

NAACCR

**Electronic Pathology
Reporting Guidelines**

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North American Association of
Central Cancer Registries, Inc.

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Preface

The first version of the Electronic Pathology (E-Path) Reporting Guidelines was developed in 2006. That document used business analyses techniques and unified modeling language to describe procedural guidelines to transmit cancer pathology reports electronically from laboratories to cancer registries. Since that time much has changed in the anatomic pathology (AP) and cancer registry communities. While the intent of this second release of the guidelines remains unchanged, this new version constitutes a paradigm shift in AP reporting of cancer pathology reports, a shift which includes the development and use of synoptic or checklist reporting. Although the vast majority of cancer pathology reports are in the traditional-text based format, more and more pathologists are using synoptic formats. The College of American Pathologists (CAP) has taken the lead in this area and has developed site and procedure-specific checklists to aid pathologists with quality and performance improvement of cancer pathology reporting. NAACCR Standards Volume V, Pathology Laboratory Electronic Reporting, Version 4.0 reflects these changes.

NAACCR Standards Volume V Version 4.0 recommends use of HL7 Version 2.5.1 message or format standards for the electronic transmission of cancer pathology reports. It is designed for those in information technology constructing and parsing the HL7 message. This Guidelines document describes the general procedures for such transmissions, and is intended for those in registry and laboratory operations.

It is the hope of the North American Association of Central Cancer Registries, Inc. (NAACCR) Pathology Data Work Group (WG) that making the NAACCR Standards Volume V standards and these procedural guidelines available to the community will make it easier for pathology laboratories, central cancer registries, and software vendors to adopt a uniform method for report transmission and processing. Our goals are to: (1) develop resources which will support standardized collection of pathology report data for cancer cases that are not identified in the traditional hospital setting, and (2) facilitate the nationwide electronic reporting of pathology reports to cancer registries.

The content of this manual provides guidance for central cancer registries to implement the NAACCR Standards Volume V specification to electronically receive and process structured and synoptic reports from pathology laboratories. The manual will continue to evolve over time as changes occur in laboratory technology, electronic reporting and other information technologies, standardized vocabularies and codes, reporting regulations, and requirements to protect the confidentiality of patient data. As noted above, this document is an update to the 2006 version which was based, in part, on the original NAACCR electronic pathology standards documentation published in January 1996; and its subsequent versions--NAACCR Volume II, Chapter 6, published in September 2000; and the draft E-Path Reporting Process document developed in March 2005.

The NAACCR Pathology Data WG would like to acknowledge the dedicated members of the Pathology Data WG as well as the Pathology CAP Checklists WG who contributed countless hours, with special acknowledgements to the Checklist WG Co-Chairs Wendy Aldinger and Robin Rossi, as well as Andrea MacLean who coordinated the contribution of many of the use-case examples. Special thanks are also warranted to Wendy Scharber and Minal Agrawal who provided critical guidance and expertise towards the development of these Guidelines. Financial support from the Centers for Disease Control and Preventions' National Program of Cancer Registries made these efforts possible.

Sincerely,

Ken Gerlach, Chair, NAACCR Interoperability Ad Hoc Committee
Jovanka Harrison, Chair, NAACCR Pathology Data Work Group

1 Background

Monitoring the occurrence of cancer¹ is a cornerstone of cancer control decision-making. This monitoring, referred to as cancer surveillance, can be used to trigger case investigations, follow trends, evaluate the effectiveness of prevention measures such as screening and early detection programs, and suggest public health priorities.

The Problem

One of the major changes in the health care delivery system in the late 1990s, and specifically with respect to the cancer patient, is the shift in diagnostic and treatment procedures from hospital to clinic and other non-hospital settings. This shift presents challenges to central cancer registries, which have traditionally relied on hospital registries as their primary source for ascertainment of reportable cancer cases. It is essential that central cancer registries ascertain cases from non-hospital sources to maintain a complete and accurate count of cancer cases occurring within the population that they serve. Because most cancers are definitively diagnosed by histology, cancer surveillance programs may utilize pathology reports to identify new cases and collect further information on cases previously reported.

An essential information source for complete cancer data collection is the pathology laboratory, which may be an independent pathology laboratory or located within a facility that may provide services only for a single hospital, or which may have a broad range of clients, including hospital facilities, clinics, and other medical practices. To date, the lack of a standardized system for reporting by pathology laboratories has required each central registry to develop procedures for capturing cases directly from pathology laboratory reports. Pathology laboratories also must comply with the different specifications from each state or province/territory to which they are required to report. The time and cost for such endeavors are frequently barriers encountered during implementation of direct reporting from the laboratories to the central registries.

The Solution – Electronic Pathology Reporting

The Pathology Data WG of the NAACCR Interoperability Ad Hoc Committee was formed to develop a recommended approach for implementing electronic pathology reporting. The result of this WG's effort is the documentation contained in this manual. Implementation guidelines have been developed to specify the reporting process, and thereby to enhance the completeness, timeliness, consistency, and efficiency with which cancer data are transmitted by pathology laboratories, and then received and processed by central cancer registries.

Goal and Objectives of this Document

The goal of this document is to describe the recommended approach for implementing standards for electronic pathology reporting between pathology laboratories and central cancer registries, vendors, and other entities that may be involved as senders or recipients of cancer pathology reports as required by state, provincial/territorial law. *It serves as a companion document for implementing the recommended standards described in NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 4.0, which describes data items, data item definitions, and transmission specifications.*

Objectives of this document are to:

- Provide a high-level description of pathology, workflow processes and the pathology report.
- Describe the scope of electronic pathology reporting to cancer registries.
- Value proposition (benefits and challenges) of electronic pathology reporting.
 - Pathology laboratory
 - Cancer registry

¹ The term **cancer** in this document relates to all reportable conditions, including benign brain and central nervous system tumors, in situ and invasive cancers.

- Describe the uses of electronic pathology reports within the central registry.
- Describe electronic pathology implementation from a variety of partner perspectives, including the role of each partner, to enhance understanding of each component.
- Provide detailed approaches, business rules and methods for performing each electronic pathology component, including identification and recruitment of participating laboratories, preparation of transmission files, testing, quality control, and monitoring efforts.
- Provide terms and definitions used in electronic pathology reporting to enhance communication between partners.

Scope of This Document

The scope of this document is limited to:

- (1) Implementation guidelines and business rules to assist central registries, pathology laboratories, and vendors in North America to respond to the call for direct pathology reporting in a uniform manner.
- (2) Guidelines for using electronic pathology reports within the central cancer registry.

Legal authority to Report to Public Health

Privacy and Security Rules

Both Canada and the United States specifically describe the ability of health care entities to report patient identifiable information for public health activities under federal privacy and security legislation. NAACCR provides a document to interpret HIPAA as it relates to cancer registration, along with an FAQ (frequently asked questions). It can be found on the NAACCR website at <http://www.naacr.org>

Canada - Privacy Act and Personal Information Protection and Electronic Documents Act

The Canadian Federal Government has several general Acts that deal with Privacy and Information. They can be found at: <http://laws.justice.gc.ca/eng/StatutesByTitle/P.html> (see Privacy Act and Personal Information Protection and Electronic Documents Act, in particular). Each province and territory has its own legislation that addresses issues of privacy in the health and e-health areas. Although each jurisdiction's Acts are slightly different, they do seem to share some common traits:

- The recognition that personal health information is highly sensitive and confidential.
- Controls over when and how a public body is allowed to collect, use, disclose, retain and destroy personal health information from the population.
- Significant requirements with regard to obtaining express, knowledgeable consent from the individual for each specific collection, use, and disclosure of personal health information.
- Requirements with regard to the safety, security and accuracy of the personal health information collected and maintained by the custodian.
- Requirements for Privacy Impact Assessments to be carried out when a new collection, use or disclosure of personal health information is contemplated or when a change is contemplated to an existing system for the collection, use or disclosure of personal health information.
- The applicability of all of these rules to all electronic health systems, be they limited to the particular province or territory or nation-wide, with significant expectations as to the security of the system and safety of the personal health information contained within it.

There are now more than 10 health privacy acts in place across Canada; each province or territory makes its own legislation available through its own governmental website. The website provided below is to the Office of the Privacy Commissioner of Canada. This webpage has a list of Canadian Provinces and Territories with links to their individual health privacy acts - http://www.priv.gc.ca/resource/prov/index_e.cfm#002.

United States - Health Insurance Portability and Accountability Act (HIPAA, or the Act), P.L. 104-191

For public health authorities within the United States HIPAA states, "Nothing in this part shall be construed to

invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” Covered entities that are named in the HIPAA legislation are “health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in Section 1173(a) of the Act.” The regulation implementing the HIPAA privacy provisions allows public health exemptions for disclosure without patient consent of individually identifiable health information for the purposes quoted above.

Under HIPAA, state cancer registries qualify as a public health authority operating as an agency authorized by law to “collect or receive such information for the purposes of preventing or controlling disease ... and for the conduct of public health surveillance, public health investigations, and public health interventions.” (45 CFR 164.512) As such, public health reporting to state agencies from pathology laboratories is exempt from HIPAA privacy rules. Pathology laboratories, as covered entities, may report this public health information to state cancer registries using the HL7 standard as described here, and HIPAA provisions will not constrain their ability to report.

2 Introduction to Anatomic Pathology

2.1 Definition of Anatomic Pathology

- The study of the essential nature of diseases and especially of the structural and functional changes produced by them.
- The anatomic and physiological deviations from the normal that constitute disease or characterize a particular disease.
- A treatise on or compilation of abnormalities <example: a new pathology of the eye>².

Anatomic Pathology is the branch of pathology that deals with tissue diagnosis of disease. For this, Anatomic Pathologists need a broad range of knowledge and understanding of the pathological and clinical aspects of many diseases.

The tissue on which the diagnosis is made may be biopsy material taken from a patient in the operating theatre, on the ward or from an autopsy (post-mortem). The latter is a small but important component of the work for establishing the cause in cases of sudden or unexpected death, for examining disease progression, including the response to treatment or lack of a response, and in criminal cases (forensic pathology), helping police in their investigations. The work of most Anatomic Pathologists is, however, on tissue from living patients. A large part of this is the detection and diagnosis of cancer. A tissue diagnosis is essential before starting treatment involving major surgery, radiation, or drugs - treatments which may have major side effects.

Modern Anatomic Pathologists examine not only samples of solid tissue, but also small specimens of separated cells. This is the subspecialty of Cytology. The specimens include fluids and tissue smears mainly for diagnosis and prevention of cancer. The pathologist collects some of these samples themselves, for example, for the diagnosis of cancer of the breast or the prostate. Often this means that a certain diagnosis can be made before the patient has left the clinic. New methods also allow samples of either separated cells or small tissue fragments to be obtained from organs, such as the pancreas, situated deep within body cavities.³

2.2 Cancer Pathology Reports

² <http://www.merriam-webster.com/medlineplus/pathology>

³ <http://www.rcpa.edu.au/Pathology/Disciplines/AnatomicalPathology.htm>

A cancer pathology report is the final, written product of the surgical pathology laboratory and it contains critical information that drives not only patient care but also cancer surveillance.⁴ Traditionally, cancer pathology reports were text-based with general headings such as Final Diagnosis, Macroscopic Description, and Microscopic Description. Each section contained narrative text describing the information relevant to the heading. For example, a Final Diagnosis could read as follows:

“Colon, right, segmental resection to include appendix and ileum: Mucinous adenocarcinoma invading through the bowel wall into the pericolonic adipose tissue. Margins are free of tumor. Benign appendix. All of twenty-two lymph nodes are free of tumor. TNM stage pT3 pN0 pMX.”

In April 1999, the College of American Pathologists (CAP), with the leadership of the CAP Cancer Committee published *Reporting on Cancer Specimens Protocols and Case Summaries*. The protocols “aid the surgical pathologist with completeness, accuracy, and uniformity in the reporting of malignant tumor specimens and with quality assurance issues related to such specimens. They may be used as a framework for full narrative reporting, alternative reporting formats, or clinical research protocols. The accompanying surgical pathology case summaries (checklists) represent synoptic forms of the information contained in each protocol, and like the protocols themselves, are tailored to individual specimen types (e.g., cytology, diagnostic biopsy, excisional biopsy or resection).”⁵ These protocols and the associated checklists were intended as guidelines to pathologists. The associated published documents are in the form of a checklist, and thus are often referred to as the CAP Cancer Checklists.

These Checklists were and are associated with the term Synoptic Reporting which is the standardized and structured documentation of a Cancer Pathology Report, with common definitions, data items, and data item values. “Synoptic” is a term which implies synopsis or summary; it typically refers to checklists designed to ensure that key data fields are not omitted. A synoptic cancer pathology report should combine discrete, standardized, human-readable data items instead of free text transcription. Ideally, each question and answer in a synoptic report is associated with specific data identifiers and terminology codes (e.g., ICD-O3 and SNOMED-CT). This approach is increasingly being deployed in North America, with the lead being taken by CAP; the CAP Cancer Checklists are recognized as the “gold standard”.⁶

Starting in 2005, these cancer protocols were incorporated into the American College of Surgeons Commission on Cancer (CoC) accreditation program. The related standards do not specify that the CAP Checklist must be used, but rather that CAP’s required data elements must be completed within the cancer pathology report. In Canada, the Canadian Association of Pathologists formally endorsed the CAP checklists as a pan-Canadian content standard for all cancer pathology reporting in July 2009.

The CAP Cancer Protocols are designed as recommendations for definitive cancer reporting. They are released as a set of documents that include guidelines, protocol definitions, checklists, and work aids. These are beginning to be implemented in the data capture user interfaces of some Pathology Laboratory Information Systems. The most commonly used fully encoded synoptic reports are the CAP electronic Cancer Checklists (eCC). These are a fully machine-readable format of the CAP Cancer Checklists, designed to make the implementation of capture and reporting of fully-coded information easier. New and improved versions of the CAP Cancer Checklists and the eCC are being released on a periodic basis by the CAP eCC Team, with oversight by the CAP Cancer Committee and CAP’s Pathology Electronic Reporting Committee (PERT). The CAP eCC advance the management and interoperability of health information through its XML format that can be integrated more easily into existing pathology laboratory systems and cancer registry systems.

⁴Reporting Guidelines for Clinical Laboratory Reports in Surgical Pathology, Goldsmith, Siegal, Suster, Wheeler, Brown; Arch Pathol Lab Med—Vol 132, October 2008, page 1608

⁵Reporting on Cancer Specimens Protocols and Case Summaries, page 7.

⁶ CAP Web-site: http://www.cap.org/apps/docs/snomed/documents/about_cap_ecc.pdf.

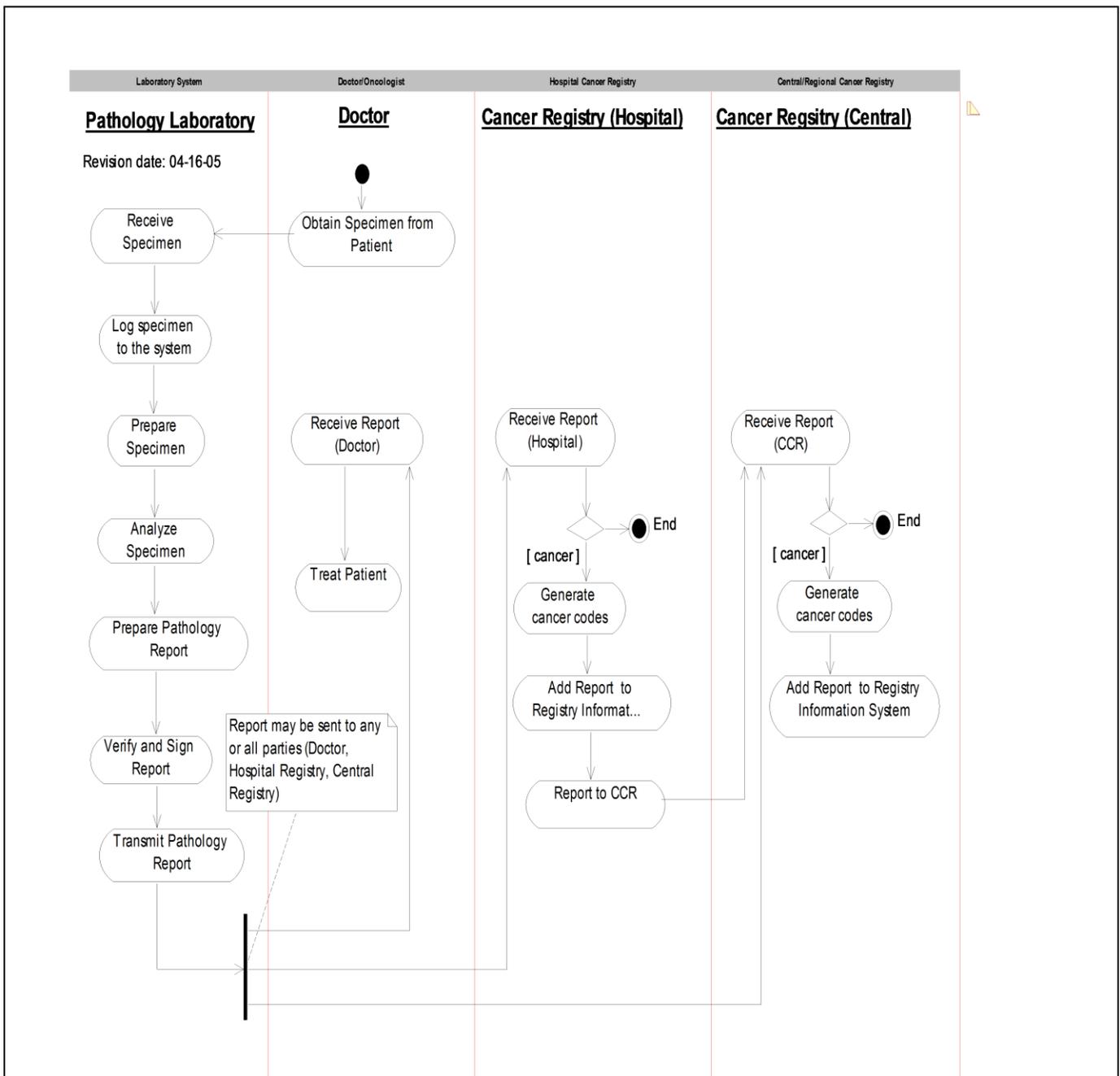
2.3 The Clinical Process – High Level

A health care provider collects a specimen (tissue, fluid, etc.) from a patient and submits the specimen to the pathology laboratory. The health care provider may be located in the hospital served by the pathology laboratory, or in a physician’s office, medical clinic, surgery center, urgent care facility, or other health service setting.

The pathology laboratory receives the specimen, logs it into the laboratory system, and prepares the specimen for analysis. The pathologist analyzes the specimen and, if creating a narrative report, dictates the findings, which are then transcribed into the laboratory system. In some cases, the pathologist will complete a paper-based checklist. If the pathologist is creating a computerized report, the pathology findings are usually entered directly into discrete locations in a data-entry form on the computer screen. The pathologist verifies the accuracy of the report and signs the transcribed report or the data-entry form.

This medical process is the same whether the reporting process follows the traditional method using paper pathology reports or an electronic pathology reporting system (Figure 1).

Figure 1. Pathology Reporting Process in Context of Overall Pathology Testing



2.4 Central Cancer Registry Use of Pathology Reports

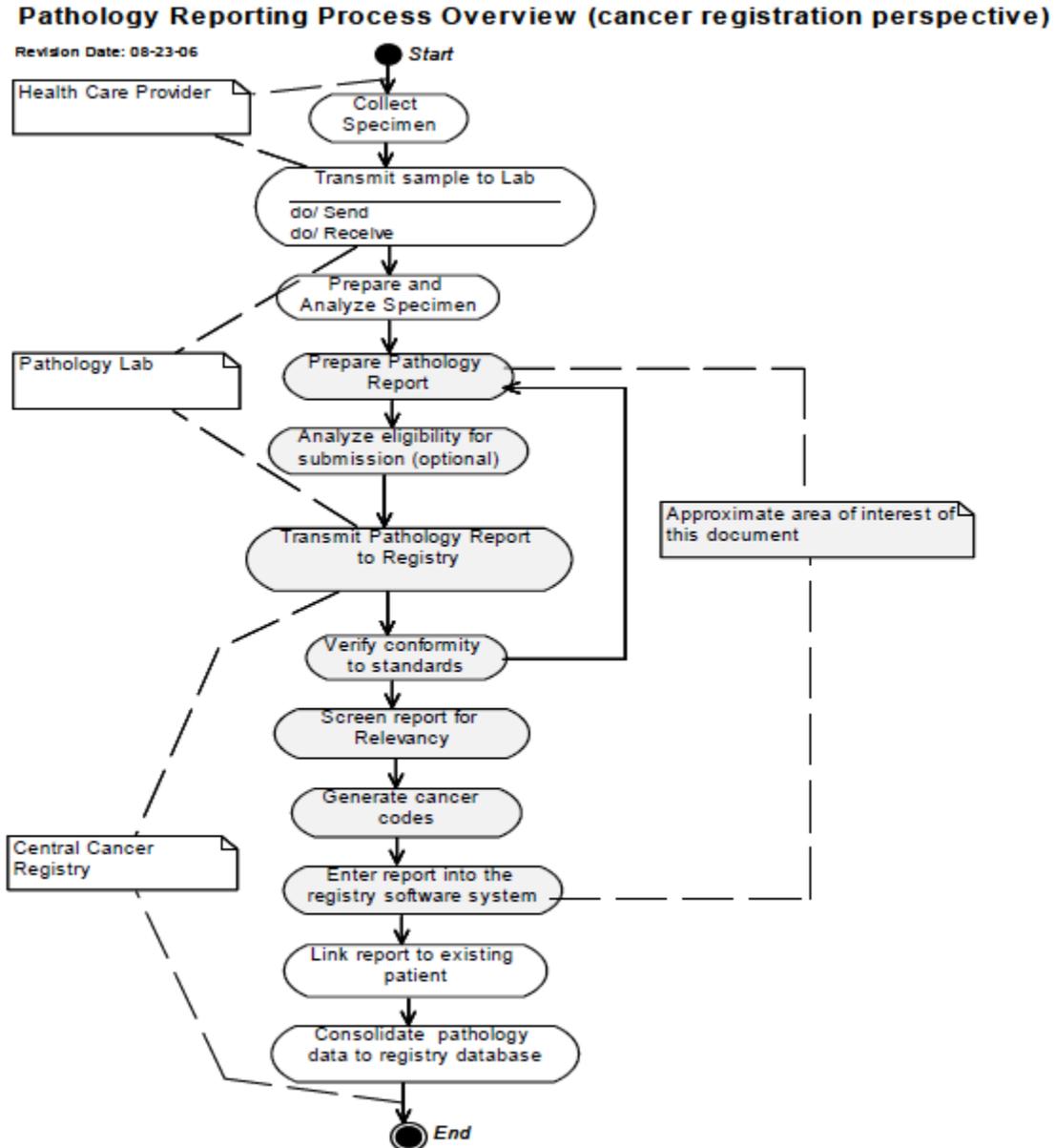
Cancer pathology reporting supports and facilitates the performance of many central cancer registries surveillance activities. These reports identify patients with cancer, provide key information about the cancer (e.g., histology, pathology stage), which is used by clinicians to treat the cancer, and which is used by public health and researchers to monitor the occurrence of cancer, inform cancer control activities and to evaluate the outcomes of various treatment methods. A detailed description of a central cancer registry's use of electronically submitted pathology reports can be found in Appendix A.

3 Description of Electronic Pathology Reporting

3.1 Description

In an electronic reporting setting, a copy of the pathology report is transmitted electronically to the central cancer registry. The process begins when the pathologist completes the pathology report, marking it as “final”; the process ends when the electronic pathology report data are loaded into the central registry's information system and is ready for use in the central registry (i.e., casefinding, updating existing records with additional information, special studies, etc.) Figure 2 depicts the scope of the electronic pathology reporting process from the cancer registration perspective.

Figure 2: Scope of Electronic Pathology Reporting



3.2 Benefits and Challenges for Electronic Pathology Reporting

As with any process, there are benefits and challenges for all partners. An electronic pathology reporting system offers many of the same benefits to both the *Hospital* and the *Central Registry*:

- Improves casefinding and follow-back for diagnoses in non-hospital data sources.
- Decreases the amount of time required by registry staff to perform case ascertainment and data entry/transcription.

- Improves the timeliness of cases in the registry, enabling rapid ascertainment functions for clinical studies within the health care facility and for specific studies conducted by epidemiologists.
- Allows the registry to produce more current preliminary cancer incidence statistics for forecasting and tracking trends in the cancer care continuum.
- Provides a database of electronic pathology report information, beyond the coded information, which can be used for research purposes, dependent on the language processing tools available.
- Ensures that consistent and uniform data identification criteria are used.
- Facilitates the automated assignment of codes to identified elements within the report, allowing a shift in the use of registry staff resources from initial coding/data entry to review activities.
- Allows the entire pathology report to be transmitted, so that the full report can be reviewed for coding purposes.
- Promotes flexibility in database design, with an opportunity to capture/recapture and code new data elements of clinical significance from a stored database of pathology reports.
 - Diagnostic patterns, waiting times, trend analysis
- Facilitates compilation of multiple reports to consolidate into a single cancer diagnosis from histologic perspective on almost a real-time basis.
- Eliminates the need to review all pathology reports, cancer related as well as non-cancer related.
- Automatically maintains HIPAA Disclosure logs.

Additionally, electronic pathology reporting allows central registries to compare hospital registry reports with electronic pathology reports for quality control of registry data, including quality parameters of timeliness, completeness, and accuracy of coding.

Benefits for the *Laboratory* include:

- Reduces staff time involved in identifying, copying, and mailing paper pathology reports.
- Eliminates the costs associated with submitting paper pathology reports to registries.
- Eliminates the need for registry personnel to use the laboratory's workspace and computer to perform casefinding.
- Automates reporting with minimal human supervision.
- Inherently improves HIPAA compliance.
 - Provides a more secure and confidential reporting than traditional manual methods
 - Reduces the risk of disclosure of patient identifiers
 - Restricts viewing of non-cancer reports because the computer eliminates those that are not relevant for cancer
 - Maintains a complete electronic audit log of reports submitted to the registry

Electronic pathology reporting presents certain challenges to all partners, the most critical being the personnel resources needed to develop, test, and implement a system. IT resources are particularly scarce at the laboratory, hospital, and central registries. Coordinating the priority level of electronic pathology reporting within each partner's operational plan is a difficult process and can have an adverse impact on the timeline for fully implementing electronic pathology reporting. A champion, someone who is dynamic, well respected, and actively supportive of implementing electronic pathology reporting in the registry and the laboratory, increases the likelihood of timely implementation.

Challenges for all partners, the *Laboratory*, the *Hospital*, and the *Central Registry*:

- Administrative approval at multiple levels.
- Evaluating operational costs for implementation and maintenance.
- Evaluating purchase of software and/or hardware for message creation and secure transmission of messages/files.
- Evaluation of content, data and informatics standards.

- Development of testing mechanisms to verify complete reporting of required pathology reports and data items, accuracy of data values.
- Access to IT and Pathologists resources.

Confidentiality issues:

- Reporting of non-reportable conditions.
- Reporting on out-of-state residents.
- Out-of-state laboratories not covered by State/provincial/territorial data confidentiality statutes and regulations.

Challenges for the *Laboratory* include:

- Planning and implementing an interface between laboratory information systems (LIS) and the registry systems.
- Resources to create a message file.
- Possible modification to data formats.
- May require infrastructure modification (i.e., firewall configuration, hardware/server).

Challenges for the *Hospital* and the *Central Registry*:

- Requires reassignment of registry staff time/duties to take advantage of new pathology information available in electronic form.
- Requires development of new quality assurance and quality control procedures.
- Requires additional software and possibly additional hardware to process and store electronic pathology reports. For the central registry, there will be a need to scale up to an “enterprise” level computing environment from their local intranet environment.
- Differences in hospital and central registry timelines can occur. The availability of the pathology report in the central registry may change their timeline needs for the additional data that hospital registries provide.
- Requires an understanding of content, data and informatics standards
- Electronic pathology reporting also will increase central registry staff time needed to review multiple pathology reports per single reportable diagnosis and compile them into a single tumor/cancer abstract.

4 Preparation for Electronic Pathology Reporting

4.1 Selection of Laboratories

Registries initiating an electronic pathology reporting system should select their partner laboratories carefully. Even in a registry where electronic pathology reporting is mandated, critical criteria are the laboratory’s active interest in and the ability to implement an electronic pathology reporting process.

Additional selection criteria may include:

- Deficiency in case reporting by the laboratory.
- Number of reportable pathology reports currently submitted.
- Timeliness of reporting.
- Adequacy of quality control activities currently required for the laboratory.
- Relationship of the laboratory to the hospital with reporting cancer registry.
- Current adoption of recognized coding systems (LOINC, SNOMED CT, ICD-O, CAP Cancer Checklists or eCCs) by the laboratory.

Methods for identifying laboratories for electronic pathology reporting include:

- Laboratory self-identifies its interest.
- Request for proposals for laboratories to report electronically.

- Solicitation of laboratories by telephone or letter. Lists can be developed with help.
 - State health departments or Provincial/Territorial Ministries of Health
 - CLIA lists
 - State and provincial pathology associations (www.cap.org)
 - Hospital registrars
 - Central registry field staff

Pathology associations can be effective partners for implementing and expanding electronic pathology reporting. Communications with pathologists and pathology laboratory personnel through the professional associations enhances the legitimacy of electronic pathology reporting as a best practice method for meeting cancer reporting requirements.

4.2 Partners for electronic laboratory reporting beyond cancer

Central registries may benefit from partnering with other programs that have laboratory reporting, such as the communicable disease programs within the state/provincial/territorial health departments. Resources can be pooled to work with the same laboratories to develop a common system for electronically reporting all state-required diseases. Laboratories benefit from having a single source for developing and implementing electronic reporting of their required cases. There are, however, challenges to address. The process needs to accommodate different data needs, standards, and time requirements for reporting. Timelines for implementation of electronic pathology reporting among partners can be complex due to a variety of differences, including funding cycles, availability of stable standards, and priority of implementation within the program.

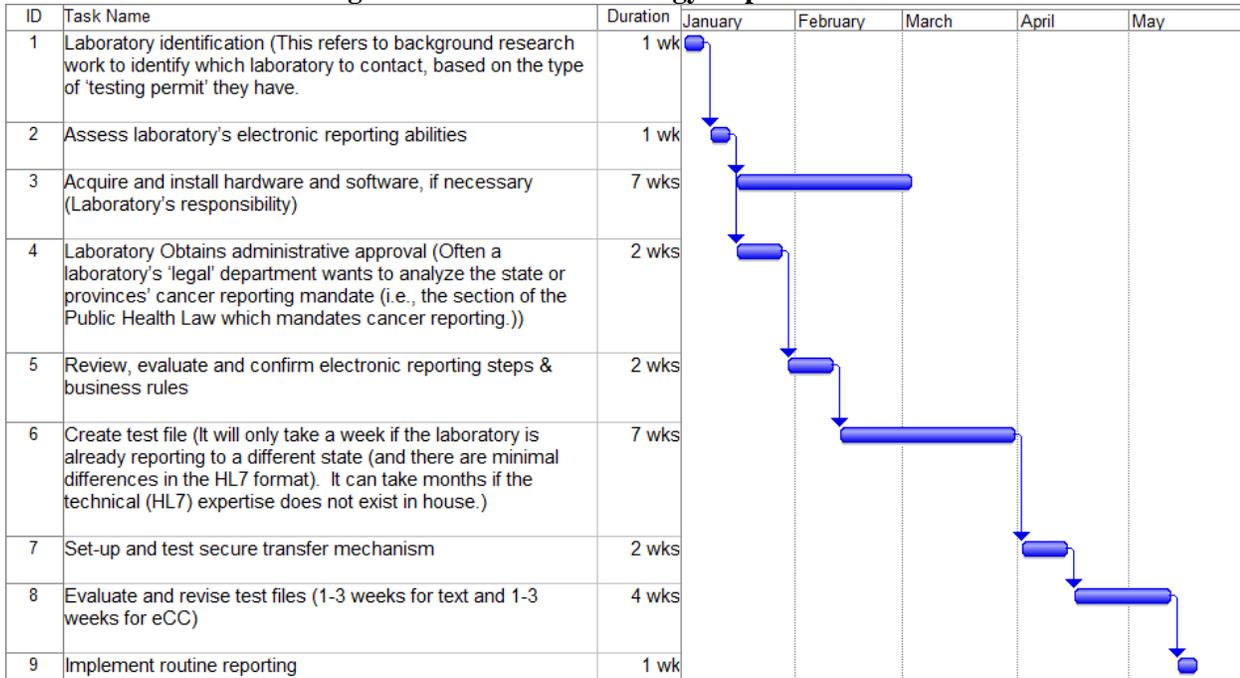
4.3 Timeline for Implementing Electronic Pathology Reporting in a laboratory

The timeline for a single laboratory to implement electronic pathology reporting depends on many factors. If all partners are committed to a short-interval for implementation, routine electronic pathology reporting can begin in as little as 5 months. Many factors, however, can slow the implementation, causing the process to extend to 9 months or even longer. These factors include:

- Administrative approval from multiple levels.
- Priority of project within the laboratory.
- Skill level of laboratory and central registry personnel (LOINC, SNOMED CT, NAACCR data standards, CAP Cancer Checklists, eCC, HL7).
- Pathology department having vendor conversion or updating their systems.
- Ability to link software systems within the laboratory (i.e., billing and clinical systems).
- Acquisition of hardware and software by the registry.

The Project Management Gantt chart below depicts the optimum and extended timeline for each step in the electronic pathology implementation process. As the chart below shows, some steps are dependent on the completion of previous steps; other steps can be performed simultaneously.

Figure 3. Electronic Pathology Implementation Timeline



5 The Electronic Pathology Reporting Process

5.1 Structure of Electronic Pathology Reporting Process

A domain diagram¹ for the electronic pathology reporting process (Figure 4), shows the major business entities involved in the process, their relationships and responsibilities. It is a high-level static representation of the main entities involved in the electronic pathology reporting process, including a description of how these entities are related.

A domain diagram also captures a business vocabulary. It presents nomenclature, terminology and concepts that appear in the process description, laying out definitions and meanings agreed on by the subject matter experts. A domain diagram provides a foundation for other modeling diagrams.

encrypted data over the Internet. A number of these programs are open source and/or freely-available (e.g. NHIN Direct, NHIN CONNECT) Many public health entities use PHINMS (Public Health Information Network Messaging System), developed by the Centers for Disease Control and Prevention (CDC), which relies upon “a common approach to security and encryption, methods for dealing with a variety of firewalls, and Internet protection schemes.”⁷

5.2 Overview of the Process

There are two Key Actors/Participants in the electronic reporting process: the Pathology laboratory (Laboratory); and the Central cancer registry (Registry).

There are four main Processes (Use Cases) involved in reporting pathology findings to the central registry:

Process Description	Key Actor(s)	Weblink
Approve a Laboratory for Reporting	Registry, Laboratory	http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_approve_path_lab_use_case.pdf
Prepare and Transmit Report	Laboratory	http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_prepare_transmit_event_report_use_case.pdf
Receive Batch File of reports	Registry	http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_receive_batch_file_use_case.pdf
Validate Reports	Registry	http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_validate_event_report_use_case.pdf

The full use case can be found on the Centers for Disease Control and Prevention National Program of Cancer Registries (CDC-NPCR) Advancing Electronic Reporting and Registry Operations (AERRO) website.

For each process, a set of conditions called Business Preconditions must be met before the procedure can begin. Following the preconditions, the Process steps for the main or best-case scenario are laid out. The main scenario describes the steps required to achieve the best possible result. Each step has one or more related business rules, which include a set of agreed on criteria for accomplishing a task in the best possible manner.

There may be alternatives to the main scenario steps for a variety of reasons. The alternative steps are given in the Alternate Scenarios sections, using the same numbers as the main scenario tasks with alphabetical designation. The alternate scenarios should be used by registries as needed, when the consensus scenario is prohibited or not appropriate.

5.3 Approve a Laboratory for Reporting

Approve a Laboratory for Reporting is the process for evaluating and subsequently approving a pathology laboratory as being qualified to perform electronic reporting that meets cancer registry standards. This step may be formal and involve an actual certification or informal and involve a review of core capabilities.

http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_approve_path_lab_use_case.pdf

⁷ <http://www.cdc.gov/phinf/tools/PHINms/index.html>

Precondition(s):

- The pathology report is available electronically.
- The laboratory is able to submit pathology information using the format in NAACCR Standards Volume V.
- The Laboratory is willing to evaluate implementing electronic pathology reporting.

Post Condition(s):

- The Pathology Laboratory has successfully created and transmitted a conformant electronic file of pathology reports.

Includes:

- An assessment of the pathology laboratories capabilities for performing electronic reporting.
- Developing and validating an HL7 message for conformance to standards.

5.4 Prepare and Transmit Pathology report.

Prepare and Transmit Pathology Report is the process whereby a pathology laboratory submits pathology reports to the cancer registry using established criteria for record layout format, required pathology report types, required data items, and transmission standards.

http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_prepare_transmit_event_report_use_case.pdf

This use case describes the process for preparing and transmitting a pathology report by a trusted pathology laboratory into the cancer registry database. It is intended for pathology laboratory staff including information technology (IT) system professionals.

Precondition(s):

- The pathology report is available for processing.

Post Condition(s):

- The pathology report has been transmitted to the cancer registry.

Includes:

- Identifying a pathology report that meets the criteria for submission to the cancer registry.
- Creating an HL7 message.
- Transmitting an HL7 message using secure connection.

5.5 Receive Batch File of Pathology Reports

Receive Batch File of Pathology Reports describes the process for receiving a batch file from a certified data source into the cancer registry database.

http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_receive_batch_file_use_case.pdf

Precondition(s):

- The batch file is received electronically.
- The batch file is from a certified pathology laboratory.

Post Condition(s):

- The received batch file has been accepted for processing.

Includes:

- Logging the batch file as received.
- Validating record layout format.
- Confirming the batch has not previously been received (duplicate batch file).
- Importing batch file into the cancer registry system.

5.6 Validate Pathology Report

Validate Pathology Report describes the process for validating the electronic pathology reports received by the central cancer registry.

http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/g_validate_event_report_use_case.pdf

Precondition(s):

- The batch file has been validated using *P4: Receive Batch File* use case above.

Post Condition(s):

- Valid pathology reports have been added to the CR database.

Includes:

- Assigning a record Id to the pathology report.
- Standardizing data values.
- Verifying pathology report is not a duplicate of a previously submitted pathology report.
- Performing data validation edits.
- Notifying the pathology laboratory of the results of processing.
- Determining reportability.

6 Quality Control/Quality Assurance of the Electronic Pathology Reporting Process

Completeness of Reporting

The registry needs to ensure that all of the reports that they are expecting are submitted (final reports, addendums, supplemental, types of reports such as histopathology, cytology, bone marrow) in addition to verifying that the selection criteria are accurate. Methods to ensure completeness of reporting also will depend on whether a registry is receiving all pathology reports, regardless of relevance to cancer and screening for reportable tumors, or if the laboratory is performing the screening to identify and submit only the relevant reports. The screening could be computer screening using automated search criteria or by manual selection by laboratory personnel. To assist in monitoring, a table of pathology report numbers submitted for each facility should be maintained by the registry.

All reports received regardless of relevancy:

On a regular basis, the registry identifies missing pathology accession numbers within a sequence and provides a list to the pathology laboratory to review, and resolve. The registry will need to routinely evaluate whether addendum and supplemental reports are being submitted by the laboratory (see Subsequent Reports on the Same Cancer below).

Relevant pathology reports received:

Relevant reports may be missed by laboratories performing the screening and not transmitted to the cancer registry for a variety of reasons, including:

- Amended/supplemental reports are not re-screened for relevant diagnoses.

- A pathology report may not get coded accurately with SNOMED-CT and/or ICD codes.
- The selection method may restrict the dates of reports under review such that reports completed outside the routine completion timeframe may be missed.
- Terminology needed for reporting (e.g., “malignant” or “invasive” terms are not used for GIST tumors and thymomas) was not used by pathologist, or was not readily identified in the report.

A registry will need to implement a quality control procedure to ensure that these and other situations are not causing relevant reports to be missed.

Subsequent Reports on the Same Cancer

A pathology report may be sent to the registry more than once. While they are often referred to as “duplicate reports” because the report has been identified as having been previously submitted to the registry a more appropriate phrase, used above, is “subsequent reports on the same cancer”. A pathology report may be resubmitted for a variety of reasons, including:

- Laboratory corrects or amends an item on the original report.
- Laboratory adds information to the original report.
- Laboratory resends the original report with no changes (true duplicate).
- The specimen is sent to another laboratory to perform a consult.

When a laboratory submits an amended report or a report with additional information (an addendum), the entire cancer pathology report with original and new information should be transmitted to the cancer registry. Transmission of only the changed or additional information is discouraged. This matter should be clarified with the laboratory prior to submission.

A second type of “subsequent reports on the same cancer” can occur when the electronic pathology transmission method itself causes a duplicate report by including portions of the report within the message more than once. Identification and processing of these reports is addressed at the cancer registry through certain automated processes and manual review. A large test file of all types of reports to be included in electronic pathology reporting can help identify this problem and allow it to be corrected prior to implementation. (See Approve a Laboratory for Reporting section.)

A third type of “subsequent reports on the same cancer” can occur when the specimen is sent to another laboratory for a second opinion or consult and both the originating and consulting laboratories submit the report on the same specimen to the cancer registry. As with other types of “subsequent reports on the same cancer”, the cancer registry must have systems in place to identify these types of duplicates and work with the sending laboratories to ensure that the transmitted cancer pathology reports contain adequate patient and laboratory identification information.

The registry must develop specific procedures to identify and process reports that have been submitted more than once. Identification may be performed by software to identify duplicate pathology report accession numbers; however, the evaluation and correct processing of the second report must be performed by the registrar to accurately determine whether new information has been added or pertinent information has been modified. It is helpful during the evaluation and implementation phase to discuss with the laboratory the scenarios that may lead to a report being resent to develop the best methods for identification and processing.

Missing Data Items Within a Pathology Report

The list of data items required for a pathology report submission is shorter than that required for a hospital registry submission. The NAACCR Standards Volume V⁸ lists the data items that should be reported on an electronic pathology report record; however, a registry will need to determine which of these data items must actually be present to accurately process the report according to local standards within the registry's area. In some situations, a pathology report may be missing a required data item and still be useful to the registry. It may be acceptable for an electronic pathology report to have missing required data items as other data sources may contribute the missing data item value to complete the full tumor/cancer record within the central registry. For example, although social security number is required for an electronic pathology submission, it may be acceptable to allow the data to remain missing as the social security number will most likely be submitted by another data source.

If the pathology report does not link with an existing record, the registry may choose to follow back to the relevant health care provider/clinician to obtain the required information (such as sex, race, date of birth, social security number). This method requires that a database of physicians and their clinic address be maintained by the registry. Currently, this is a labor-intensive process.

Patient address is one of the most frequently absent data items, and one which affects reportability. A registry should develop policies and procedures for confirming residency of those patients whose pathology report did not match with an existing record within the registry. This helps to exclude those patients that do not fall within the registry's population area. Registries with a non-transient population may choose to consider these patients as residents of the state, with an unknown specific location, and only follow-up on those patients whose reports were provided by a laboratory close to the state's border. Electronic pathology reports from large reference laboratories, which frequently perform tests for clinicians and facilities outside of the laboratory's business location, may need to be scrutinized closely for residency.

7 Inclusion of Electronic Pathology Reports in Cancer Registry Systems

One of the decisions a central registry must make when implementing electronic pathology reporting is the ultimate status of stored electronic pathology reports in comparison with other electronic source reports. Two general approaches may be adopted. One approach uses electronic pathology reports for reference purposes. The other approach creates abstracted source reports from the electronic pathology reports. A registry may determine to use only one approach or may adopt both approaches depending on the source of the electronic pathology reports. For example, a central registry receiving pathology reports from hospital-based laboratories may choose to use them as a reference for quality control for the hospital. On the other hand, pathology reports from an independent laboratory may represent the sole source for some reports and the registry may choose to abstract these reports.

For the reference approach, these reports can be stored and linked with the patient records to identify cases that have not been reported by the registry's official reporting sources and to perform quality control studies between the pathology report data and the registry's data. Registries most often choose this method when their primary purpose for electronic pathology reporting is to identify missing cases. Matched cases can either be discarded or permanently linked with the existing cases. Missing cases are followed back to the clinician with a request to complete a notification form following the registry's routine case reporting methods. When electronic pathology reports do not match an existing case and clinicians do not complete a routine case report, the case must be specifically added to the patient database as "Pathology Laboratory Only" reporting source. Specific software must be developed to perform this task, some of which may in fact require manual intervention. Some central cancer registry systems have incorporated electronic cancer pathology reporting tables and functionality into the

⁸ ¹⁶NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0 (November 2005)

core software capabilities. Depending on the design and flexibility of the central registry's database system, it may be necessary to store reference reports in an external database. In this situation, performing quality control and data accuracy checks with electronic pathology reports outside the main database may be cumbersome and may require the development of specialized software to perform these tasks.

Alternately, for the abstract approach, a registry creates a regular source record for electronic pathology report in the registry database. This method allows the software that processes routine case abstracts from official facilities to be used for electronic pathology reports, ensuring that all data are processed consistently, regardless of reporting source, and using the same linkage, consolidation and resolution criteria, and procedures. Currently, NAACCR Standards for Cancer Registries Volume II contains many of the NAACCR Standards Volume V data items allowing the corresponding pathology report to be transformed into the Volume II format and loaded into a central cancer registry system.

The abstract approach requires more resources to abstract the encoded data elements. Fortunately, automated software applications exist that assist in this process. Incorporating abstracts of electronic pathology reports immediately upon receipt decreases the lag time between the diagnosis and the availability of the case information for analyses. Rapid ascertainment studies can locate their cases using the same mechanism as for retrospective studies. Incidence data [the type of cancer, age grouping] for 95% of cases could be available within 2 to 3 months of diagnosis rather than the traditional 18–24 months. Over-counts due to unknown residency and the inability to confirm the number of primaries for certain patients will occur; however, these can be identified during analysis, minimizing their impact on the results.

Incorporating electronic pathology reports as abstracted source records in the registry database requires more sophisticated tumor linkage and consolidation software to minimize the manual resources required to adjudicate discrepancies between reporting sources. Reporting sources must be preassigned “weights” for selecting a data item value among various values; Judgement must be used to determine if a non-exact match represents a match or a mismatch; this requires manual review and resolution. Additionally, a standard for data items needs to be included on a “Pathology Laboratory Only” source record to ensure that consistent data are available and default values are used.

Reports that do not link to an official facility record will eventually be followed back in the same manner as described above. If the clinician does not submit a routine case report form, the case is already in the database, identified as a pathology report submission. The final reporting source for this cancer can automatically be updated to “Pathology Reporting Only” at the end of the clean-up year.

8 Appendix A: Central Registry Use of Electronically Submitted Pathology Reports

Traditional Cancer Surveillance Activities

Electronic pathology reporting supports and facilitates cancer registry activities.

Case ascertainment: Electronic pathology reports represent a stream of data from which relevant reports can be electronically extracted and moved into the registry database. For those registries that have reviewed paper reports, electronic reporting promotes greater efficiency in report processing, allowing the registry to combine casefinding, coding, and data entry into a single in-house procedure.

Rapid case ascertainment: Because electronic pathology reports are coming into the registry on a near real-time basis depending on the volume, they can be made available to researchers with very little delay from the time of final diagnosis.

Abstracting: Many of the required data elements can be directly captured from the incoming data message and distributed into the registry's database system. Pathology reports contain information relating to site, histology and staging parameters. As implementation of the College of American Pathologists (CAP) Cancer Protocols and Checklists increases, automatic population of the cancer registry will become more useful.

Verification of reporting from hospital registries and other reporting sources: Central registries can expand their quality review activities in monitoring hospital reporting, not only for completeness of case ascertainment but also for accuracy of coding site, histology, and staging parameters.

Consolidation of multiple reports into a single tumor/cancer record: Electronic pathology reporting adds another dimension to case consolidation, in that registry software must be developed to correctly link all electronic pathology reports for particular diagnoses from hospital laboratories with the abstracts for those cancers coming from the hospital registry databases. Electronic pathology reports frequently do not contain all demographic data items, creating a challenge for accurate patient linkage. Enhancement of existing linkage software may be needed to minimize the additional number of records that must be manually reviewed and linked. Automated tools for tumor linkage and data item consolidation becomes more important when registries have electronic pathology reporting as manually processing the increased number of records is time consuming and expensive.

Registry resource evaluation: Electronic pathology reporting also allows the automated accumulation of descriptive statistics on pathology reports and coding, and data entry activities that may be of interest in quantifying the activities of the central registry.

Use of pathology reports on cancer cases where there is no residual malignancy: Pathology reports with no residual malignancy have not traditionally been received or maintained by central cancer registries⁹. Reports where "no residual tumor" is found may be of particular interest to a central registry to validate stage and treatment information submitted by hospital cancer registries. Reports with "no residual tumor" diagnosed occur most frequently in breast cancer and melanoma cases, and similar language also is seen in bone marrow specimens assessing disease following chemotherapy for leukemias.

Electronic reporting assistance in identifying pathology specimen material for research through virtual, real, or discard repositories: Pathology specimens in the form of microscopic slides (on which the information in pathology reports is based) and/or paraffin tissue blocks from which the slides have been prepared are proving to be an increasingly valuable source for research material when fresh or frozen tissue is not available. This is

⁹ In certain jurisdictions, legislation may prevent these reports from being transmitted to the cancer registry.

particularly the case in population-based retrospective studies that involve subjects from more than one hospital or laboratory facility. The extensive files of paraffin blocks retained in individual laboratories provide a “virtual” repository of blocks that may be obtainable. The electronic pathology report allows the investigator to identify which specimens may be useful and/or have enough tissue remaining.

9 Appendix B: Types of Pathology Reports

There are a variety of ways in which pathology reports are captured, formatted, and transmitted to cancer registries depending upon jurisdictional rules and local customary practice. In addition to the Pathology Study Report itself, there may be supplemental reports on additional cancers, special studies, other laboratory procedures, supporting clinical information, etc. The most common kinds of reports sent to registries are detailed below. The relationship between the different concepts outlined below is shown graphically in Figure 5.

Primary Report:

This is the principle pathology report that contains all of the pathologic and prognostic information associated with the patient's surgical case (specimen(s)). Typically the primary pathology report is broken into general headings: clinical history, final diagnosis, macroscopic or gross description, microscopic description, and comments.

Supplemental Pathology Reports: This refers to additional information attached to the pathology report, generally after the original report has been issued¹⁰. These reports may address subsequent testing or stains, comparison with previous specimens, second opinions from other pathologists or laboratories, or a change in diagnosis resulting from re-examining the specimen(s) or sampling new areas within the specimen. These reports may occur within any of the format styles or levels discussed below, e.g. an addendum could be in traditional narrative format or a synoptic format. Below is a description of some of the different types of supplemental pathology reports.

Some kinds of supplemental reports have specific LOINC codes, and others may not. For those that do not have a particular LOINC code for the report itself, the general code 22639-9 Pathology report supplemental reports may be used to identify the report. This code can be used for any type of supplemental report, but since there are explicit LOINC codes for consult reports and addenda, the use of this code is discouraged for these report types. The exception to this rule is amended reports, see Amendments section below. For reporting on subsequent testing or staining where there is no specific LOINC code for the type of report on the study done, the LOINC code 22639-9 may be used.

Addenda: An addendum report is a type of ancillary report that contains additional information, typically the results of ancillary diagnostic studies completed after the original pathology report has been released. By definition, addendum reports provide additional information that may come from flow cytometry, and immunohistochemistry as examples. This additional information does not result in a change to the final diagnosis of the original pathology report. If the intent of this ancillary report is to change a previously rendered diagnosis or to change other content, then the report should be titled "Amended Report" (see below). These reports may be appended to the original pathology report and resubmitted to the cancer registry.

There are two different LOINC codes for addenda depending upon whether they are narrative or synoptic. See below for more detail.

- LOINC code for an addendum report which is narrative in style: 35265-8 Path report.addendum.
- LOINC code for an addendum report which is synoptic in style: 60569-1 Report addendum.synoptic.

Amendments: Amended reports are created to correct errors or discrepancies in the original final report. Typical reasons to create an amended report include correction of typographical errors, modification of the final diagnosis, or documentation of the resolution of a specimen labeling discrepancy.

Note: No special LOINC code is required for Amendments. The LOINC code selected is the code for the report that is being amended, whatever kind the report is, and whatever style the amendment is. In these situations the Result Status (OBR-25) designation will change from "F" for "Final Result" to "C" for "Correction to Result".

¹⁰ Goldsmith et al, Surgical Pathology Report Recommendations. Arch Pathol Lab Med: Vol 132, Oct 2008: 1608-1616

See NAACCR Standards Volume V, Identifiers in HL7 Pathology Report Messages section. In general, only pathology reports with codes of “F” and “C” are transmitted to cancer registries, see NAACCR Standards Volume V.

Consultation notes (consults): A consultation report is a report that provides advice or guidance by a second or additional expert; or a deliberation by pathologists on a diagnosis and/or interpretation of diagnostic test results. This may be a second opinion of the specimen diagnosis.

LOINC code for a Consultation Note which is narrative in style: 60570-9 Consultation note

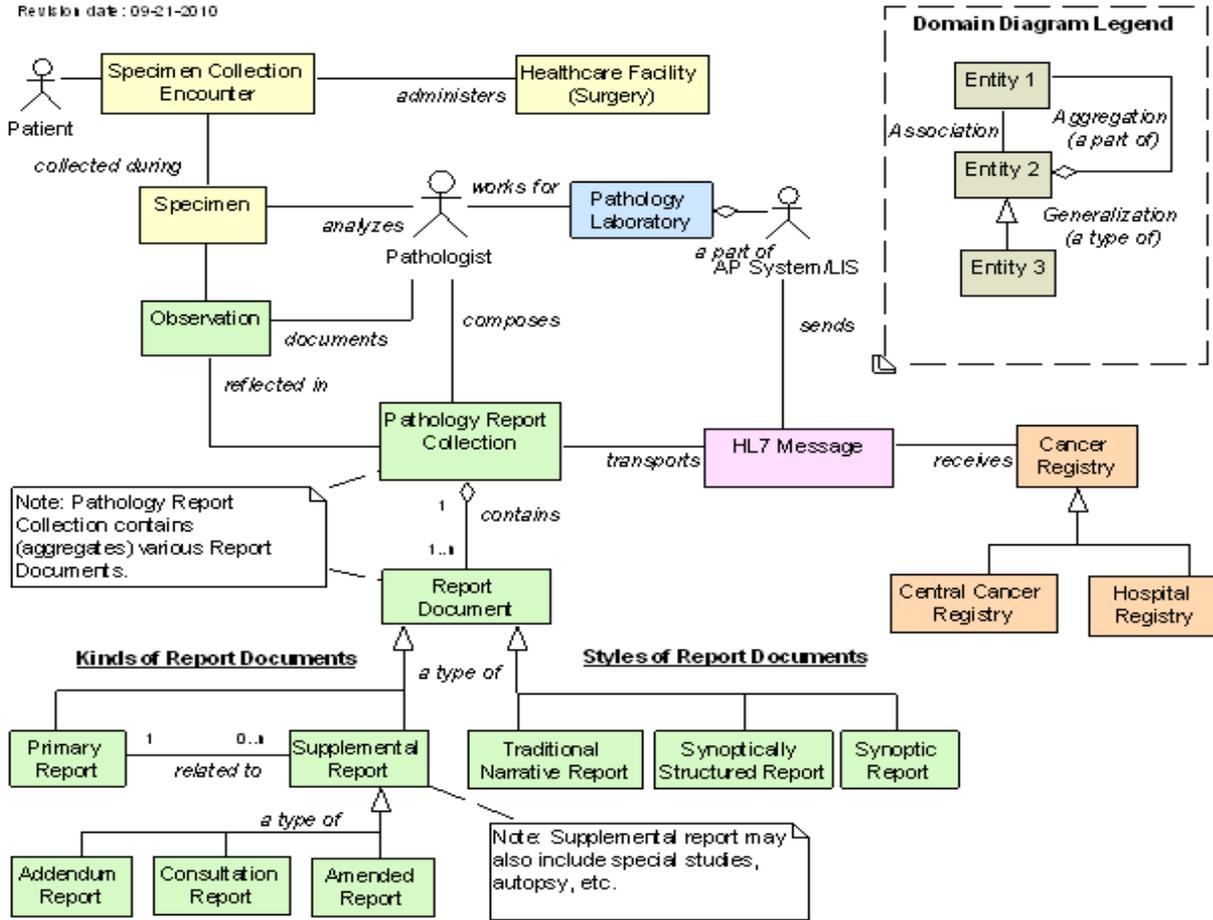
LOINC code for a Consultation Note which is synoptic in style: 60571-7 Consultation note.synoptic

Autopsy Report: This is a pathology report that contains all clinical and pathologic information obtained at the time of death and at a postmortem examination. At this time there are no synoptic autopsy reports, so there is only a LOINC code for a narrative style Autopsy report: 18743-5 Autopsy note

Pathology Report Collection: Sometimes several kinds of reports are transmitted together in a single HL7 message. These are grouped together as a comprehensive collection, as they often need to be interpreted together as a set. This entire collection is labeled with the LOINC code 60567-5 Comprehensive pathology report panel, and all of the other kinds of reports listed above are components of this panel.

Additional information about the LOINC coding of different types of reports is included in NAACCR Standards Volume V, Pathology Report Descriptions and Definitions section.

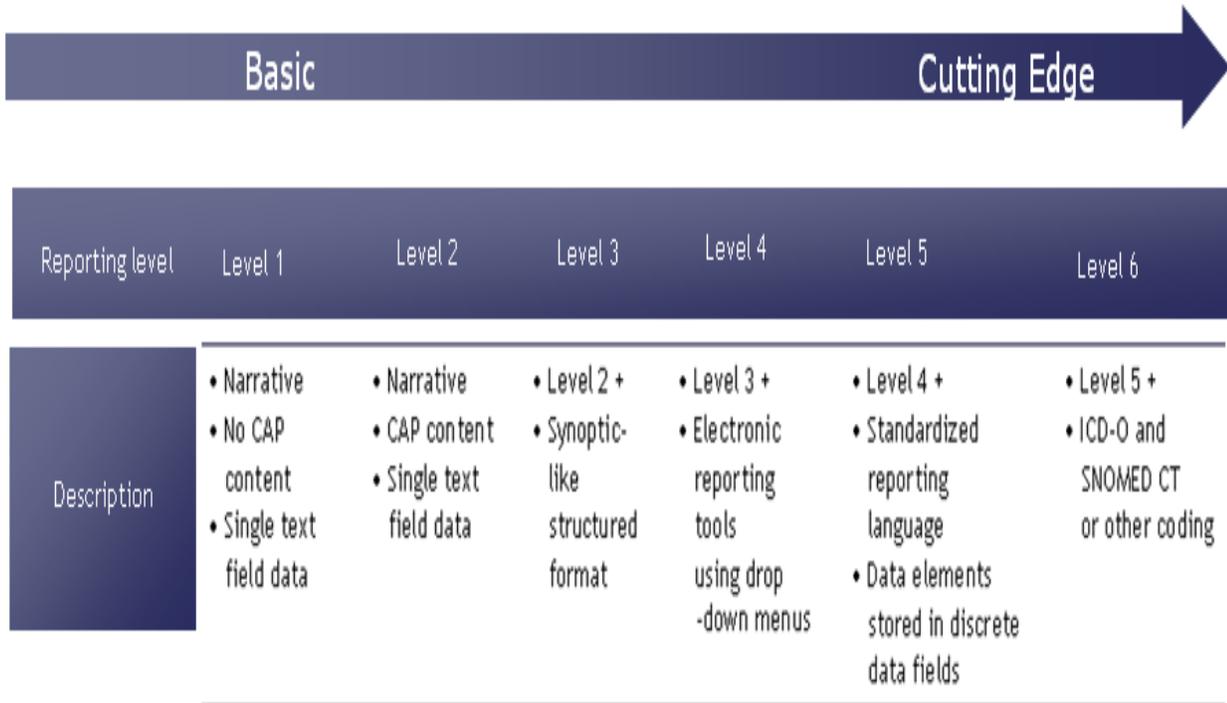
Figure 5. Relationship of Reports and Styles of Reporting



10 Appendix C: Levels of Pathology Reporting

In North America today, there is a spectrum of pathology reporting practices in use denoting differing levels of detail, structure, and encoding capabilities. Anatomic pathology (AP) laboratories use a mixture of traditional narrative, synoptically structured (synoptic like) and synoptic reporting. The diagram, below, developed by Srigley et al¹¹ (Cancer Care Ontario) illustrates the progression or continuum of cancer pathology reports from traditional narrative to discrete, fully encoded pathology reports.

Figure 6. Spectrum of Pathology Reporting Practices



Level 1 and Level 2 refer to traditional narrative reporting.

Traditional Narrative: Traditionally, cancer pathology reports are in a text-based or narrative-style format with specific information contained in the narrative. These reports are generally dictated by a pathologist and then transcribed by a transcriptionist. In this format each pathologist describes key features of the cancer in a narrative style. Generally, the location of information needed for cancer registration purposes (and clinical care) is buried in the body of the narrative and is dependent on the literary style of the dictating pathologist. Typically the reports are broken into general headings: clinical history, final diagnosis, macroscopic or gross description, microscopic description, and comments. See Sections Headers and Descriptions below. The reports may or may not include the mandatory and/or optional elements found in the CAP cancer protocols and checklists (see Traditional Narrative Report Sections below), but if they do, they are captured in narrative form.

Level 1 refers to traditional narrative reporting where there is little or no CAP cancer checklist content within the body of the report. The data is captured in a single text field which may be split into narrative sections

¹¹ Srigley et al, Standardized Synoptic Cancer Pathology Reporting: A Populations-Based Approach Journal of Surgical Oncology 2009; 99: 517-524

Level 2 refers to traditional narrative reporting based on the CAP cancer checklists. The data is captured in a single text field which may be split into narrative sections

Example of a traditional narrative report (Level 1 and 2)

FINAL DIAGNOSIS: Biopsy of the right nipple showing Paget’s disease.
CLINICAL HISTORY: Inflamed (used steroid cream). Mammo - normal. Clinical diagnosis - ? Paget’s.
SPECIMEN SUBMITTED: Breast lesion, right, nipple biopsy. **GROSS DESCRIPTION:** The specimen container labeled “..... - biopsy right nipple” contains an ellipse of skin measuring 0.6 x 0.4 excised to a depth of 0.2 cm. The skin surface....
MICROSCOPIC DESCRIPTION: The sections of the skin biopsy show that there are glands growing along the basal layer of the epidermis which show apocrine change. Immunohistochemistry shows that both the glands as well as the individual cells stain with CAM 5.2 and with EMA. These features are in keeping with Paget’s disease.

Level 3 and Level 4 Synoptic-like (Synoptically Structured)

Level 3 refers to reports in which the diagnostic and prognostic information is presented in a more structured format. Information is reported under headings (eg. macroscopic, microscopic) or in similar groupings (eg. TNM or lymph node information groupings) and may appear as questions and answer pairs. The reporting language has not been standardized and the data is captured in a single text field which may be split into narrative sections.

Level 4 reporting introduces the concept of capturing pathology data using electronic synoptic pathology reporting tools. The question and answer pairs are standardized against the CAP cancer checklists and answers are selected from pre-programmed drop down menus or pick lists. The data is captured in a single text field which may be split into narrative sections.

Example of a synoptic-like (Synoptically Structured) report (Level 3 and 4)

Specimen:RIGHT BREAST, LATERAL ASPECT (stereotactic core needle biopsy)RIGHT BREAST, MEDIAL ASPECT (stereotactic core needle biopsy)

CLINICAL INFORMATION

Lateral microcalcifications 5/5, medial microcalcifications seen in at least 4.6.

GROSS DESCRIPTION

The specimens are received in formalin in two containers. The first is labelled "RIGHT BREAST, LATERAL"The second container is labelled "RIGHT BREAST, MEDIAL"

SUMMARY OF SECTIONS

1 RIGHT BREAST, CORE BIOPSY
 2 RIGHT BREAST, CORE BIOPSY (LATERAL)

DIAGNOSIS
 RIGHT BREAST, LATERAL ASPECT (stereotactic core needle biopsy):

- Atypical ductal hyperplasia, see comment.
- Calcifications present.

RIGHT BREAST, MEDIAL ASPECT (stereotactic core needle biopsy):

- Focal atypical ductal hyperplasia.
- Calcifications were not identified on initial levels. Deeper levels are ordered and the result will be reported in an addendum.

COMMENT

Although the atypical cells in the first specimen (lateral aspect) are seen in only two ducts, ductal carcinoma in-situ (D.C.I.S.) cannot be entirely ruled out.

Level 5 and Level 6 (Synoptic Reporting Style)

Synoptic: These reports conform to the CAP definition of synoptic reporting but the data is fully encoded, captured, and stored in the laboratory information or synoptic reporting application as discrete question and answer pairs. In order to make the CAP checklists interoperable and more compatible with electronic medical records, the CAP has created an electronic tool for use within the pathology community, the CAP electronic Cancer Checklists (eCC). http://www.cap.org/apps/docs/snomed/documents/about_cap_ecc.pdf

Typically, AP LIS vendors incorporate the CAP eCC into their solutions. The diagnostic parameter pairs (Observations and Results or Questions and Answers) are encoded (ICD-O-3, SNOMED CT or other) when stored in the application. These encoded diagnostic parameter pairs may be transmitted discretely from the source application to a cancer registry in an HL7 message.

The use of synoptic reports with encoded discrete data items does not prohibit the pathologist from using narrative information within the report. It is common practice to see additional narrative information in the comments section of the report or added to a particular question and answer pair to further annotate the diagnostic finding. The initial data elements of the synoptic report identify the specific report and its type eg. “CAP eCC”, “COLON AND RECTUM: Resection, Including Transanal Disk Excision of Rectal Neoplasms”.

Level 5 reporting also refers to reporting that is completed using standardized electronic synoptic reporting tools; however, in this case, the data is captured and stored in the application or laboratory information system as discrete question and answer pairs in the AP database and are typically grouped into sections.

Level 6 is the same as Level 5 reporting, however at this level, the question and answer pairs are captured and stored discretely and are fully encoded (ex. SNOMED CT, ICD-O(3), LOINC, CKEYS, etc) in the AP database.

Example of a synoptic report (Level 5 and 6)

Neoadjuvant Treatment: unknown - not provided clinically
Specimen Type: lumpectomy
Lymph Node Sampling: sentinel lymph node biopsy
Specimen Size:
Greatest Dimension (cm): 7.1
Comments: as described grossly
Laterality: left
Comments: as described clinically

Invasive Carcinoma: present
Histologic Type: invasive ductal carcinoma
Comments: with prominent lobular differentiation; for instance, the carcinoma spreads as individual cells and small groups of cells at the edge of the main tumour mass

It is important to note that one does not need to advance through each level of reporting style to achieve level 6 reporting. If the electronic pathology solution being initially implemented is based on the eCC provided by the CAP, and the data is being captured, transmitted and stored as discrete, encoded data elements (observations and results) then one has achieved level 6 reporting.. In some jurisdictions, there has been a steady migration from level 1 to level 6 reporting as a result of steady progression of these tools are provided by the CAP and their vendor.

11 Appendix D: Description of Synoptic Pathology Reporting

The process diagram “Process Model/Workflow diagram: Synoptic Pathology Reporting”, presented on the Figure 7 below, illustrates the high-level conceptual overview of a general workflow associated with the synoptic pathology reporting to a Cancer Registry.

In order to group together activities handled by different process participants, the process diagram on the Figure 7 has been partitioned into distinct regions, called “swim lanes”. There are four swim lanes on this diagram (left to right):

1. Hospital.
2. Pathology Laboratory: Staff and AP System/LIS.
3. Pathologist.
4. Hospital and/or Central Cancer Registry.

Such a partition of activities among swim lanes allows clear representation of a) responsibilities for tasks in the business workflow among participants of the synoptic reporting process and b) interactions among these participants. For example, activity “17 Transmit Pathology Report Collection” is performed by the Pathology Laboratory. The output of this activity, object “HL7 Message (Pathology Report Collection)”, used as the input for the activity “18 Receive Pathology Report Collection” in a Cancer Registry.

NAACCR Standards Volume V, Synoptic Reporting section contains a related top to bottom Interaction Model which illustrates the data transfer between actors. Table X “Synoptic Pathology Reporting: Process Model/Workflow Definitions” below provides a detailed description of the activities presented in the Interaction Model diagram.

Figure 7. Diagram of Synoptic Pathology Reporting

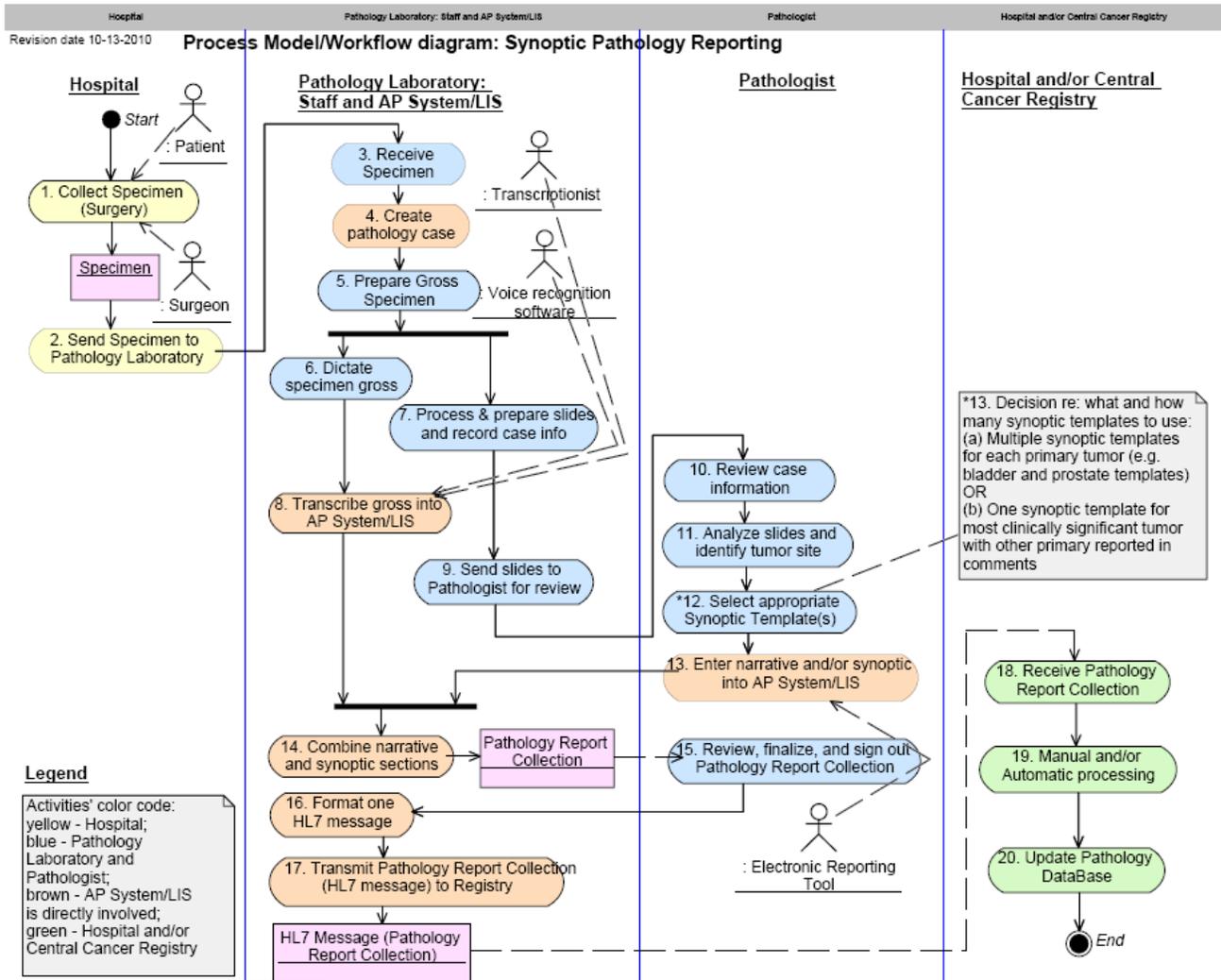


Figure 8. Synoptic Pathology Reporting: Process Model/Workflow Definitions

1.	Collect Specimen	<p><u>Collect Specimen</u> - A specimen is a piece of tissue or other material collected during a medical procedure from a patient and delivered to a pathology department or facility for examination and which is uniquely identified. If a specimen is separated into parts, each of those parts, which is uniquely identified, is also a specimen and has a relationship to the piece from which it was separated. The specimen may also be a collection of samples with a single identifier which is uniquely associated with the collection. It is a specimen if it is considered a single discrete, uniquely identified unit that is the subject of one or more steps in the laboratory workflow. A specimen may be a tissue item, tissue section, tissue core, tissue spot, smear sample, touch preparation, dispersion, or other similar subject of study. Each of the assigned identifiers is created and tracked by LIS systems and laboratory procedures. The tissue specimen is collected during the surgical procedure and is placed into a specimen container with the appropriate fixative. The container is labeled with the Patient Identifier and a Requisition Number. The specimen may be accompanied by an additional surgical pathology requisition form</p>
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		or surgical note containing additional details about the patient’s specimen and clinical history. The information on both requisitions is typically filled out in Surgery.
2.	Send Specimen to Pathology Laboratory	<u>Send To Pathology Laboratory</u> - The specimen collection, along with the Patient Identifier and the Requisition information, are sent to the Pathology Laboratory. The Requisition information is usually sent non-electronically, but there may be an evolution in the future to integrate electronic ordering systems and synoptic surgical reporting solutions with AP systems.
3.	Receive Specimen	<u>Receive Specimen</u> - The specimen collection, along with the Patient Identifier and the Requisition information, are received in the Pathology Laboratory
4.	Create Pathology Case	<u>Create Pathology Case</u> - The Patient Identifier and Requisition information is entered into the AP system at the Pathology Laboratory, and the case record is created in the system. <u>Assign Accession Number</u> - An Accession ID is assigned to the specimen collection and associated with the case in the LIS. One or more Specimen IDs may also be assigned at this point, depending upon whether or not the case is comprised of multiple individually identified specimens.
5.	Prepare Gross Specimen	<u>Prepare Gross Specimen</u> - In the most common situation a laboratory professional, either a Pathology Assistant or the Pathologist, examines the specimen or the collection and dictates its gross observations. Further observations are dictated as the specimen is sliced or otherwise divided into portions to be processed for slide preparation. Specimen processing usually involves paraffin embedding, but may also involve cryogenic or other operations. These dictated observations are usually referred to as “Gross Findings” or “Gross Observations”.
6.	Dictate specimen gross	<u>Dictate Specimen Gross</u> - The Pathology Assistant or Pathologist who is examining the specimen or collection dictates the gross description of the specimen. This dictation includes the following information: <ul style="list-style-type: none"> • Patient’s name • Patient identification number • Surgical pathology specimen number • Description of the specimen and/or its component parts • Physical description (size, weight, physical color, surgical procedure information, specimen collection time, information regarding the fixative used, etc)
7.	Process and Prepare Slides and Record Case Information	<u>Process and Prepare Slides and Record Case Information</u> - After the “grossing” process is complete, the prepared portions of the specimen(s) are transferred to other laboratory personnel who perform the slicing, mounting, and staining of the tissue, and finalization of the slides. The slides are almost always labeled with individual identifying information. In most cases, the procedural details of staining and slide preparation are not dictated into the patient record. Occasionally, additional iterations of processing and slide preparation for additional studies may be triggered at this time.

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8.	Transcribe Gross into AP System/LIS	<u>Transcribe Gross into AP System</u> - The Gross Observations are entered into the case record into the Pathology LIS. This may be done at the time of gross with the use of voice recognition software or may be dictated by either the Pathologists or Pathologist's assistant and later transcribed into the LIS by a transcriptionist. Either way, these observations are made available to the Pathologist when the slides are read.
9.	Send Slides to Pathologist for Review	<u>Send Slides to Pathologist for Review</u> - The stained slides along with the Record Case Information are sent to pathologist
10.	Review Case Information	<u>Review Case Information</u> - The slides are made available to the Pathologist together with the necessary identification information to access the Gross Observations and any Patient or Surgical information that was received from Surgery with the specimen.
11.	Analyze Slides and Identify Tumor Site	<u>Analyze Slides and Identify Tumor Site</u> - The Pathologist examines the slides and records their observations and findings. Additional iterations of processing and preparing slides for additional studies may be triggered at this time.
12.	Select Appropriate Synoptic Template(s)	<u>Selection of Appropriate Synoptic Template(s)</u> - Upon determining that the case is indeed cancer, the pathologist selects the appropriate checklist(s) from their AP system/LIS. The Pathologist determines the type and quantity of synoptic templates to use based on tumor site(s), histologic type(s), and the number of primary tumors identified.
13.	Enter Narrative and/or Synoptic into AP System/LIS	<u>Enter Narrative and/or Synoptic into AP System/LIS</u> - The observations and findings are entered into the Pathology LIS, and the system groups and assembles the separate observations into the final report. This may be done by separate staff using a dictation from the Pathologist, or may be entered directly into a system by the Pathologist or other staff. Regardless of where the reading is done, the results are entered into the system at the Pathology Laboratory. The report then goes through various stages of error checking and validation.
14.	Combine Narrative and Synoptic Sections	<u>Combine Narrative and Synoptic Sections</u> - Once the case has been completed, the AP system/LIS will generate a Pathology Report which displays all of the components of the report (i.e. Clinical Diagnosis/Comment, Clinical History, Gross Pathology, Synoptic, etc.)
15.	Review, Finalize and Sign out Pathology Report	<u>Review, Finalize and Sign out Pathology Report</u> - The report is verified and approved (signed) by the pathologist
16.	Format one HL7 message	<u>Format One HL7 message</u> - The final Pathology Report is converted into an HL7 ORU_R01 message by the laboratory.
17.	Transmit Pathology Report Collection	<u>Transmit Pathology Report Collection</u> - Using a secure message transport tool the HL7 ORU_R01 message of the pathology report is transmitted to the cancer registry.

	(HL7 message) to Registry	
18.	Receive Pathology Report Collection	<p><u>Receive the Pathology Report Collection</u> - The results are received at the Cancer Registry via the HL7 interface and unbundled from the message</p> <p><u>Send acknowledgement of successful transmission</u> - The system that receives the HL7 message at the Cancer Registry sends an acknowledgement message back to the Pathology Laboratory messaging system upon successful receipt of the HL7 message. Note that in every case that HL7 messages are transmitted, the ACK message is used to acknowledge receipt of the message; however, not all Cancer Registries have implemented this at the current time. In the other interaction diagrams in this chapter, this interaction is not shown explicitly in order to simplify the diagrams, but this is always performed. Note that this acknowledges the communication of the message; using standard HL7 acknowledgement protocol, the data received may not yet have been committed to the destination database.</p>
19.	Manual and/or Automatic Processing	<p><u>Manual and/or Automatic Processing</u> - The Cancer Registry processes the results received via the HL7 interface, subjecting them to any conventional manual or automated processing</p>
20.	Update Pathology Database	<p><u>Update Pathology Database</u> - The results are stored in the Cancer Registry database upon successful receipt and processing.</p>

Figure 9. Surgical Pathology Requisition Form Example

Breast Surgical Pathology Requisition Form

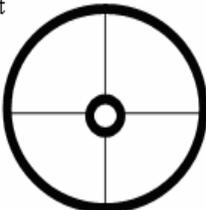
Surgeon Name: _____
 Date of Operation: ____/____/____ (dd/mm/yyyy)
 Radiology imaging available Yes__ or No__

PATIENT
 IDENTIFICATION
 INFORMATION

HISTORY:
 Previous Breast Cancer: YES NO Site: _____
 Previous Therapy: Radiation
 Hormone Therapy
 Chemotherapy
 Inflammatory Carcinoma: YES NO
 Distant Metastasis: YES NO UNKNOWN

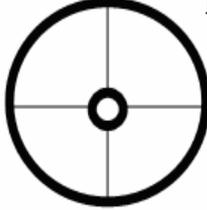
SITE

Right



_____ O' Clock

Left



_____ O' Clock

Time of Tissue collection * in the OR or Radiology Department: _____
Warm ischemic time: time from interruption of blood supply to the tumor by the surgeon or radiologist to the excision of the tissue specimen. See reference.
Time Tissue placed in formalin* in OR or Radiology Department: _____
*10% neutral buffered formalin (NBF) strongly recommended
 Cold ischemic time is the time from excision to the initiation of tissue fixation

Time received in Lab: _____
Time sectioned for optimal fixation in Lab: _____
Time of Fixation in Lab: _____

SPECIMEN ORIENTATION
 Short Suture Superior, Long Suture Lateral, Double Suture Deep
 Other _____

Comments: _____

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Reference: M. Elizabeth Hammond et al: Journal of Clinical Oncology/College of American Pathologist Guideline Recommendations for Immunohistochemical testing of Estrogen & Progesterone Receptors in Breast Cancer. April 30, 2010.

12 Appendix E: Complexity of Cancer Pathology Reports

Cancer pathology reports range from the relatively simple with a single specimen and a single cancer (or tumor) to complex with multiple specimens from multiple topographic sites with multiple cancers (or tumors). The following examples of pathology reports illustrate some of these different types of cancer pathology reports using the synoptically structured reporting style. In these examples the content is to be transmitted from the anatomic pathology laboratory (in a hospital or free-standing to a cancer registry). NAACCR Standards Volume V, Cancer Registry Message Definition section contains flow diagrams that illustrate the transmission process of these types of pathology reports.

When pathologists are completing a cancer pathology report on an accessioned case with multiple cancers they may complete a synoptic report for each cancer or one synoptic report for one of the cancers with the narrative describing the second or third cancers. Guidance from the pathology leadership on this issue is in development and dissemination, although some has been clarified. In addition, the rules for multiple primary determination used within the cancer registry community are not identical to those used within the pathology community. This creates a challenge for the cancer registry community and requires flexibility.

Below are four examples.

1. Single Body Site with a Single Primary in One Report (1a)
2. Multiple Body Sites with a Single Primary in One Report (1b)
3. Single Body Site with Multiple Primaries in One Report (2a)
4. Multiple Body Sites with Multiple Primaries in One Report (2b)

12.1 Single Body Site with a Single Primary in One Report

This example represents a single surgery of a single body site where a **single primary cancer** is identified. This example should require that **one synoptic report** be included in the message (regardless of the number of specimens submitted for the site(s)).

Diagnosis: C50.2 L Breast upper inner quadrant M-8500/3 Invasive ductal carcinoma

Report Identification		Patient Information			
Facility ID:	33D1234567	Chart/MRN:	00466144	Address	495 East Overshoot Drive
Pathology ID:	97 810430	SSN/SIN:	123456789		
Report Date:	2004-07-28	Surname:	MCMUFFIN	City/Town:	Delmar
Report Type:	Final	Given Name:	CANDY	State/Prov:	NY
Requester ID:	594110NY	Sex:	F	Zip/Post Code:	12054
Requester:	CARING, CAREN M.D. Albany Medical Center, 43 New Scotland Ave. NY, Albany 12208	Date of Birth:	1957-07-06	Country: USA	
Procedure Date:	2004-07-20	Age:	47 (at procedure date)		

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Surgeon ID:	123456	Insurer:	USHC		
Surgeon:	MYELOMUS, JOHN	Insurance No:	3270686987		
Pathologist ID:	109771	Race:	White		
Pathologist:	GLANCE, JUSTIN	Ethnicity:			
Clinical History	Left Breast Carcinoma, Right Breast Lump.				
Tissue Submitted	A: Left Breast Mastectomy and Axillary Contents And Right Breast Lumpectomy (S**-****)				
Gross Pathology	Received: 45 Stained slides labelled S**-***** – 1, 2 (H/E - 1A to 1Q and 2A, 2B, 2C1 TO 2C7 and immunostains) From: ***** Hospital on ***** Return stained slides				
Macroscopic	Specimen Type: Modified radical mastectomy Lymph Node Sampling: Axillary dissection Laterality: Left Tumor Site: Upper inner quadrant				
Microscopic	<p>This synoptic report is based on: the 6th Edition of the AJCC Cancer Staging Manual</p> <p>Microscopic Invasive Carcinoma: Invasive ductal carcinoma, NOS Size of Tumor Note: There are two foci, one in the inner upper quadrant measures 3.2x2.5x1.7 cm. The second tumor, more inferior granular area measures 4.5x3x2.5 cm and shows 0.3 cm (3 millimeters) of invasive component.</p> <p>Histologic Grade : Nottingham System Score: II out of III Overall Score: 6/9 Tubule Formation: 2/3 Nuclear Pleomorphism: 2/3 Mitotic Score: 2/3</p> <p>Confluent Tumor Necrosis: Absent Lymphovascular Invasion: Present within peritumoral tissue Note: multifocal, including tumour emboli in the peri-nodal axillary tissue. Perineural Invasion: Absent Noninvasive carcinoma: Ductal carcinoma in situ In Situ Histologic Type: Cribriform In Situ Nuclear grade: 3/3 Comedo Necrosis: Present, extensive Extent away from Tumor: Present Microcalcifications: Present both in tumor and in benign breast parenchyma Skin: No skin involvement Margins to Invasive Carcinoma: Negative Distance from closest uninvolved margin(mm): 13 Closest margin: Posterior Margins to In Situ Carcinoma: Negative Distance from closest uninvolved margin(mm): 15</p>				

	<p>Closest margin: Posterior Surrounding Breast Parenchyma: Proliferative fibrocystic changes Biopsy Site Reaction: Present Lymph node summary Lymph Nodes Sampled: Yes Number Examined: 13 Number Involved: 3 Extracapsular Extension: Present Extranodal Tumor Deposits: Absent Diameter of Largest Nodal Metastasis(mm): 18</p>
<p>Synoptic Data</p>	<p>Specimen type: mastectomy. Lymph node sampling: axillary dissection. Laterality: left. Tumor site: upper inner quadrant. Histologic type: invasive ductal carcinoma. Invasive component size: cannot be determined. Total Nottingham score: grade ii. Tubule formation: moderate score 2. Nuclear pleomorphism: score 2. Mitotic count 40x: score 2. Venous lymphatic invasion: present. Comments: multifocal, including tumor emboli in the peri-nodal axillary tissue.. Histologic type: ductal carcinoma in situ. Microcalcifications: present in tumor and non neoplastic tissue. Margins: margins uninvolved by invasive carcinoma. Closest uninvolved margin distance invasive carcinoma: 13 mm. Closest uninvolved margin invasive carcinoma: deep margin. Margins: margins uninvolved by DCIS. Closest uninvolved margin distance DCIS: 15 mm. Closest uninvolved margin DCIS: deep margin. Regional lymph nodes examined: 13. regional lymph nodes involved: 3. Primary tumor: pT1c. Regional lymph nodes: pN1a. Distant metastasis: pMX. Neo-adjuvant treatment: unknown. Clinical metastasis: X. cs extension: cannot be assessed</p>
<p>Final Dx</p>	<p>Left breast mastectomy and axillary contents and right breast lumpectomy (S**-*****): Left breast, mastectomy: - TWO FOCI OF INVASIVE DUCTAL CARCINOMA: Tumour #1 - INVASIVE DUCTAL CARCINOMA NOS, MEASURES 3.2 CM, WITH 10-20% DUCTAL CARCINOMA IN SITU COMPONENT - EXTENSIVE LYMPHOVASCULAR INVASION - METASTATIC CARCINOMA IN 3 OF 13 LYMPH NODES (3/13) - POSITIVE FOR ESTROGEN RECEPTOR (70%, TESTED IN NYGH) - NEGATIVE FOR PROGESTERONE RECEPTOR (<1% TESTED IN NYGH) - POSITIVE FOR HER2/NEU GENE AMPLIFICATION (FISH RATIO 4.24, AS PER THE ORIGINAL REPORT)</p>

	<p>Tumour # 2- - INVASIVE DUCTAL CARCINOMA WITH EXTENSIVE INTRADUCTAL COMPONENT, THE INVASIVE COMPONENT MEASURES 0.3 CM (3 MILLIMETERS), AND THE ENTIRE LESION SPANS OVER 4.5 CM</p> <p>Right breast, lumpectomy: - LARGE DUCT PAPILLOMA WITH ATYPICAL HYPERPLASIA, COMPLETELY EXCISED - PROLIFERATIVE FIBROCYSTIC CHANGES WITH FLORID DUCTAL HYPERPLASIA - BIOPSY SITE REACTION</p> <p>Comment: my review is in complete agreement with the original report. Tumour #2 characteristics are essentially similar to tumour #1.</p>
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12.2 Multiple Body Sites with a Single Primary in One Report

This example represents a single surgery of multiple body sites where a **single primary cancer** is identified. This example should require that **one synoptic report** be included in the message (regardless of the number of specimens submitted for the site(s)).

Diagnosis: C67.9 Bladder NOS M-8120/3 Urothelial carcinoma

Report Identification		Patient Information			
Facility ID:	01A1234592	Chart/MRN:	11437148	Address	59 East Grand River Drive
Pathology ID:	06784294	SSN/SIN:	234567890		
Report Date:	2007-11-11	Surname:	DOE	City/Town:	Detroit
Report Type:	Final	Given Name:	JOHN	State/Prov:	MI
Requester ID:	822340MI	Sex:	M	Zip/Post Code:	42054
Requester:	DUNCAN, DONALD M.D. Michigan Medical Center, 460 New Haven Ave. MI, Detroit 42208	Date of Birth:	1950-12-06	Country: USA	
Procedure Date:	2007-11-10	Age:	57 (at procedure date)		
Surgeon ID:	7890123	Insurer:	MIHS		
Surgeon:	SMITH, JANE	Insurance No:	19456780035		
Pathologist ID:	452013	Race:	White		
Pathologist:	LEE, MICHAEL	Ethnicity:			
Clinical Dx/Comments	<p>The prostate gland is grossly unremarkable. Routine sections of the prostate show atrophy, acute and chronic inflammation.</p> <p>Internal consult: Dr. ***** has reviewed selected slides</p>				
Tissue Submitted	1: Bladder Urinary, and Prostate				

	2: Ureter, Right, Distal
Gross Pathology	<p>1. The specimen container is labeled with the patient's identification and as "bladder" and contains a cystoprostatectomy specimen measuring 10.6 cm SI x 8.7 cm ML x 6.7 cm AP. The bladder measures 5.6 cm SI x 4.3 cm ML by approximately 4.2 cm AP. A portion of prostatic urethra measures 2.6 cm in length. The prostate gland measures 3.5 cm from base to apex x 4.3 cm from right to left x 3.7 cm from anterior to posterior. The right ureter measures 2.1 cm in length x 0.6 cm in diameter. The left ureter measures 4.2 cm in length x 0.6 cm in diameter. Resection margins of the specimen are painted with silver nitrate. The right side of the prostate gland is painted with green ink, the left side with blue ink.</p> <p>The bladder mucosa is completely obliterated by and ill defined, friable tan and gray lesion measuring approximately 4.8 cm in greatest dimension. This lesion appears to be circumferential, and has a tan and gray appearance, extending to within 2.6 cm of the prostatic urethral margin. Serial cuts through the lesion demonstrate complete obliteration of the bladder muscularis. Tumor is identified within the left ureter, and extends to within 1.8 cm of the left ureteric origin. This tumor is present within 0.1 cm of each of the anterior, right and left soft tissue margins, extending to within 0.2 cm of the posterior soft tissue margin. The prostate gland has a tan and yellow appearance, and shows involvement by the lesion on the left side, at the base. Portion of the prosthetic urethra has a granular, tan and brown appearance that may be representative of gross involvement.</p> <p>The remaining prostatic parenchyma has a nodular tan and yellow appearance, with no further lesions grossly identified. Palpation of the adjacent perivesicular tissue reveal some ovoid nodules, which may be representative of lymph nodes measuring up to 1.3 cm in greatest dimension. The seminal vesicles have a gray-tan, congested appearance. No residual bladder mucosa remains.</p> <p>Photographs of the specimen are taken.</p> <p>Representative sections:</p> <ul style="list-style-type: none"> - 1 right ureter and vas deferens margins, en face - 2 left ureter and vas deferens margins, en face - 3 prostatic urethral margin, en face - 4 left ureter with intraluminal tumor - 5 tumor with extension into left ureter - 6 tumor with seminal vesicle involvement - 7 tumor with anterior soft tissue margin - 8 tumor with posterior soft tissue margin - 9 posterior with right side soft tissue margin - 10 tumor with left side soft tissue margin - 11 and - 12 tumor with obliteration through bladder wall - 13 to - 15 tumor involving left bladder prostate and seminal vesicles - 16 right prostate and ?tumour - 17 tumor at bladder dome - 18 anterior aspect of bladder with tumor - 19 and - 20 1 nodular area bisected each cassette <p>2. The specimen container is labeled with the patient's identification and as "right distal ureter" and contains a tubular piece of tan and pink tissue measuring 1.4 cm in length x 0.6 cm in diameter. The lumen is identified which has a wrinkled tan and gray appearance. Orientation of the specimen is not provided. Serial cuts show a patent lumen, that is</p>

	unremarkable. Submitted in toto: - 1 margin en face - 2 mid substance
Microscopic	Incorporated in diagnosis
Synoptic Data	Procedure: Radical cystoprostatectomy Tumor Size: Greatest dimension: 4.2 cm Histologic Type: Urothelial (transitional cell) carcinoma with focal squamous differentiation Histologic Grade: High grade Margins: Margins uninvolved by carcinoma Lymph-Vascular Invasion : Present extensively Pathologic Staging (pTNM) Primary Tumor (pT): pT3b: Tumor invades perivesical tissue macroscopically Regional Lymph Nodes (pN): pN0: There is no evidence of malignancy in two lymph nodes (0/2) Distant Metastasis (pM): Not applicable
Final Dx	1. Bladder and prostate, cystoprostatectomy: -Urothelial carcinoma, high grade. -AJCC TN status: pT3b -Please refer to synoptic report 2. Ureter (right distal): -Negative for malignancy. Electronically verified by: DR. *****

12.3 Single Body Site with Multiple Primaries in One Report

This example represents a single surgery of a single body site where **multiple primary cancers** are identified. This should require that **multiple synoptic reports be completed for each primary cancer** and that this information should be included in the message (regardless of the number of specimens submitted for the site(s)). Alternatively one synoptic report could be submitted with the other cancers being described in the narrative of the report. In this later alternative, the tumor registrar will need to identify and code the additional cancer information.

Diagnosis: C50.4R Breast upper outer quadrant M-8575/3 Metaplastic carcinoma
C50.2R Breast upper inner quadrant M-8523/3 Infiltrating duct & apocrine carcinoma
C50.1R Breast central M-8500/3 Invasive duct carcinoma

Report Identification		Patient Information			
Facility ID:	1440	Chart/MRN:	2349558874	Address	5844 Lakeside Dr
Pathology ID:	09S-45972	SSN/SIN:			
Report Date:	2009-11-04	Surname:	GREEN	City/Town:	Smithtown
Report Type:	Final	Given Name:	GWEN	State/Prov:	ON
Requester ID:	85552	Sex:	F	Zip/Post Code:	L2L 4V5

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Requester:	SMITH, ALEX M.D. Toronto West Health, 1200 Sinclair Ave. ON, Toronto M5X 2H7	Date of Birth:	1970-10-06	Country: Canada	
Procedure Date:	2009-11-02	Age:	39 (at procedure date)		
Surgeon ID:	16784	Insurer:			
Surgeon:	JACKSON, JANE	Insurance No:	3497562318 TA		
Pathologist ID:	06978	Race:			
Pathologist:	MCDONALD, MAGGIE	Ethnicity:			
Clinical Dx/ Comment	<p>Mastectomy specimen, Right breast: Two tumour masses were noted grossly; the sections show two larger foci of invasive duct carcinoma with occasional smaller foci and occasional microinvasive foci, with extensive in situ duct carcinoma in the background.</p> <p>The largest focus of invasive carcinoma, referred to as T1 in the gross description, is present in slice 6 of the specimen (slice 1 medial, nipple in slice 5), the maximum dimension is 2.1cm (microscopically, section 2T). This is invasive duct carcinoma with squamous differentiation (metaplastic carcinoma), there are also apocrine features.</p> <p>The second largest focus of invasive carcinoma, referred to as T2 in the gross description, was approximately 0.5cm from T1, in slice 7 and measures approximately 1.3cm maximum dimension (microscopically, section 2AG). This invasive duct carcinoma shows apocrine features but less atypia than T1 and is overall moderately differentiated.</p> <p>Additional smaller foci of invasive carcinoma are identified in sections 2G (slice 4) and 2M (slice 5), these measure between 2mm and 5mm each and appear overall invasive duct carcinoma, no special type.</p> <p>There is variable, in areas heavy, lymphocytic reaction associated with the invasive carcinoma. Occasional additional foci of microinvasive carcinoma are identified associated with DCIS (sections 2R slice 5, 2AR slice 8).</p> <p>There is extensive in situ duct carcinoma in the specimen, this occupies approximately 15% of T1, is adjacent to T1 and both adjacent to and within the smaller foci of invasive carcinoma, and extends beyond invasive carcinoma. DCIS is present in sections from consecutive slices 4-10 of the specimen (in 7 out of a total of 14 slices of the specimen) and is estimated to extend over a maximum dimension of approximately 13cm mediolateral (based on specimen measures 26.5cm ML, serially sliced into 14 slices, with DCIS in 7 slices).</p> <p>Other tissue findings are: focal atypical ductal hyperplasia and flat epithelial atypia, columnar cell change and hyperplasia, proliferative fibrocystic changes</p> <p>The closest resection margin is posterior, estimated to be 5mm from both DCIS and microinvasive carcinoma (section 2R slice 5), the closest resection margin to invasive carcinoma is posterior - estimated 1.6cm per gross measurement (to T2).</p> <p>Immunohistochemical stains for estrogen and progesterone receptor protein and HER2 protein expression are pending, a supplementary report will follow.</p>				

Tissue Submitted	<p>1. Axilla: Right Sentinel lymph node #1 2. Breast: Right breast stitch lateral</p>
Gross Pathology	<p>1. The specimen container, labeled as " Axilla: Right sentinel lymph node #1", contains a piece of fibrofatty tissue measuring 1.0 x 4.0 x 1.0 cm, received fresh. This contains one lymph node measuring 2.0 x 2.0 x 0.9 cm. This is bisected and examined in toto at intraoperative consultation by frozen section performed on the entire lymph node as 1A and 1B. The specimen is submitted in toto as follows: 1A-1B frozen sections resubmitted and 1C remainder of specimen</p> <p>2. The specimen container, labeled as "Breast: Right breast stitch lateral", contains a breast without axillary contents, received fresh. The breast measures 26.5 cm ML x 21.2 cm SI x 4.1 cm AP, the anterior ellipse of skin measures 23.0 cm ML x 10.5 cm SI. The nipple and areola are central in the skin, the nipple measures 0.9 cm in maximum diameter and is grossly unremarkable, the areola measures 5.1 cm in maximum diameter and is grossly unremarkable; the skin is also grossly unremarkable. The margins of the specimen are painted with silver nitrate. The breast is serially sliced in the SI plane from medial to lateral into slices 1- 14, slice 1 is medial, the nipple is in slice 5. There are two tumour masses identified, the larger is designated T1 and the smaller T2. T1 is in mid slice 6, it measures 1.2 cm ML x 2.0 cm SI x 2.0 cm AP. The cut surface of T1 is tan in color, solid and firm with ill-defined borders. The distance from T1 to closest resection margins is as follows: 2.5 cm anterior skin, 3.0 cm posterior, 9.5 cm superior, 9.6 cm inferior, 6.7 cm medial and 12.2 cm lateral. T2 is in mid slice 7, approximately 0.5cm obliquely from T1. T2 measures 1.0 cm ML x 1.4 cm SI x 1.8 cm AP, the cut surface is tan in color, solid and firm with ill-defined borders. The distance from T2 to closest resection margins is as follows: 4.4 cm anterior skin, 1.6 cm posterior 7.0 cm superior, 10.0 cm inferior, 9.1 cm medial and 10.0 cm lateral.</p> <p>Away from the tumours, the cut surface of the remainder of the breast tissue is overall 50% fibrous; there is a distinct firm irregular indurated area with comedo like areas on the cut surface in mid slice 5.</p> <p>Representative sections are submitted as follows: 2A 2AY multiple selected sections of the specimen are taken from medial to lateral, section details are recorded in the specimen diagram, which is retained in Pics Plus (please note, sections of slices 1 and 14 are submitted perpendicular to the slices) 2AZ to 2BO additional selected sections of the specimen are taken from medial to lateral, section details are recorded in the specimen diagram, which is retained in Pics Plus</p>
Synoptic Data	<p>Specimen Type: Mastectomy Laterality: Right Tumor Site: Upper outer quadrant Upper inner quadrant Central Axillary Lymph Node Sampling: Sentinel lymph nodes Focality: More than one focus Invasive Tumor Size: Greatest dimension: 2.1 cm Histologic Type: Invasive duct carcinoma with squamous differentiation (metaplastic carcinoma) and with apocrine features Histologic Grade: Nottingham Score - Grade III/III Tubule formation - 3/3 Nuclear pleomorphism - 3/3 Mitotic count - 2/3 Invasive Tumor Necrosis: Present Lymphovascular Invasion: Absent</p>

	<p>Percent DCIS: <25% within invasive carcinoma present beyond invasive carcinoma DCIS Size: Greatest dimension: 1.3 cm DCIS Architecture: Solid Cribriform Micropapillary Clinging, with apocrine features DCIS Nuclear Grade: 2/3, 3/3 DCIS Confluent Necrosis: Present DCIS Calcification: Present Other Findings: Atypical ductal hyperplasia Flat epithelial atypia Resection Margins: Margins uninvolved by invasive carcinoma - 5mm to closest margin Posterior margin is closest margin to invasive carcinoma Margins uninvolved by DCIS - 5 mm to closest margin Posterior margin is closest margin to DCIS Lymph Node Status: Sentinel nodes: Number examined: 1 Number involved: 0 Pathologic Staging (pTMN): pT2: Tumor more than 2.0 cm but not more than 5.0 cm in greatest dimension pN0(i-): No regional lymph node metastasis histologically, negative morphologic (any morphologic technique, including hematoxylin-eosin and immunohistochemistry) findings for ITCs Number of nodes examined: 1 Number of nodes involved: 0 pMX: Distant metastasis cannot be assessed Microcalcifications: Present in non-neoplastic tissue Neoadjuvant Treatment: Unknown Extension of Tumor: Confined to breast tissue and fat</p>
<p>Final Dx</p>	<p>1. Right axilla, Sentinel lymph node #1: - One (1) lymph node, negative for metastatic carcinoma 2. Mastectomy specimen, Right breast: - Invasive duct carcinoma, more than one focus, with in situ duct carcinoma extending beyond invasive carcinoma see below and comment for details, see synoptic data for summary with details of largest focus of invasive carcinoma</p> <p>A) Largest mass of invasive carcinoma - Invasive duct carcinoma with squamous differentiation (ie metaplastic carcinoma) and with apocrine features a) Maximum dimension 2.1 cm microscopic b) Nottingham histologic score III/III (tubule formation 3/3, nuclear pleomorphism 3/3, mitoses 2/3, overall score 8/9) c) Confluent necrosis of invasive carcinoma - present d) Lymphatic/vascular invasion - not identified</p> <p>B) Largest mass of invasive carcinoma - Invasive duct carcinoma with squamous differentiation (i.e. metaplastic carcinoma) and with apocrine features a) Maximum dimension 2.1 cm microscopic b) Nottingham histologic score III/III (tubule formation 3/3, nuclear pleomorphism 3/3, mitoses 2/3, overall score 8/9) c) Confluent necrosis of invasive carcinoma - present d) Lymphatic/vascular invasion - not identified</p> <p>C) Smaller foci of invasive duct carcinoma, no special type</p>

	<p>a) Three larger foci identified, maximum microscopic dimension ranges from 2 mm to 5mm microscopic, occasional additional microinvasive foci present</p> <p>b) Nottingham histologic score II/III (tubule formation 3/3, nuclear pleomorphism 2/3, mitoses 1/3, overall score 6/9)</p> <p>c) Confluent necrosis of invasive carcinoma - not identified</p> <p>d) Lymphatic/vascular invasion - not identified</p> <p>D) In situ duct carcinoma</p> <p>a) Maximum dimension estimated 13cm</p> <p>b) Nuclear grade 3/3 and 2/3</p> <p>c) Architecture cribriform, solid, micropapillary, clinging, with apocrine features</p> <p>d) Confluent central necrosis of DCIS - present</p> <p>e) Calcification in DCIS – present</p> <p>E) Other tissue findings - focal atypical ductal hyperplasia and flat epithelial atypia, columnar cell change and hyperplasia, proliferative fibrocystic changes</p> <p>3) Resection margins - estimated closest margin - posterior - 5mm to both DCIS and microinvasive carcinoma, invasive carcinoma estimated 1.6cm from closest - posterior margin</p>
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12.4 Multiple Body Sites with Multiple Primaries in One Report

This example represents a single surgery of a multiple body sites where **multiple primary cancers** are identified. This should require that **multiple synoptic reports be completed for each primary cancer** and that this information should be included in the message (regardless of the number of specimens submitted for the site(s)). Alternatively one synoptic report could be submitted with the other cancers being described in the narrative of the report. In this later alternative, the tumor registrar will need to identify and code the additional cancer information.

Diagnosis: C61.9 Prostate M-8140/3 Adenocarcinoma
 C67.9 Bladder NOS M-8120/3 Urothelial carcinoma

Report Identification		Patient Information			
Facility ID:	92G1234525	Chart/MRN:	3294558847	Address	12564 Washington Blvd
Pathology ID:	36485120	SSN/SIN:	987654321		
Report Date:	2010-01-20	Surname:	JONES	City/Town:	New York
Report Type:	Final	Given Name:	JAMES	State/Prov:	NY
Requester ID:	85552	Sex:	M	Zip/Post Code:	12310
Requester:	HILL, DONALD M.D. NYC Medical Center, 200 Westdale Ave. NY, New York 12205	Date of Birth:	1940-12-30	Country: USA	
Procedure Date:	2010-01-15	Age:	69 (at		

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			procedure date)		
Surgeon ID:	234875	Insurer:	YCHC		
Surgeon:	YOUNG,WILLIAM	Insurance No:	2370686870		
Pathologist ID:	023487	Race:	White		
Pathologist:	SMITH,JACK	Ethnicity:			
Clinical History	<p>Clinical Diagnosis: Bladder cancer. Surgical Procedure: Radical cysto-prostatectomy, ileo-conduit, lymph node dissection, appendectomy. Clinical History: Not provided. Special Request: Not provided.</p>				
Tissue Submitted	<p>Time specimen placed in formalin: 15:00 A) left external iliac node B) Bladder and prostate C) right obturator and right external iliac D) Appendix E) distal left ureter</p>				
Gross Pathology	<p>A) Specimen: left external iliac node The specimen consists of a portion of fibrofatty tissue measuring 4.5 x 4.0 x 1.8 cm with a possible node, the largest measures 2.5 cm. The tissue is submitted as follows: Cassette #1: bisected node. Cassette #2: single node. Cassettes #3-4: bisected node Representative sections are embedded in four cassettes.</p> <p>B) Specimen: Bladder and prostate The specimen consists of a radical cysto-prostatectomy specimen including an intact bladder (6.0 x 4.0 x 3.0 cm) with attached bilateral ureteral stumps (left side 1.2 cm long and 0.5 cm wide; right side 0.9 cm long and 0.2 cm wide) and attached prostate gland (5.5 cm from right to left, 3.5 cm from anterior to posterior x 4.5 cm). The penile urethra measures 2.0 cm long and 1.0 cm wide. There is a brown-tan ulcerating mass (5.5 x 2.8 cm surface x 1.0 cm in thickness) located at the posterior bladder wall extending to the right side. Penetration of the muscularis propria cannot grossly be assessed. The serosa is inked. No puckering is identified. The remaining mucosal surface shows some granular tan brown tissue surrounding the left trigone (1.5 x 1.5 cm surface area). The remaining tissue is edematous and appears regular. The urethra is dilated and shows an ulcerated lesion extending towards but not involving the apex of prostate. A possible diverticulum of the bladder is present on the right side. The prostate gland, seminal vesicles and vas deferentia appear to be uninvolved by the tumor. The specimen is submitted as follows: Cassette #1: right ureter, resection margin. Cassette #2: left ureter, resection margin. Cassette #3: right urethra, apex, perpendicular. Cassette #4: left urethra apex, perpendicular. Cassettes #5-9: full thickness of mass. Cassette #10: possible diverticulum. Cassette #11: bladder neck. Cassette #12: right trigone.</p>				

	<p>Cassette #13: left trigone. Cassette #14: anterior aspect. Cassette #15: posterior aspect. Cassette #16: dome. Cassette #17: left irregular mucosa near ureter opening. Cassettes #18-20: right prostate. Cassette #21: right seminal vesicle, vas deferens, representative sections. Cassettes #22-24: left prostate, representative sections embedded. Cassette #25: left seminal vesicle, vas deferens, representative sections.</p> <p>Representative sections are embedded in twenty-five cassettes.</p> <p>C) Specimen: right obturator and right external iliac The specimen consists of a portion of nodular rubbery tissue measuring 8.0 x 3.0 x 2.0 cm. The area is serially sectioned and submitted in ten cassettes.</p> <p>D) Specimen: Appendix The specimen consists of a vermiform appendix (4.5 cm long and 0.7 cm wide) with attached mesoappendix (2.5 x 1.3 x 0.5 cm). The specimen is submitted as follows: Cassette #1: appendix base. Cassette #2: tip. Representative sections are embedded in two cassettes.</p> <p>E) Specimen: distal left ureter The specimen consists of a portion of tissue measuring 1.0 x 0.5 x 0.5 cm. It is bisected and submitted in total in one cassette.</p>
Microscopic	<p>A and C) Sections of the left external, right external and obturator lymph nodes show reactive changes. There is no evidence of metastatic carcinoma.</p> <p>D and E) Sections of the vermiform appendix and the distal left ureter submitted show no involvement by the urinary bladder tumour.</p> <p>B) There is an ulcerating high grade invasive transitional cell/urothelial carcinoma present involving the muscular layer and shows both lympho-vascular and peri-neural invasion. However, the tumour does not involve the prostate gland, seminal vesicles and the vas deferens. The right ureteral resection margin appears to be involved by the tumour.</p> <p>The prostate gland shows mostly adenomuscular hyperplasia and significant areas of granulomatous prostatitis. A few small foci of moderately differentiated invasive adenocarcinoma of the prostate are noted on the right side. The Gleason sum of these small foci are 3 + 3 = 6 out of 10.</p> <p>Following is a Synoptic Report on Urinary Bladder Carcinoma:</p>
Synoptic Data	<p>DIAGNOSIS: - Transitional cell/urothelial carcinoma.</p>

	<p>HISTOLOGIC GRADE: - High grade/poorly differentiated tumour.</p> <p>GROWTH PATTERN: - Ulcerating and infiltrating/Nodular growth pattern.</p> <p>LOCAL INVASION: - Tumour infiltrates the deep half of the muscularis propria (pT3a).</p> <p>TUMOUR EXTENSION: - Tumour extends to the right ureter.</p> <p>LYMPHOVASCULAR INVASION: - Present.</p> <p>PERINEURIAL INVASION: - Present.</p> <p>SURGICAL MARGINS INVOLVEMENT: Following surgical margin appears to be involved by the tumour: - Right ureteral margin.</p> <p>NON-NEOPLASTIC MUCOSA: - Chronic/granulomatous cystitis with ulceration.</p> <p>PROSTATE: - Nodular hyperplasia and granulomatous inflammation.</p> <p>SEMINAL VESICLES: - Unremarkable.</p> <p>LYMPH NODES: - One lymph node notably present in the wall of the urinary bladder shows metastatic tumour deposits. However, the right and left external iliac and right obturator lymph nodes are uninvolved by this tumour.</p> <p>COMMENTS: Based on this submitted specimen, this tumour appears to be a Stage pT3a, N1, MX. As mentioned previously, the right ureteral resection margin is involved by tumour.</p>
Final Dx	<p>A, C, D and E) Left external lymph nodes, right external and obturator lymph nodes, vermiform appendix and distal left ureter: - Uninvolved by the tumour.</p> <p>B) Urinary bladder and prostate, radical cysto-prostatectomy and ileo-conduit with: 1) High grade invasive transitional cell/urothelial carcinoma: - posterior and right urinary bladder wall. 2) Tumour stage pT3a, N1, MX.</p>

	<ul style="list-style-type: none">3) Adenomuscular hyperplasia of prostate.4) Foci of invasive prostatic adenocarcinoma - right prostate.5) Right ureteral resection margin - involved by tumour.
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13 Appendix F: Definitions, Acronyms and Abbreviations

Term	Definition
AIM	Artificial Intelligence in Medicine Inc.
AJCC	American Joint Commission on Cancer
AP	Anatomic Pathology
BRD	Business Requirements Document
CAP	College of American Pathologists
CAP-ACP	Canadian Association of Pathologists
CCR	Canadian Cancer Registry
CHI	Canada Health Infoway is a national body in Canada responsible for establishing and maintaining informatics standards in order to enable inter-operability and the pan-Canadian electronic medical record
CIHI	Canadian Institute for Health Information
CKeys	Unique checklist line item identifier provided by the CAP with the eCC. These are mapped to existing SNOMED CT codes, where they exist and serve to assist in electronic CAP checklist version control
CS	Collaborative Stage: a cancer staging data system used to collect data to derive AJCC TNM Best Stage, Extent of Disease and SEER Summary Stage
DDF	Discrete Data Fields: the data is stored and captured as discrete data elements using a standardized reporting nomenclature such as LOINC and SNOMED CT.
eCC	CAP electronic Cancer Checklists
HL7	Health Level Seven: specification used to transmit electronic reports from the source to the destination. For example, from the pathology laboratory to the to the cancer registry
ICD-O-3	International Classification of Diseases for Oncology; 3rd edition
IM	Information Management (Informatics)
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers, Names and Codes
NAACCR	North American Association of Central Cancer Registries
Partnership	Canadian Partnership Against Cancer
PATH	Pathology
PHI	Personal Health Information
SEER	Surveillance Epidemiology and End Results
PTCR	Provincial and Territorial Cancer Registry
SNOMED CT	Systematized Nomenclature of Medicine-Clinical Terms
Synoptic Pathology Reporting	The electronic capture of Pathology data as per the College of American Pathologists cancer checklists and protocols
TNM	Cancer Stage information - Tumour, Node, Metastasis System. Based on the extent of the primary tumour (T) extent of node involvement (N) & extent of metastases (M) as promoted by the AJCC and UICC
Regenstrief	an internationally recognized informatics and healthcare research organization who is responsible for the development, assignment and maintenance of LOINC codes
UICC	International Union Against Cancer is another organization similar to the AJCC which also supports TMN staging.

14 Associated References

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CAP Web-site: http://www.cap.org/apps/docs/snomed/documents/about_cap_ecc.pdf

15 Glossary

Below is a pair of Web links to online healthcare related glossaries:

<http://www.skmtglossary.org>

http://www.cdc.gov/cancer/npcr/informatics/aerro2/pdf/NPCR_AERRO_Glossary_07262010.pdf.