Development of a Policy and Procedure Manual for the Surveillance and Epidemiology Unit, Cancer Care Nova Scotia

by

Alison Zwaagstra B00202643 alisonz@cs.dal.ca

Performed at
Surveillance and Epidemiology Unit
Cancer Care Nova Scotia
Room 555-C Bethune Building
1278 Tower Road,
Halifax, Nova Scotia
B3H 2Y9

In partial fulfillment of the requirements of the Master of Health Informatics Program,
Dalhousie University

Report of Internship for the period April 23 – August 10, 2007

Date Submitted: September 17, 2007

Acknowledgement and Endorsement

Alison Zwaagstra has written this internship report in partial fulfillment of the requirements for the Master of Health Informatics Program at Dalhousie University. This report has not received any previous academic credit at Dalhousie University or any other institution. The Policy and Procedure Manual document that was submitted to the Surveillance and Epidemiology (SEU) at *Cancer Care Nova Scotia* is included. Some of the information contained in this document is used in the Internship Report where appropriate.

I would like to thank Maureen MacIntyre, SEU Director, for providing me with the opportunity to complete my internship at the SEU. She was very supportive throughout the project and made the internship an enjoyable experience. I also would like to thank everyone at the SEU for their valuable input and ideas during the development of the Policy and Procedure Manual.

Alison Zwaagstra

Executive Summary

The internship was completed at the Surveillance and Epidemiology Unit (SEU) at *Cancer Care Nova Scotia* (*CCNS*). The SEU is responsible for collecting and analyzing data on all diagnosed cases of cancer in Nova Scotia. This data is stored in the Nova Scotia Cancer Registry database which has been in existence since 1964. The main objective of the internship was to construct a Policy and Procedure Manual that provided a detailed overview of all core SEU processes.

The internship work was performed from April 23 to August 10, 2007. The project involved documenting each policy and procedure in written format as well as presenting them graphically through flowcharts developed using Microsoft Visio. Information was obtained through reviewing existing documentation, staff meetings and observing work flow at the SEU. An objective of the project was to improve information and work flows wherever possible.

One major problem identified by the author while analyzing the business processes at the SEU was that the current method of receiving pathology reports via letter mail from laboratories around the province is highly inefficient. A significant amount of time is spent opening the mail, sorting the reports for patient enrollment and filing the completed reports. Filing space is limited at the SEU and it is a challenge to find locations for new filing cabinets. Another problem with paper-based case ascertainment is that the SEU has to reply on transcriptionists to identify cancer cases and send copies of the pathology reports to the SEU. This method is subject to human error and cases could be missed which could potentially impact incidence rates.

Case ascertainment would be much more efficient if the SEU adopted electronic pathology reporting or E-path, an IT solution that allows pathology reports to be submitted electronically to a cancer registry. The introduction of E-path at the SEU would eliminate time consuming tasks such as filing or data entry since the information would be digitized. In addition, E-path would allow case finding to be done automatically using an autocoding module and filtering logic.

The internship was a valuable learning experience for the author. Developing a policy and procedure manual is a time-consuming but useful process that allows an organization to discover inefficiencies and identify areas for improvement.

Table of Contents

1	Introduction	1
2	Description of the Organization	2
3	Work Performed for the Internship	4
	3.1 Description and Role	4
	3.2 Project Phases	5
	3.2.1 Defining the Project	
	3.2.2 Research	
	3.2.3 Writing Phase	
	3.2.4 Revision and Review	
	3.2.5 Completion of Final Draft	6
4	The Relationship with Health Informatics	6
5	Health Informatics Problem and Solution	7
	5.1 Problem: Paper-based Case Ascertainment	7
	5.2 Proposed Solution: E-Path Reporting	8
	5.2 Solution: E-Path Reporting	
	5.2.1 Comparison of Paper-Based and E-Path Workflow	
	5.2.2 E-Path at the Ontario Cancer Registry	
	5.2.3 Automated Electronic Case Finding	11
6	Conclusions	12
7	Recommendations	13
8	References	14
9	Appendix	15
	• •	

1 Introduction

Cancer is a disease affecting approximately 159,900 Canadians each year [1]. In Nova Scotia alone, there were nearly 8,400 residents diagnosed with some form of cancer and approximately 28,000 (1 in 34) living with an invasive cancer in 2004 [2]. Collecting cancer data is very important in order to understand the burden of cancer and to set priorities for cancer programs such as prevention, screening and treatment. Cancer data collection is a primary responsibility of the Surveillance and Epidemiology Unit (SEU) at *Cancer Care Nova Scotia (CCNS)*. The SEU operates the Nova Scotia Cancer Registry (NSCR), a database used to collect and analyze information on all diagnosed cases of cancer in Nova Scotia.

In recent years, changes have been made to data collection standards within the SEU. In 2001, there was a shift from coding disease information using the second edition of the International Classification of Diseases for Oncology (ICD-O) to the third edition of ICD-O. The volume and scope of data collected by the SEU increased in 2004 when staging data began to be captured. As theses changes occurred, core business processes needed to be updated and the SEU developed some documentation reflecting these changes. However, the SEU did not have a complete set of documentation that described all processes and procedures required to maintain the NSCR. Furthermore, the majority of documentation focused on data definitions and standards without describing business process models.

The internship objective was to develop a Policy and Procedure Manual for the SEU outlining the operational requirements of the NSCR. The project involved working with SEU staff to document work flows and business processes. Information was gathered though staff meetings, observing work flow and reviewing existing documentation. As each process was documented, recommendations were made to improve information flow and changes were made accordingly. In the Policy and Procedure Manual, business models were described in written format and were also presented graphically through flowcharts created with Microsoft Visio.

This report outlines the process taken to develop a Policy and Procedure Manual for the SEU. The report will first provide an overview of the SEU and *CCNS*. It will then describe the work performed during the internship and how this work relates to health informatics. Finally, the report will discuss how case ascertainment at the SEU could be improved by adopting E-Path, an

information technology solution offered by vendors such as Artificial Intelligence in Medicine Inc. that allows pathology laboratories to submit reports electronically to a cancer registry, rather than having to send paper reports via letter mail.

2 Description of the Organization

The SEU is responsible for collecting and analyzing data on all diagnosed cases of cancer in Nova Scotia and manages the Nova Scotia Cancer Registry (NSCR) database [3]. The NSCR is a population based registry and its main priority as stated by the National Cancer Institute in the United States, is to "record and consolidate information regarding all cases diagnosed within a specific geographic area and therefore provide data that can determine rates across regions of the country" [7]. By analyzing the data contained in the NSCR, the SEU provides annual cancer reports to the nine District Health Authorities in the province and publishes a monograph every five years offering a detailed statistical overview of the cancer profile in Nova Scotia [5].

Cancer is a reportable disease and legislation governing the mandatory reporting of cancer is outlined in Section 101 of the Nova Scotia Health Act [4]. This legislation was introduced in 1964 the same year the NSCR was established and was reissued in 2006 during a review of the Health Act. In the past, the NSCR had been affiliated with the Cancer Treatment and Research Foundation of Nova Scotia and then was operated by the Queen Elizabeth II Health Sciences Centre for about five years. The NSCR was formally moved under the responsibility of *CCNS* in 2000 when the SEU was established [5]. *CCNS* is a program of the Nova Scotia Department of Health established in 1998 to strengthen the cancer system in the province and to serve as the body responsible for overall cancer control. *CCNS* program areas include prevention, screening, education, treatment and palliation [6].

The data management program used for the NSCR is the Oncology Patient Information System (OPIS). It is a relational database that was custom designed and developed. In addition to its registry based functions, OPIS is the patient information system for the Nova Scotia Cancer Centre (NSCC) located in Halifax as part of the Capital District Health Authority (CDHA) and the Cape Breton Cancer Centre (CBCC) in Sydney, which is managed by the Cape Breton District Health Authority (CBDHA) [5].

All staff at the SEU follow strict guidelines to maintain data confidentiality. These guidelines carry through from the initial case registration to research and reporting activities [2]. Staff at the SEU also work diligently to ensure operations meet cancer registration standards outlined by the Canadian Cancer Registry (CCR) and the North American Association of Central Cancer Registries (NAACCR). The SEU submits data to both the CCR and NAACCR on an annual basis. NAACCR offers an annual certification review of data quality for the NSCR data set which serves as an external validation of the work conducted by the SEU [5].

The SEU is a 12-person team consisting of clerical, technical and professional staff. All SEU staff report to the SEU Director. The SEU Director reports to the Chief Operating Officer (COO) of *CCNS*. SEU personnel include the following [5]:

- Administrative Assistant
 - o Provides administrative support to SEU staff.
- Analytical Staff (3 Epidemiologists and 1 Statistical Research Associate)
 - Create and maintain data sets for analysis.
 - o Provide analytical support for the production of key surveillance indicators.
- Director
 - Directs key surveillance components of the cancer control program in NS and provides leadership for the SEU.
- *Health Information Management (HIM) Professionals* (3)
 - Abstract and code cancer information including disease classification, staging and prognostic variables obtained from source documents.
 - o Carry out special studies as assigned.
- Patient Enrollment Clerk
 - o Processes all paperwork and is responsible for editing, updating and entry of registration data (e.g. patient demographics) in the NSCR database.
 - o Files reports in designated areas once disease registration has been completed.
- Registry Assistant
 - o Responsible for coordinating and managing registry-based research initiatives.
 - Prepares ethics submissions for registry projects and assists staff with research proposals, publications and presentations

• Registry Team Leader

- o Responsible for data management operations at the SEU and advises the registry team on issues related to data collection, abstracting, processing and reporting.
- o Monitors data quality and adherence to defined standards (e.g. CCR and NAACCR).
- o Oversees data submission to CCR and serves as primary contact for data requests.

3 Work Performed for the Internship

3.1 Description and Role

The objective of the internship was to develop a Policy and Procedure Manual for the SEU that provided a detailed overview of SEU program activities and core business processes particularly as they relate to the NSCR mandate. The main intent of developing the Policy and Procedure Manual was to have documentation explaining why and how each business process at the SEU is done. The completed manual will help to ensure the SEU operates smoothly and will serve as an excellent reference for new staff. Section II.A.3.a of NAACCR's Standards for Completeness, Quality, Analysis, and Management of Data (Standards for Cancer Registries, Volume III) states: "Permanent, current, widely distributed written documentation of all aspects of the registry's definitions and methods is essential to establish standardization, maintain continuity of meaning, document changes over time, develop training, and inform data users" [8].

The role of the author was to meet with staff members to observe SEU activities in order to produce accurate documentation of work flows and business processes. It was important to pay close attention to detail and to ensure the documentation was both clear and precise. Microsoft Visio was used to create flowcharts that accompanied the documentation.

For this project, a work plan was established and timelines were identified in order to complete the project. Meetings were held with the SEU Director approximately every one to two weeks to report project progress.

3.2 Project Phases

The Policy and Procedure Manual was completed in five phases. These included: 1. defining the project, 2. research, 3. writing, 4. review and revision, and 5. completion of final draft. Each of the five phases will be discussed in the following sections.

3.2.1 Defining the Project

During the first week of the internship the author had a meeting with the SEU Director to discuss project requirements. The final deliverable was to be a Policy and Procedure Manual for the SEU covering the core business processes. It was expected that a flow chart would be created for each business process that provided a clear picture of the information/work flow. An outline was developed that listed items to include in the manual. This was based on procedure guidelines from NAACCR for developing a policy and procedure manual [9].

3.2.2 Research

The research phase involved becoming more familiar with cancer organizations in Canada and the United States including the Canadian Council of Cancer Registries (CCCR) and NAACCR as well as cancer registry management practices. All existing SEU policies and procedures were reviewed. The Alberta Cancer Registry was contacted and various policy related documentation was received. The author reviewed policies and procedures for *CCNS* and the Capital District Health Authority (CDHA) to learn about policy formatting and writing style. A template for the SEU was created based on the *CCNS* template.

Information was also obtained on how to document work flow and produce business process models. A similar project was conducted by CDHA Management Engineering that documented work flows for the Nova Scotia Cancer Centre. It was strongly recommended by Mr. Kris Dove, who worked on this project, that Microsoft Visio be used to create the flowcharts. Mr. Dove kindly gave the author an orientation to Visio and common symbols used in flowcharts.

3.2.3 Writing

In order to document the business processes, it was necessary to meet with the staff member(s) involved with each process and have them describe in detail their various work activities. An initial draft was produced based on the information gathered in these meetings. A flowchart was

then created that provided a graphical representation of the written documentation. The author also included sections as recommended by NAACCR including registry information, administration, office management, information technology and legislation [9].

3.2.4 Revision and Review

Once the initial draft for a policy and procedure was completed, it was circulated via email to the appropriate staff member(s) as well as the Registry Team Leader and SEU Director. Review sessions were held when major updates had to be made to existing documentation or if workflow changes needed to be proposed.

3.2.5 Completion of Final Draft

After all staff members were satisfied with all updates and changes, the final draft was submitted to the SEU Director for approval. The NAACCR documentation and the policies and procedures were then combined together to form the manual. The Policy and Procedure Manual will be stored on the SEU shared drive so it can be accessed by all staff members. One paper copy will be available from the Registry Team Leader. All policies and procedures will be reviewed and updated as necessary, but not less than once every three years. New policies and procedures will be written when required. For example, policies and procedures may need to be updated due to staffing changes or information system upgrades [5].

4 The Relationship with Health Informatics

The internship involved meeting with staff and reviewing existing processes to gain an understanding of the work and information flow at the SEU for maintaining the NSCR. The work was closely aligned with the content of the Health Information: Its Flow and Use course in the Master of Health Informatics program. For that course, the author had completed a similar project dealing with the information flow of the SEU with respect to the NSCR operational requirements. The internship work was an expansion of this project and each business process was examined in much greater detail. The business process models considered person-to-person and person-to-computer system interactions.

All activities required to process a case and enter information on OPIS were documented in the Policy and Procedure Manual. The goal was to ensure the various tasks at the SEU were completed consistently by all staff. The flow charts that accompany the policies and procedures will serve as a good reference for SEU staff. The diagrams have a number of decision points outlining the different pathways for each possible scenario.

When documenting the business processes and creating the models, the goal was to improve information and work flow wherever possible. In some instances, unnecessary or redundant tasks were eliminated to streamline the process. It was observed that some tasks were completed by multiple staff members that only needed to be handled by one person. Recommendations were also made to make processes more efficient. For example, the author recommended that disease registration and disease staging be completed as one continuous process. The same patient information was needed to complete both disease registration and disease staging but the processes were being done separately. It was determined that time would be saved if SEU staff did not have to access the same information on the various information systems on separate occasions.

5 Health Informatics Problem and Solution

5.1 Problem: Paper-Based Case Ascertainment

The majority of the information entered on OPIS by the SEU is obtained from paper-based pathology reports. Pathology reports are mailed to the SEU from all pathology laboratories across the province. Some laboratories submit pathology reports to the SEU on a daily basis while others send pathology reports once every one to two months.

While analyzing the business processes and modeling the flow of information at the SEU, it was observed that paper-based case ascertainment poses a number of problems. The paper-based system is inefficient and a significant amount of time is spent opening the mail and sorting the reports each day for patient enrollment. Filing the pathology reports once disease information has been entered on OPIS by the HIM professionals is also time-consuming. In addition, filing space for storing the pathology reports is very limited. It is a constant struggle at the SEU to find locations for new filing cabinets.

Another problem with paper-based case-ascertainment is that the SEU has to rely on staff at the pathology laboratories to identify, copy and mail the paper documents. The SEU has provided the laboratories with a list outlining all diagnoses and types of cancer that need to be reported to the NSCR. With a manual system, it is possible cases may be missed due to human error. Furthermore, timeliness of reporting can be an issue because there are costs associated with mailing the documents. Some rural hospitals only send reports on a monthly basis to the SEU since there are only a small number of cases seen at their facility.

5.2 Proposed Solution: E-Path Reporting

In order to improve case ascertainment and eliminate the time consuming tasks associated with paper reports, the SEU should consider implementing E-Path. This is an information technology solution that allows pathology reports to be obtained electronically to cancer registries rather than by mail or facsimile. According to NAACCR, E-Path is the most efficient way to ascertain cases from pathology laboratories and allows pathology reports to be sent and received as electronic data streams [10].

The NAACCR IT committee has made electronic pathology reporting a priority in recent years and formed the Pathology Laboratory Subcommittee. A set of guidelines were created for transmitting cancer information from pathology laboratories to cancer registries. The Pathology Laboratory Subcommittee has recommended the use of Health Level Seven (HL7) as the data format for transmitting electronic pathology reports [10]. HL7 is highly useful because it allows data laboratories to transfer files containing different amounts of text without being concerned about maximum character length. NAACCR has also developed procedural guidelines for implementing standards for E-Path reporting [11].

One vendor that offers the E-Path technology is Artificial Intelligence in Medicine (AIM) Inc. based in Toronto. There are currently 15 cancer registries in the United States using AIM's E-Path solution. In Canada, E-Path has been implemented by the Ontario Cancer Registry at CancerCare Ontario as well as the Newfoundland Treatment and Research Foundation [12].

5.2.1 Comparison of Paper-Based and E-Path Workflow

Figure 1 shows the traditional workflow for processing paper used before the introduction of AIM's E-Path by the Ontario Cancer Registry [13]. This is quite similar to the processes carried out by the SEU. Please refer to the Mail, Patient Enrollment, and Disease Registry and Staging Procedures in the SEU Policy and Procedure Manual for more details on data collection and processing at the SEU.

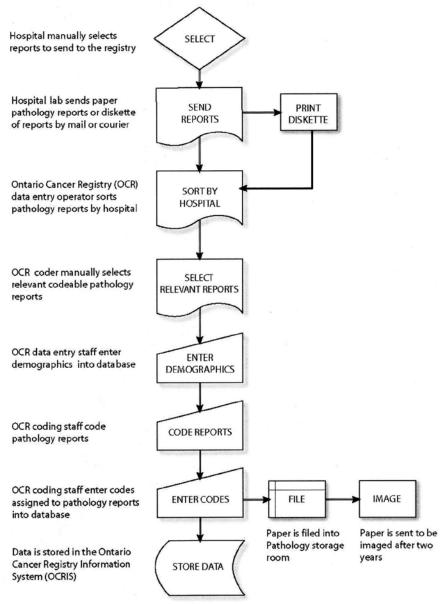


Figure 1. Paper Based Processing of Pathology Reports at the Ontario Cancer Registry [13]

With the E-Path system, the reporting process is streamlined and reduced to three steps. These include: 1. laboratory prepares report within LIS; 2. report is transmitted from the laboratory to the registry; and 3. report is processed by the registry. NAACCR has established a detailed set of business rules for each of these three steps based on the current NAACCR and HL7 standards [11].

The introduction of E-Path at the SEU would eliminate the need for entering data manually since everything would already be digitized. Data obtained through E-Path would also be more complete. This is because patient information contained within the LIS that may be left out on a paper pathology report could be included with electronic pathology. There also would no longer be a need to sort and file reports since the reports would be stored electronically. In addition, E-Path offers an ICD-O autocoding feature to help HIM professionals select codes for classifying the site and histology of cancers.

5.2.2 E-Path at the Ontario Cancer Registry

In order to enable pathology reports to be submitted electronically from laboratories to the Ontario Cancer Registry (OCR), the Pathology Information Management System (PIMS) was implemented in 1999-2000 to connect pathology laboratories to the OCR. The physical implementation of electronic pathology reporting is shown in Figure 2.

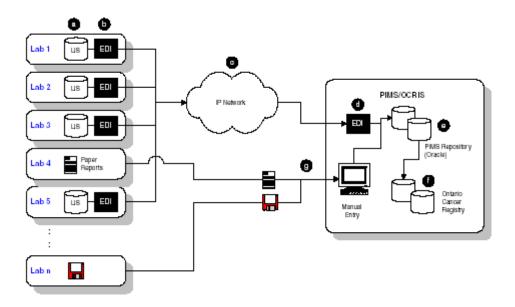


Figure 2. Physical Implementation of Electronic Pathology Reporting [13]

The following is a description of each of the character labels (a, b, c, ...) in the diagram as outlined in [14]:.

- a) Pathology reports prepared using laboratory information system (LIS).
- b) Each laboratory has an electronic data interchange (EDI) engine that converts laboratory reports from LIS format to HL7 messages for electronic transmission to the registry.
- c) All transactions occur on an Internet Protocol (IP) network. Each transaction is highly secure through the use of encryption.
- d) The EDI engine at the registry receives and authenticates reports arriving from pathology laboratories and each report is registered in the PIMS repository.
- e) Pathology reports are stored in the PIMS repository.
- f) Pathology data in the PIMS repository is consolidated with OCR.
- g) Since all laboratories are not computerized some reports may continue to be provided ion paper or as files on diskettes. These cases will need to be manually entered into the PIMS repository.

A study was conducted at the OCR to see how the new system performed in comparison to traditional paper-based methods [13]. After conducting an analysis of cancer registry operations between August 1, 2001 and October 31, 2001, it was determined that E-Path technology allowed data processing to be more efficient, leading to a reduction in the overall costs for the registry. It was also found that E-Path improved timeliness of reporting, completeness of data collection and enhanced the quality of the data in the registry.

5.2.3 Automated Electronic Case Finding

Implementing E-Path at the SEU would also improve case finding by eliminating the human errors that occur with the manual process. The E-Path solution offered by AIM Inc. has a SNOMED autocoding module that converts the text in pathology reports into SNOMED topography (site) and morphology (behaviour) codes. Filtering logic is then applied to automatically determine whether or not a pathology report should be sent to the cancer registry [14]. The selection criteria would be based on the reportable list of topographies and morphologies required to be reported to the registry (see p. 17 of the SEU Policy and Procedure Manual for the Reportable List).

Although automated case finding eliminates the need for human inspection of pathology reports to identify which ones need to be reported to the registry, there may be reports sent to the registry that were falsely selected as cancer cases. These false positives may occur due to wording such as "no evidence of malignancy" or "specimen is free of tumor" [13]. The case finding dictionaries and selection criteria allow for a high false positive rate to assure a false negative selection rate as close to zero as possible. Despite the fact that false positive reports are received with automated electronic case finding, workflow is still more efficient using E-path and costs are significantly reduced as compared to paper-based methods [13].

6 Conclusions

The internship performed at the SEU was a valuable learning experience that allowed the author to apply the knowledge and skills obtained through the Master of Health Informatics program. Some conclusions drawn from the experience include:

- Developing a Policy and Procedure Manual is very time consuming. Each business process was analyzed by the author in great detail. Information for developing the policies and procedures had to be obtained from a variety of sources including existing documentation, NAACCR guidelines and meeting with SEU staff.
- When making updates to policies and procedures, it can be a challenge to have all staff members agree on the proposed changes. For some policies and procedures, a series of review sessions were required to finalize the documentation.
- Documenting information and work flow for an organization is a useful process for finding inefficiencies and identifying areas for improvement. Unnecessary and redundant tasks were discovered by analyzing business processes.
- By analyzing the work flow it was determined that some tasks were being performed differently by various staff members. Developing the Policy and Procedure Manual was a way to improve consistency among all staff members.
- The current paper-based case ascertainment process at the SEU is highly inefficient.
 Information technology solutions are needed so staff can focus on more important activities such as quality assurance and information analysis.

7 Recommendations

The SEU Policy and Procedure Manual will serve as a useful reference for all staff members. It is important that the information in this document is kept as current as possible. This involves reviewing each policy and procedure at least once every three years and adding new policies and procedures when required.

This report addressed the need for implementing E-path to improve case ascertainment and to eliminate time consuming tasks such as filing and data entry. The SEU should consider the following key factors for successful implementation of E-Path [14]:

- Obtain support and cooperation from both IT staff and laboratory personnel.
- Ensure a robust technological infrastructure is present to support a wide variety of features and functions and to allow the system to be scalable over time.
- Implement an E-Path system that is portable to ensure it can interact with the different laboratory information systems around the province.

In the future, the SEU should also expand the electronic reporting to hospital health record departments. Currently, registry forms are submitted by all hospital health record by facsimile or mail, when a new cancer diagnosis is noted on an abstracted record (e.g. inpatient or day surgery). The electronic reporting system for hospitals would be the same as E-Path except information would be coming from the patient medical records rather than the LIS. Such a system would more feasible once the electronic health record is fully implemented in the province. The system would be beneficial by eliminating the need for HIM professionals working at the hospital health record departments to fill out a form when a new cancer diagnosis is identified. Instead, an abstract of all key information required to be included on OPIS could be sent electronically whenever cancer is coded on a patient's abstract. Cancer cases could be identified automatically as in E-path but the selection criteria would be based on the ranges of ICD-10 codes that are provided on the reportable list.

8 References

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9 Appendix

The SEU Policy and Procedure Manual is being submitted to accompany the internship report.