. Reflecting the structure and success of this data collection model, it has been adopted as the Binational Colorectal Cancer Database of the Colorectal Surgical Society of Australia and

New Zealand. To ensure scalability, the database has been modified to allow participation at the level of the current data set (“Extended Data Set”) or at a minimum data set level, allowing participation by smaller, and less well supported clinical centers. Binational roll-out is anticipated to occur in late 2013, and more than 87 centers have contracted to participate.

Having demonstrated the success of this model within the scale of 2 high-volume contributing centers, the obvious challenge is maintaining this degree of success with extension of the database model to the point of a binational Australasian registry. The acceptance of the Colorectal Surgical Society of Australia and New Zealand of this model as their binational model, and the enthusiastic uptake by multiple centers, needs to be supported to ensure that these results, both in terms of data completeness and clinical outcome, can be generalized. Commensurate with this, a substantial rewrite of the software has occurred at the level of the browser-based front end to ensure stability when being accessed by a much larger number of users. In addition, it is recognized that the resources required at a tertiary hospital for completeness of an extended data set are not resources available to surgeons in solo practice and in remote areas. To this end, the minimum data set has been constructed, allowing data entry to be maintained entirely by an individual clinician without the required support of a paid data manager. All participants will therefore be able to, at the time of sign up, participate at the level of a minimum data set or extended data set. Minimum parameters for available support, including the presence of a funded data manager, and willingness to participate at an agreed level of data completeness will be mandated for any center that elects to participate at the level of the extended data set. At the level of the minimum data set, guidelines and support will be provided through the Colorectal Surgical Society of Australia and New Zealand (CSSANZ), encouraging clinicians to participate in an at least monthly data review meeting, with colleagues, to ensure data completeness and accuracy. It is hoped and anticipated that with the expected success of the binational roll-out of the scalable database, governmental and institutional funding will follow.

A central aim of both our own department, and of the CSSANZ, is the translation of this initiative into approved outcomes for patients. The governance structures of both the Cabrini Monash Department of Surgery and of the CSSANZ include provision for facilitation of both clinical and translational research projects, linked to tissue banking, of patients who participate in the database, after appropriate ethics approval. Projects linked to the database through the Cabrini Monash Department of Surgery have already achieved grant success through the National Health and Medical Research Council of Australia. In addition, the structure of the current system will allow facilitation of completion of a quality assurance loop, ensuring

the quality of clinical work of both individuals and of unit clusters. Completion of this loop, however, would require considerable input from all stakeholders, including the clinicians themselves, local health boards and hospital boards, and the CSSANZ itself.

## CONCLUSION

This series demonstrates that a Web-based model of data collection, with appropriate resources, can be used to obtain complete data collection with engagement of surgeons in both the private and public sector.

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