Cabrini Monash University Department of Surgery
Colorectal Cancer Database Overview

1. Overview

The Colorectal Cancer Database (the system) supports the collection and storage of clinical research data throughout the patient management cycle from the time of presentation and diagnosis, through to surgical and oncological treatment and ongoing follow ups.

Within the system, the Consultant is the primary data owner with full data access to their own patient data. The Consultant is supported by the roles of Database Manager and hospital specific Site Managers for data management and data collection.

The system has been developed as a research data repository, therefore making it an additional process to the Consultant’s existing patient management. In order to support the ongoing use of the system at both the Consultant and support levels, activity tasks and workflow reminders have been included and the data collection has been structured to match the patient management cycle.

2. Technical Considerations

The system is composed of a front end web based application which provides the user interface and a backend database for storage and management of the data.

- The front end application has been developed in the ‘Ruby’ web programming language, using the ‘Ruby on Rails’ application framework. It also uses multiple plug-ins, many of which have been custom developed for the application. It is currently hosted on a virtual server at the Monash University Clayton campus which is administered by the Monash Web Team.
- The developer of the front end application is Adam Meehan, Research Path Pty. Ltd.
- 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 at the Alfred.
- The front end application connects to the back end database via the Monash University network.
- Website security is provided by an SSL (Secure Sockets Layer internet data encryption) Certificate, hosted by Thawte Inc.
3. Front End Web Based Application

The application has been developed so that a Consultant can enter data throughout the entire patient management process with support by the Database Manager and Site Managers. It has the following components and features:

3.1. General

- A series of secure web forms which serve as the user interface and data entry screens.
- The application can be accessed at https://crcaudit.org.au.
- No direct access to the back end tables is possible from the front end application, thus providing controlled and secure user access.
- The application has been configured and tested to run on Internet Explorer, Mozilla Firefox and Safari.
- The application can be accessed by multiple users concurrently at remote sites wherever an internet connection is available.

3.2. Data Entry Web Forms

All user access, data entry, data display and data management is done via the web forms.

- A search function is included to allow a Consultant to search for a patient.
- The web forms are presented as data groupings based on the patient management process as follows:

3.2.1. General Patient Details
- Patient demographic data.

3.2.2. Treatment Episodes
- Surgical and oncological treatment data (see below).
- As a patient may present for multiple treatments, the application allows for multiple Treatment Episodes per patient.

3.2.3. Follow Up
- Follow up consultation information including data on recurrences of disease and management of the recurrences.

3.2.4. Previous Colorectal Malignancies
- Past colorectal malignancy information to assist with risk determination.

3.2.5. Previous Malignancies
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Within the Treatment Episode grouping, further web forms allow for the capture of specific treatment data as follows:

3.2.6. Treatment Episode Details
- Information on the treating Consultant, hospital and a patient’s preoperative cancer diagnosis.

3.2.7. Preoperative
Co-morbidity and risk factor information to assist with determining risk.

3.2.8. Operative
- Operation/surgery specific information.
- The system allows for more than one operation (referred to as a procedure) and more than one tumour for a given surgical treatment.

3.2.9. Postoperative Pathology Data
- Pathology results and tumour staging from a patient’s operation.
- Tumour details that are recorded on the Operative forms are automatically transferred into the Pathology forms to allow tumours to be tracked from operation to pathology.

3.2.10. Postoperative Complications and Discharge
- Information on surgical and medical complications during a patient’s stay post operation.
- Includes if the patient has been returned to theatre for a complication.

3.2.11. Adjuvant Treatment
- Post operative chemotherapy or radiotherapy treatment information.
- Note that for the current Version 1 system, adjuvant treatment data is based on a minimum data set, with a larger data set to be considered for future implementation.

3.2.12. Follow Up
- Information to allow a patient to be followed up over a specified period of time after they have been discharged from hospital.
- The system allows multiple follow ups to be recorded.
- The follow up data group incorporates recurrences and metastases information.

3.3. Tasks

Each data grouping (as outlined above) can be considered as a record which requires a number of individual data items. The system tracks the completion of a record (data grouping) as a series of tasks for each patient.
- A task is defined as the action of successfully entering all data for a data grouping.
- Tasks have a status of:
  - Start ‘Data group’ e.g. Start ‘Operative for Patient’
  - Complete ‘Data group’ e.g. ‘Complete Operative for Patient’
- A task is deemed to be complete where all data in a data grouping are successfully entered and validated.
- Where a data group has missing data, the record can be saved but will remain as an open task (to be completed) until all data fields are entered.
- The Database Manager has the ability to close a task even if data fields are missing as part of a data audit process.
3.4. Outstanding Tasks

To assist with data entry and management, each Consultant is presented with an Outstanding Task list. The list shows:

- The task status e.g. ‘Start’ and ‘Complete’.
- The missing data items required to complete the task e.g. ‘serum cea’.
- A link that takes the Consultant directly to the data entry screen to complete the task.
- Tasks can be sorted by patient and by task type.

3.5. Due Tasks

Where a task is based on a timing event it is displayed in an ‘Items Due’ list as an adjunct to the Outstanding Task list. The following timing events are tracked in the system:

- Where a Treatment Episode is created and a ‘Proposed Surgery Date’ is entered, a due task is created 1 day after the proposed surgery date, to complete the Operative data group.
- At 10 days following the date of surgery a due task is created to complete the Postoperative Complications and Discharge data group.
- After a patient is discharged there is a time lag of 30 days until the Postoperative Complications and Discharge data grouping can be completed. The system creates a due task at 30 days post discharge to complete the data group.
- At 6 weeks post discharge a due task is created sent to start the Adjuvant Treatment data group.
- When Adjuvant Treatment data is entered, there is a time lag (23 weeks default) until treatment is completed and final data can be entered. The system creates a due task at the completion of the specified time lag.
- When an initial 6 month and subsequent 12 monthly patient Follow ups are due, the system creates a due task to complete the Follow up data group.

Whenever a data grouping is successfully entered and a task is completed by a Consultant or Site Manager, the system notifies the Database Manager by email for the purposes of cross checking.

Note that the system will only create due tasks at the allotted times, where a task has not been started. Where a task has been started or completed, a due task is not created.

3.6. Recent Patients and Activity Lists

Additional lists are included to further support data management by allowing quick navigation to recent patients and data entry activities.

- The five most recently added patients appear in a listing with direct links to the patient record.
The five most recent patient activities (e.g. created Operative for Patient) appears in a listing with direct links to the data entry screen for that activity.

3.7 User Access, Roles and Administration

The system supports the following roles:

3.7.1 Database Manager
- Has access to all patient records in the database.
- Can create a patient and assign a Consultant to the patient.
- Can delete patient records with the action logged. This allows for the removal of a record when a patient opts out of the database.
- Has access to maintain users, roles and access levels.
- Can close a data grouping record/task even if data fields are missing as part of a data audit process. Conversely the Database Manager can reopen a closed task.

3.7.2 Consultant
- A Consultant has the ability to create a patient in the database and is assigned all access rights to that patient.
- Where the Database or Site Manager creates the patient, the assigned Consultant is granted full access rights within a Treatment Episode.
- When a Consultant logs into the database, they only see the patients they have access to.
- For the purposes of reporting (see below) a Consultant can be assigned to one or more Hospitals. The Hospital does not incorporate any access rights, it is used for reporting purposes and for allowing a hospital specific site manager to view all patients at a particular hospital.

3.7.3 Oncologist
- The system incorporates an Oncologist role which allows an Oncologist to be assigned to a patient in the Adjuvant Treatment data grouping.
- An oncologist may be a chemotherapy oncologist or a radiotherapy oncologist.
- The system has been developed so that once assigned, an Oncologist has access to the patient and can complete the Adjuvant Treatment data grouping as a task.
- Note that in this implementation of the database, an operational decision has been made where the Oncologist role is only used to assign an Oncologist’s name within an Adjuvant Treatment data grouping. Therefore, no Oncologist patient access, tasks or email notifications are operational but they are built in to allow for subsequent activation.
3.7.4. Site Manager
- A Site Manager role has been incorporated to support data management and entry at a specific site.
- A site is defined as a hospital e.g. Cabrini Malvern, Alfred etc.
- A Site Manager has access to all patients within their site – as set in a patients Treatment Episode or as created by the Site Manager.
- A Site Manager can create a patient and assign a Consultant to the patient.

3.8. Reports

This version of the front end application includes two standard reports that can be run by a Consultant at any time.
- The reports produce total patient numbers and averages based on specific data fields. No further data analysis is incorporated into the reports.
- Extensive and long term data analysis will be completed by the Monash University Department of Epidemiology and Preventive Medicine at the Alfred.

3.8.1. Comparison Report

- This report allows a Consultant to compare their own or hospital results with those of the overall database (totals and averages) for a number of demographic fields:
  - Total patient numbers
  - Total treatment episodes/diagnoses
  - Patient age
  - Cancer type
  - ASA status
  - Operation type
  - Resection status
  - Curability status
  - Pathology stage
- The fields are based on the Association of Coloproctology of Great Britain and Ireland (ACPGBI) Bowel Cancer Study 2004, unit report model.

3.8.2. Outcomes Report

- This report allows a Consultant to look at treatment outcome data for themselves, against their hospital and the total database (totals and averages). The selection fields are based on:
  - Cancer type
  - Operation type
- The outcome data includes:
  - Surgical outcomes
  - Medical outcomes
  - Return to theatre
4. Back end database

The development of the system includes the storage of data in a series of tables in a back end database. The back end database is in turn stored and managed within a Microsoft SQL Server 2008 Relational Database Management System (RDBMS).

The back end database development consists of three main entities: tables, a table schema and a data dictionary. The RDBMS contains an administration module (MS SQL Server Management Studio) which provides administration and management of the database entities. The administration module also allows direct SQL query access to the database tables.

4.1. Tables
- The tables are based on the data groupings as presented in the front end application.
- The tables consist of the records and data fields which store the data.

4.2. Table Schema
- The table schema represents the relationships between the tables that allow data groupings to reference each other.
- The table schema also allows a data hierarchy to be set e.g. a Patient is the parent data group which contains child data groups of Treatment Episodes, Follow Ups etc.

4.3. Data Dictionary
- The RDBMS creates the data dictionary dynamically as part of the tables.
- The data dictionary acts as the metadata (data about the data) repository for all the data fields in the database, grouped by table/data grouping.
- It is maintained by the Database Manager to ensure that all relevant information relating to the data is captured and stored.

Direct access to the database entities can only be done via the RDBMS administration module.

- In-patient death
- Readmittance within 30 days
- Length of hospital stay