

# Scoping the Processes and Feasibility of a Synoptic Breast Pathology Reporting Module

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## Acknowledgement and Endorsement

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## Executive Summary

This report presents the work that has been done in the Department of Diagnostic Radiology at Dalhousie University in collaboration with the Nova Scotia Breast Screening Program during the summer term from May to August 2012. The internship work exclusively focused on issues that are related to health informatics. With biomedical engineering background and some programming skills, this internship experience was very useful for combining the health fields and informatics. The internship work experience at the organization related directly with the materials that had been taught in the Master of Health Informatics program. This report is part of the internship course requirements. It gives a short description of the organization and describes the work duties and responsibilities that were assigned by the supervisor.

The pathologists have been facing difficulties in preparing pathology reports for cancer cases. The process of creating templates in Millennium is not user friendly and requires more time to create the final report. In addition, there is an extensive amount of editing and deleting when preparing the pathology report templates. This report presents the solution for pathology reporting for breast cancer. The main task was to scope out the processes involved and the feasibility of implementing breast cancer pathology synoptic reporting in the clinical setting, and to investigate the suitability of the Caisis platform for this purpose. The synoptic report will improve the time required for and the quality of data management, reduce missing information, and guarantee the completeness of the essential information. In addition, the report will present a specific problem and approach solution to map the breast cancer protocol to Caisis data tables.

The author's internship work has provided skills to create an exciting solution for the healthcare organization. This solution will help pathologists who are doing the pathology reporting for breast cancer to get more benefits than from traditional pathology reporting. As well, oncologists, pathologists, surgeons, researchers, and other clinicians can benefit from this solution. By adopting the solution of an electronic synoptic report, the organization can comply with the requirements for the College of American Pathologists. In addition, the electronic reporting template for cancer synoptic protocol can be useful for designing a model that can help to create medical records. The computerized synoptic reporting will improve pathology reporting for breast cancer. The synoptic report will reduce the time required for pathologists to prepare their reports and improve the quality of data management. In addition, it can help to reduce missing information and guarantee the completeness of the essential information. The benefits of adopting synoptic pathology reports will make it easier to extract information from the report.

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## 1 Introduction

The internship course is a great opportunity for students to use their informatics skills and knowledge in the real world and to gain professional work experience in the health care environment. This report is a part of the academic requirements of the internship course. It will demonstrate the work that was done by the author during the internship period from May to August 2012 in the Department of Diagnostic Radiology at Dalhousie University in collaboration with the Nova Scotia Breast Screening Program (NSBSP).

Pathologists have been facing difficulties in preparing pathology reports for cancer cases. This report will present a solution for pathology reporting for invasive and non-invasive breast cancer. First, this report will discuss briefly about breast cancer and how is reported. Then, it will give a short description about the NSBSP organization, and describe the work duties and responsibilities that were assigned by the supervisor. After that, the report will present the actual work and its relationship with health informatics. In addition, the report will present a specific problem and approach solution to map the breast cancer protocol to Caisis data tables. Finally, the paper will end with conclusions and recommendations.

## 2 Background

Normal human cells behave in an orderly manner, growing and splitting to replace damaged cells, while cancer cells behave abnormally and damage normal tissue. Because the DNA for the body cells gets damaged, the cell becomes a cancer cell (American Cancer Society [ACS], 2012). The damaged cancer cells, instead of dying or being replaced, produce more damaged DNA cells, which may spread the cancer in the human body (ACS, 2012).

“Breast cancer” refers to a malignant tumor (cancerous cells) that begins in the breast cells (ACS, 2012). Commonly, breast cancer either starts in the cells of mammary glands (lobules) or in the tiny canal between lobules and nipples (ducts) (Breastcancer.org, 2012.). Rarely, breast cancer starts in the supporting and connective tissues (stromal tissues) (Breastcancer.org, 2012). Ductal carcinoma in situ (DCIS) is the most commonly diagnosed type of non-invasive breast cancer (ACS, 2012). In this type of breast cancer, the effected cells are located inside the milk ducts. However, these cells have not developed across the ducts’ walls to any surrounding tissues. For invasive breast cancer, there are two common types: ductal carcinoma, which begins from the ducts and spreads over the wall, and lobular carcinoma, which begins from the mammary glands and spreads to other parts of the body (ACS, 2012).

According to Canadian Cancer Statistics (2012), breast cancer is the most common type of cancer among women and is the second leading cause of death among cancer patients (Canadian Cancer Society's Steering Committee on Cancer Statistics, 2012). In Canada, Nova Scotia has the highest incidence rate of breast cancer (CCSSCCS, 2012). During

an individual's lifetime, it is expected that one out of nine women have the chance to develop breast cancer (CCSSCCS, 2012).

Currently, effective and efficient treatment combined with early detection of breast cancer through orderly breast screening programs are the best solutions available to reduce the mortality rate due to breast cancer among women (Khatib & Modjtabai, 2006). Furthermore, all professional groups involved in the reduction of the mortality rate from breast cancer are required to perform to the highest standard. The level of quality services for pathology reporting is of the utmost importance. The pathologists provide important details that can be helpful for cancer treatment. However, several issues may affect the quality of the pathology report. The large amount of information that needs to be recorded for each case may cause valuable information from the pathology report to be mislaid (Qu et al., 2007). In addition, the variety of terminology used in the reporting and individual style of writing may create barriers for communication (Qu et al., 2007). In order to address these issues and make the process of reporting more efficient and uniform, standardized reporting forms and checklists have been developed.

## 2.1 CAP Checklists

The College of American Pathologists (CAP) has developed pathology reporting procedures, protocols and checklists for common malignant tumors that affect the human body (Qu et al., 2007). The CAP cancer protocol checklists are comprehensive and document inclusive details such as tumor site, architectural patterns, and ancillary studies, which are non-mandatory elements. Also, the checklists include elements, such as specimen procedure, size, and laterality, which are mandatory. The CAP provides the checklists in Microsoft Word format and Portable Document Format (pdf). CAP pathology checklists can be useful to create and design standardized synoptic templates. Synoptic reports can be created for different surgical procedures in multiple standards (Gur, 2012). Becher (2011) defines synoptic reports as "reports that present data in an outline, list, or table format with clearly identified headers and responses." (p. 789).

## 3 Nova Scotia Breast Screening Program

The Nova Scotia Breast Screen Program (NSBSP) was founded and has been supported by the Nova Scotia Department of Health and Wellness since 1991 (NSBSP, 2011). NSBSP is an early detection program of breast cancer that targets women between the ages of 50 to 69. The main purpose of the breast screening program is to reduce the mortality and morbidity rates from breast cancer through early detection (NSBSP, 2011). NSBSP's aim is to reduce the mortality rate from breast cancer to one-third of the current rate and to provide a high quality standardized provincial screening program (Public Health Agency of Canada, 2007).

Women may take the breast screening examination through an invitation or a referral letter. The breast screening test is provided at fixed-sites in urban areas or mobile-sites in

remote areas. In a normal case, women who have normal results are invited back for screening after 24 months. In contrast, women who have abnormal results are informed for follow up visits (Miller, 2000).

Lately, NSBSP has been involved in the development of the Breast Imaging Electronic Medical Record (built on the Caisis platform) that will replace the current Mammography Information System, in order to provide an advanced and user-friendly interface (Wills, 2012). Caisis will also reduce the time and effort that is required for documentations (Alqatami, 2012). Caisis is an open-source software developed to integrate research data with clinical care practices (Caisis, n.d.). It provides many features for generating and organizing templates for clinical data, documentations for medical records and frameworks to look through clinical history (Fearn & Sculli, 2010). Caisis is also a web-based application that is designed to serve as a cancer data management system for data quality and accuracy (Alqatami, 2012). Caisis is different from other data management systems because it collects data required for research during patient visits (Fearn et al., 2007).

## 4 Internship Work

### 4.1 Job Description

The Diagnostic Radiology Department, CDHA in collaboration with the Nova Scotia Breast Screening Program provided the intern with an opportunity to work alongside the Breast Imaging Electronic Medical Record (BIEMR) team to implement a synoptic breast pathology-reporting module on the Caisis platform. The BIEMR team is made up of members from different specialties, including pathologists, radiologists, radiation technologists, breast screening managers, informaticians, and epidemiologists.

The intern also participated in the development of the best solutions to create a simple way to transfer the final pathology synoptic report from the Caisis platform to the Cerner Millennium, Hospital Information Systems (HIS).

### 4.2 Role and Responsibilities

The major duty in the internship was to create and design two electronic synoptic reports, which represented a protocol for pathology testing of samples from breast cancer patients with Ductal Carcinoma In Situ (DCIS) and a protocol for pathology testing of samples from breast cancer patients with invasive carcinoma.

The intern had opportunities to improve their technical and programming skills. Some highly recommended programming skills that are required for this internship, from high to low include: XML, HTML, XSLT, C# or similar object oriented language, Javascript, and SQL. In addition, the intern had to be familiar with relational database concept.

The intern was required to communicate regularly and clearly with a multidisciplinary team, both locally and internationally, and possess solid project management skills. This entailed scoping the requirements, implementing the module, conducting UAT, incorporating feedback, and documenting the final product.

## 5 The Internship Work

### 5.1 Current Workflow

In the beginning of the work, we had a meeting with the pathologist to identify the actual workflow for the pathology reporting for breast cancer [Appendix A]. This helped us to get a complete idea about the issues that pathologists encounter during breast cancer reporting. Usually, there are two major parts for pathology reporting: the pathologists collect data from the surgical specimen, and the collected data then has to be transferred to the Cerner Millennium (HIS).

The process of cancer reporting begins from the pathologist who receives the specimen from the pathology lab. This specimen is taken from the patient who had abnormal results from the breast screening. The pathologist has to login to the Cerner Millennium where they can view the lists of specimen cases, select the examination case, and prepare the pathology reporting templates.

Currently, the pathologists are using their own template forms for breast cancer reporting [Appendix B]. However, these forms are not installed in Millennium. The pathologists have to create and design the templates according to the type of case for every single report. The process of creating templates in the Millennium is not user friendly and requires more time to create the final report.

In order to minimize the time that is required for typing templates, staff from the IT department have created speed keys or hotkeys that are custom mapped to particular templates created by the pathologists. The hotkeys are used to invoke the templates by typing abbreviations (or any short symbols), which have been pre-assigned by the IT staff, and then pressing specific keyboard keys. Although the hotkeys help the pathologists to create synoptic reports, they have to do extensive editing, including deletion of unneeded elements from the templates that obscure important information, and addition of elements to the template as required for each case.

After that, the pathologists check and review all contents of the report before storing the report in the system. If any authorized organization wants to view the report, the clerk can access the system and send the requested copy. In some cases, additional steps might be required, such as downloading and printing the standard pathology reporting templates in order to check and review the content of the report. Furthermore, pathologists might receive calls from oncologists and surgeons for additional information or for clarifications, which may cause additional work.



The most common drawback in this type of reporting is typographic errors, which are very difficult to avoid (Qu et al., 2007). Because the reporting template is not integrated in the system and does not link to patient demographic information, a separation can happen within a single pathology report. Also the mismatch between patients' reports is another weakness of the system. A very major weakness of the system is that the synoptic reports are essentially stored as free text, such that the data is not stored as individual data elements in discrete form for retrieval in a well-structured manner that can be easily queried.

## 5.2 Open Source Solution

Healthcare organizations are experiencing challenges to manage their needs with limited resources. Thus, the market demands for open source solutions have been growing and many developers are taking a serious step toward managing healthcare needs and developing more solutions. Healthcare institutions are looking for solutions that provide acceptable performance while simultaneously reducing costs.

One of the greatest advantages of the open source solution is that it can be obtained easily (Goulde & Brown, 2006). Most of the open source software can be found in many websites with no license fees. Often the open source software is developed by a group of programmers who do not get paid for their work, which shifts the cost of development to providing services related to the software (Goulde & Brown, 2006). In addition, the availability of the source codes can help the developer to understand the method of programming, which can help to solve the issues and, develop and modify the software (Goulde & Brown, 2006). Another advantage of the open source is that it can be obtained from different vendors (Goulde & Brown, 2006). Therefore, healthcare organizations are not obliged to depend on one vendor. To combine all these benefits (easy to obtain, low cost, vendor independence, and opportunity to innovate) an open source solution such as Caisis is the most suitable solution for under-resourced organizations.

## 5.3 Installing and Learning

In order to be familiar with Caisis, the intern has to download and install Caisis on the computer. The installation steps are available on the link <http://caisis.org/wiki/index.php?title=Installation>. In addition, the previous year's summer interns (summer 2011) documented the steps of installation (Alqatami, 2012). The next step is to learn about the programming languages C# and .NET that help with modifying and creating new templates. There are various tutorials on websites that can be helpful in learning these programming languages.

## 5.4 Pathology Breast Cancer Reporting Requirement Elements

The CAP invasive and non-invasive breast cancer protocol checklists are listed in the CAP website [Appendix C]. These CAP checklists have been downloaded and printed in order to specify the requirements of the pathologists for their pathology reporting. As

part of another MHI thesis (Khalid Tearo, 2012), a survey revealed that our consulting pathologist along with other colleagues have identified a number of elements from the CAP Breast Cancer Protocol Checklists that are required for their pathology reporting for breast cancer. Pathologists marked the selected elements from CAP checklists as following [Appendix D]:

1. Fill in: for elements that need to fill in text or number
2. Choose one: elements that require a single value
3. Choose any: elements that might have multiple values
4. Omit: elements that are not required

### 5.5 Requirements for Synoptic Reports

The main purpose of the synoptic report is to create a document that has all essential information relevant to clinical components (Donahoe et al., 2012). Pathology reports should be complete and comprehensive for managing clinical data of patients. This is important for communication among the health care team members (Austin et al., 2009). In order to improve patient management and to specify the effect of different treatment protocols and detection of cancer, it is necessary to reduce the inconsistency in reporting and to improve the understanding by following a standard checklist for reporting and assessment of cancer (Austin et al., 2009).

Because of the involvement of multiple specialists, including pathologists, oncologists, surgeons, and radiologists on the treatment of a cancer patient, the information in the synoptic report should be complete and accurate. The required information must be easily extracted by any clinician who is involved in patient care (Donahoe et al., 2012).

Some useful approaches have been recommended for developing pathology reporting for breast cancer (Austin et al., 2009):

- Educational quality improvement program focus on tools that help pathologists to improve their work performance.
- Developing clinical communications by building a standardized cancer report.
- Reporting of all absent and present elements to avoid the misunderstanding that an element may not have been evaluated.

In order to implement a pathology synoptic report, the following requirements should be considered:

- The pathology synoptic report for breast cancer will be based on the requirements of the pathologists and the CAP cancer protocol examination checklists.

- The pathology synoptic report should include all essential information in a brief and comprehensive view.
- The operating system should be easy to login to, simple to function, and require little time to use. The data stored can be easily retrieved and can be used by other authorized institutions for research (Iyer et al., 2011).
- The pathology synoptic report should combine free text and synoptic format in order to clarify some elements' values in the pathology report (Haydu et al., 2010).
- The breast synoptic report should include comments fields for any additional information that is not included within the elements fields. The comments field is very useful for pathologists, surgeons and oncologists who want to add more details or additional findings (Chambers, Pasiaka, & Temple, 2009),
- The structure format for the synoptic report should be designed in such a way to avoid neglecting important details, thereby enhancing learning in clinical practice (Gur, 2012)
- The CAP checklists contain extensive information details provided in long pages. However, the synoptic report should only use words and phrases to predict the information quickly and it should be easy to fill out.
- The pathology synoptic report should be in electronic format with drop-down lists, check boxes, and separate data fields that can be helpful for encouraging pathologists and non-pathologists to generate a comprehensive synoptic report (Messenger, McLeod, & Kirsch, 2011).
- The pathology synoptic report should use a hidden function for the elements that are not mandatory and the elements that are not applicable for certain cases.
- The final format of the synoptic pathology report needs to be reviewed and approved by the consulting pathologist.

## 5.6 Mapping between CAP elements and Caisis Database

The Caisis database platform has been used as a base for designing the pathology synoptic report (Iyer et al., 2011). Numerous hospitals and health institutions in North America have adopted Caisis as a hospital database system and for research purposes (Iyer et al., 2011). In this phase, all CAP elements that are required by pathologists must map to Caisis data tables. However, while some elements have been mapped successfully, other elements could not be found. Figure 1 presents part of the mapping. The consulting pathologist helps us to map some of the unmapped elements, while a developer from the Caisis core development team guided us toward the best solution for the remaining unmapped elements. The process of mapping will be discussed in depth in the section of "Problem and Approach Solution".

NON INVASIVE CAP Checklist								
Label (CAP Page)	CAP Checklist			Required by pathologist	Mapped (yes/No)	Caisis DataDictionary		Comments
	Elements	Values				Table	Field	
4	Specimen	Partial breast Total breast (including nipple and skin) Other (specify): Not specified	No					
4	Procedure	Excision without wire-guided localization Excision with wire-guided localization Total mastectomy Other (specify) Not specified	yes (choose any)	no				
4	Lymph Node Sampling	No lymph nodes present Sentinel lymph node(s) Axillary dissection Lymph nodes present within the breast specimen Other lymph nodes Specify location, if provided	yes (choose any)	no				
4	Specimen Integrity	Single intact specimen Multiple designated specimens Fragmented Other (specify)	yes (choose one)	no				
4	Specimen Size	Greatest dimension: ___ cm Cannot be determined Additional dimensions: ___ x ___ cm	yes	yes No	NodePathFinding	PathFindMaxDim	117	
4	Specimen Laterality	Right Left Not specified	yes (choose one)	yes	PathologyFinding	PathFindSide	126	

Figure 1 A Screenshot for Excel table shows the mapping between CAP checklists and Caisis database. On the left side, the CAP checklist column contains the CAP elements and their values. On the right side, the Caisis Data Dictionary contains data tables and fields. The middle two columns show the mapped elements and elements required by pathologists.

### 5.7 Electronic form Creation

After mapping all possible elements from CAP checklists to Caisis data tables, the author created and updated tables. The tables editing phase was done through the Microsoft SQL Server. After that, the author created new store procedures and edited the existing store procedures. Finally, the author designed an electronic form based on the Caisis eforms templates and pathologists' requirements [Appendix E].

### 5.8 Accessing and Generating Pathology Reporting

Pathologists will generate the synoptic report from Caisis. Caisis has a strong security system that follows the guidelines of HIPAA regulations. The access to data in Caisis is identified by the organization and only shared across the health community to maintain the privacy and confidentiality of patient information (Iyer et al., 2011). Pathologists will be given a user access for Caisis. Caisis is a web based application and it can be accessed through the most common web browsers, such as Internet Explorer, FireFox, and Safari.

### 5.9 Transferring Synoptic Reporting to HIS

After the synoptic pathology reporting for breast cancer was generated from Caisis, the solution was developed for transferring the synoptic reporting to Cerner Millennium. This solution is based on Java coding that allows the pathologists to transfer all information in the final synoptic report from Caisis to Millennium by clicking a button.

## 5.10 Expectation

The adoption of a web based synoptic reporting system will have a major impact on breast cancer reporting. It is expected that the amount of missing information will decrease after using synoptic reporting (Hammond & Flinner, 1997). Synoptic reporting will help to improve the overall time required for pathology reporting and will improve the quality of data management. In addition, it will facilitate the extraction of useful information for research and guarantee consistency in reporting (Haydu et al., 2010).

It is expected that synoptic reporting will spread the benefits among clinicians and pathologists. With synoptic reports, a high degree of satisfaction is expected from pathologists who have a difficult time preparing pathology reports. In addition, oncologists will also benefit from the standardization of synoptic reporting. They depend on the cancer report to provide them with information about specimens, lymph nodes, histologic grading, pathology staging, and other information that can be helpful for patient treatment (Hammond & Flinner, 1997).

One of the greatest advantages of using the computerized synoptic report is to guarantee the completeness of the report. Because the pathologists have to complete all mandatory fields before generating a final report, the report will include all essential elements (Chambers, Pasioka, & Temple, 2009).

The synoptic report has information that can add a major educational impact. Such preoperative information as previous clinical history, methods of detecting, tumor sites and clinical conditions familiarize the physician with the patients' condition (Gur, 2012). In addition, it emphasizes the resident's learning about the process of pre-surgical decision-making. Furthermore, it provides further information about major procedure points during the surgery (Gur, 2012).

## 6 Problems and Approach Solutions

As discussed before, the major task in the internship was to scope out the processes involved and the feasibility of implementing breast cancer pathology synoptic reporting in the clinical setting; one protocol for pathology testing of samples from breast cancer patients with Ductal Carcinoma In Situ (DCIS) and another protocol for pathology testing of samples from breast cancer patients with invasive carcinoma. However, during the prototype development phase the author faced some challenges. One of these challenges was the mapping between CAP elements and Caisis data tables. This section will discuss controlled terminologies and some useful strategies for mapping.

### 6.1 Controlled terminologies

The demand for controlled medical terminologies in clinical systems is standardized across the literature. With the expansion of clinical applications, the needs for standardized data entry become substantial. Each time a new system is invented,

programmers must take an effort to standardize vocabularies. However, more effort is required for the legacy systems that do not have controlled vocabularies.

Matching between the terminologies is required in order to create interoperability among systems, and it is an essential step toward knowledge sharing (Wang, Patrick, Miller, & O'Halloran, 2006). The method of mapping is an identification of the matching concept for terminology. Much of literature discusses the effort to automate the terminology mapping process (Wang et al., 2006). However, in this task the mapping had to be done manually. The process of manual data mapping took several weeks to complete because the process required searching for the right match from several terminology concepts.

## 6.2 NCI Metathesaurus

For an accurate mapping, NCI Metathesaurus is used as a source of information for biomedical terminologies. NCI Metathesaurus is based on Unified Medical Language System (UMLS). Before mapping is started, understanding the meaning of the term is required to find the accurate match. Metathesaurus was used to search for definitions and synonyms for the CAP protocol terminologies. Then, the author searched for these synonyms in the Caisis data tables.

## 6.3 Caisis data dictionary

The Caisis developers created a data dictionary for Caisis databases that contain tables and descriptions of data terms. Data dictionaries are a quick way for programmers to find the definition of terms. However, in order to get the full benefits of the data dictionary, the developer has to make sure to include the accurate description of terms.

## 6.4 Strategies for mapping

To ensure vocabulary control during the mapping between the CAP protocol and Caisis data tables, strategies of mapping have been introduced by Aronson (2006) and Wang et al. (2006).

1. Analyze the text

The first step is to analyze the text into noun phrases. For the CAP protocol elements, this step was not necessary because elements are in noun phrase form. However, this step was applied for the elements values which have a long text.

2. Generate variants

For each noun phrase, variants have been generated. Basically the variant is formed of one or more noun phrases (Aronson, 2006). The variants are meaningful words in a noun phrase (Aronson, 2006). For example, the variants for the CAP element Tumor Size are Tumor Size, Tumor, and Size.

3. Normalize the terminology

A noun phrase is normalized by removing the suffix and punctuation, and converting terms to atomic forms (Wang et al., 2006). In addition, stop words such as “is”, “the”, “at”, “on”, “of”, “a” etc. are removed.

4. Expand the terminology

Most of abbreviations are identified in the NCI Metathesaurus. For example, the TNM Category refers to Tumor-Node-Metastasis Category. However, some other abbreviations are not defined, such as pT, which refers to Primary Tumor. In order to eliminate any confusion that might happen, it is better to expand the abbreviations.

5. Use substring terminology

Substring terminology is helpful in increasing the mapping coverage (Wang et al., 2006). For example, the term Staging is a substring of cancer staging.

6. Define the Candidates terminology

To select the candidate term, each phrase is searched and reviewed in Metathesaurus. Then a decision is made to choose the preferred term, which is the candidate term.

7. Use Metathesaurus

The process of mapping required the use of biomedical thesauruses to search for the different variations and meanings of the terminologies. For the cancer terminologies, NCI Metathesaurus is a very useful tool to search for syntactic and semantic information (Schuyler, Hole, Tuttle, & Sherertz, 1993). NCI Metathesaurus provides a list of synonymous words for the medical terminologies. NCI Metathesaurus is organized in concepts, and its databases contain more than 1.4 million concepts which are mapped to 3.6 million terms. NCI Metathesaurus is a great tool to standardize clinical terminology in data tables. This process allows consistency in recording information

## 6.5 Mapping Examination

Each terminology from the NCI Metathesaurus synonym is mapped to Caisis data tables and according to the mapping results, the terms are classified into one of four groups (Aronson, 2006):

1. Simple mapping: the map is simple when the noun phrase absolutely maps to one field in Caisis data tables (Aronson, 2006). For example, the term Nuclear Pleomorphism absolutely maps to Nuclear Pleomorphism.
2. Complex mapping: the map is complex when each words in the phrase has simple mapping (Aronson, 2006). For example, Lymph Nodes Sampling maps to Lymph Nodes and Sampling.

3. Partial mapping: the map is partial when the Caisis data field or/and terminology from the Metathesaurus have at least one word that does not map (Aronson, 2006).
  - a. Normal: when the phrase maps to a term without a gap or vice versa. For example, necrosis mapped to tumor necrosis. In this case mapping does not include tumor.
  - b. Gapped: when the phrase maps to a term and there is a gap or vice versa. For example, Respiratory Disease maps to Respiratory System Disease, so the gap is System.
  - c. Overmatch: When the phrase maps to many overmatches. For example, "Application" mapped to "Computer Application" and "Regulatory Application".
4. No mapping: when there is no mapping between any words from the term and Caisis data tables (Aronson, 2006).

## 6.6 Unmapped elements

The strategies of mapping that have been introduced can be helpful to assure quality control of mapping. By applying all these steps, two solutions for unmapped elements can be processed:

1. Add new fields in the existing set of tables
2. Create new fields in a new table

## 7 Relation to Health Informatics

The internship work was exclusively focused on the issues that are related to health informatics. With biomedical engineering background and some programming skills, this internship experience was very useful for combining the health fields and informatics. The internship work experience at the organization related directly with the materials that had been taught in the Master of Health Informatics.

This internship was a great example of how to connect multiple courses in a single work task. From the course Health Information Flow and Use, the author learned about the Canadian health care system, the structure of the health care system, and the clinical workflow. This course helped me to understand the structure of organization and explored the workflow process inside the health care institution. The second course that has connection with internship work is the Health Information Flow and Standards; this course taught me about issues related to information flow and taught about the tools that can be used to map between biomedical terminologies. This course was helpful in tracking the information flow during pathology reporting and searching for the gap in the information. In addition, it helps me to follow the strategies during the mapping between the CAP elements and the Caisis data tables.



From the Project Management for Health Informatics course, the author learned how to plan and control a timeline and how to work in a team with different specialties. This course introduced some tools such as Gantt Charts to illustrate the project schedule and develop a planned and timeline for each task [Appendix F]. From the Networks and the Web for Health Informatics, the author learned how to design databases and how to store and retrieve information. This course was essential in the internship work as it taught me a lot about the network connection and relational database concepts. The final course that helped during the internship work is the Electronic Text Design. This course taught in theoretical and practical ways how to create an electronic text web page. It provided the programming skills that are required to create a text website and introduce the standards of presenting electronic documents in the webpage.

## 8 Conclusions

The internship work was a great opportunity to gain experience and knowledge about the applications of health informatics in the health care environment. This report presents the solution for pathology reporting for breast cancer. The main task was to scope out the processes involved and the feasibility of implementing breast cancer pathology synoptic reporting in the clinical setting, and to investigate the suitability of the Caisis platform for this purpose.

There were a number of challenges that the author encountered during the internship work. The main issue was the mapping between CAP elements and the Caisis data tables. This issue arose because of the differences in the terminologies between the CAP protocol and the Caisis data tables. Mapping strategies were introduced to facilitate the process of mapping and to assure the accuracy of mapping. In addition, applying the strategies of mapping will guarantee that the new terms are standardized and controlled.

Computerized synoptic reporting has the potential to significantly improve pathology reporting for breast cancer. The synoptic report will reduce the time required for pathologists to prepare their reports and improve the quality of data management. In addition, it can help to reduce missing information and guarantee the completeness of the essential information. The benefits of adopting synoptic pathology reports will make it easier to extract information from the report.

## 9 Recommendations

It is recommended to follow the mapping strategies which guarantee the quality control implementation of new terminologies.

The Caisis data dictionary required a revision to standardize the definition of fields according to the biomedical thesauruses.

It is recommended to adopt a coding system such as SNOMED CT for Caisis data tables to ensure smooth interoperability between other clinical systems. Integration of the CAP XML files into CAISIS that implement the CAP checklist would provide such a solution.

For future work, it is recommended to create a comprehensive integration for synoptic reporting with other healthcare interventions that are involved in the care of cancer patients. Furthermore, there are more opportunities for internship to implement additional pathology synoptic reports in the Caisis platform.

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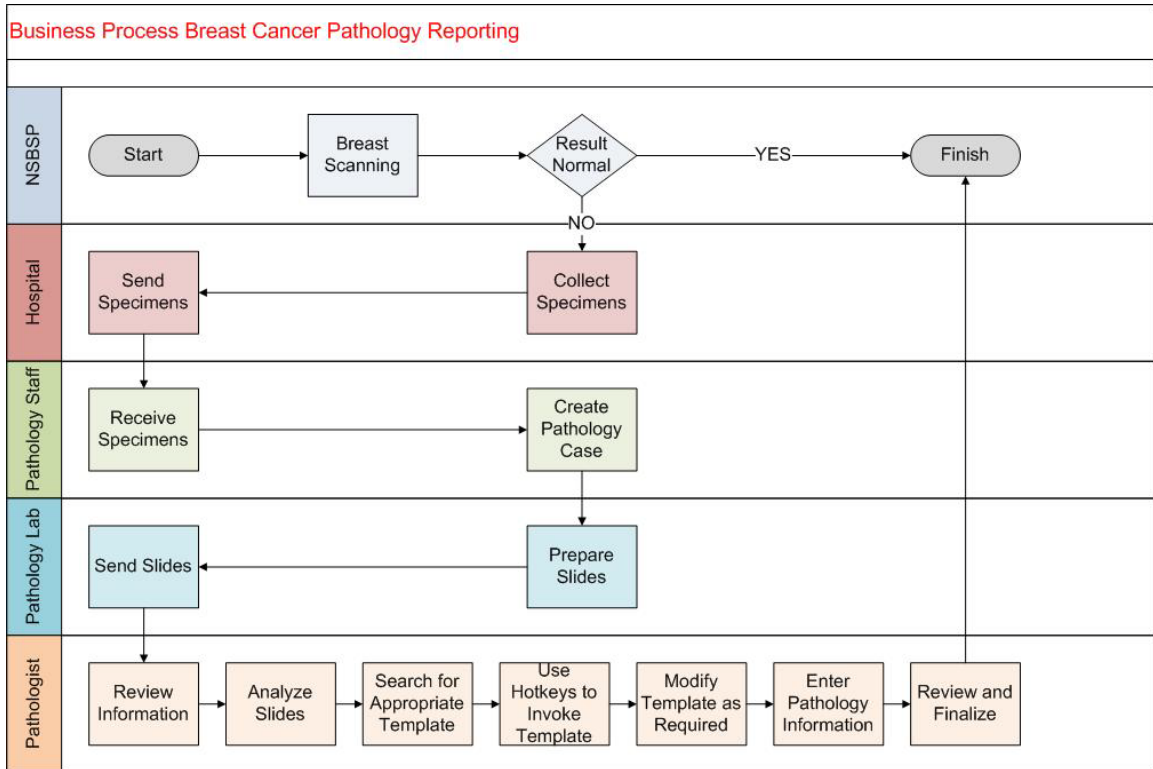
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# Appendices

## Appendix A

### The Business Process for Pathology Reporting



## Appendix B

The current templates for pathology reporting for invasive and non-invasive breast cancer are used by pathologists at Capital Health, Halifax.

TEMPLATE FOR MICROSCOPY OF INVASIVE BREAST CARCINOMA - EXCISION		
Procedure:	—	<sup>1</sup> (wide local excision/lumpectomy, mastectomy, wire localization excision, re-excision)
Axillary Surgery:	—	(no)
	—	(yes) - axillary node dissection, sentinel node biopsy)
Side:	—	(right, left)
Tumor Location(s):	—	(not determined, central, upper outer quadrant, upper inner quadrant, lower outer quadrant, lower inner quadrant)
Histologic Type(s):	—	(invasive ductal-NOS, invasive lobular – <i>specify variants, special types</i> )
Distribution of Tumor:	—	Unifocal
	—	<sup>2,3</sup> Multifocal
	—	<sup>2,3</sup> Multicentric
Tumor Size:	—	maximum diameter in cm ( <i>specify whether microscopic or macroscopic measurement</i> )
Nottingham Grade:		
Tubule Formation Score:	—/3	<sup>4</sup> (1,2,3)
Nuclear Grade	—/3	<sup>4</sup> (1,2,3)
Mitotic Score	—/3	<sup>4</sup> (1,2,3)
Total	—/9	( <u>  </u> /9)
Grade	—	(1,2,3)
Lymphatic/Vascular Invasion:	—	(not identified, present – ( <i>specify focal vs extensive</i> ))
In Situ Component:	—	(absent, lobular, ductal – <i>specify type, size of DCIS, presence of necrosis (punctate/comedo)</i> )
Nuclear Grade	—	(not applicable, low, intermediate, high)
EIC Status:	—	<sup>5</sup> (indeterminate, negative, positive)
Calcification:	—	(absent, in benign breast tissue, in in-situ component, in invasive tumor)



Resection Margins Involvement:	
Invasive carcinoma	<input type="checkbox"/> Negative, ___ mm from closest ___ margin. <input type="checkbox"/> Positive (specify) margin(s). _____ (specify blocks with close and/or involved margins)
DCIS	<input type="checkbox"/> Negative, ___ mm from closest ___ margin. <input type="checkbox"/> Positive (specify) margin(s). _____ (specify blocks with close and/or involved margins)
Lymph Nodes:	(if none present – delete this section)
Involved	_____ (number)
Resected	_____ (number)
Size of nodal metastasis	_____ (largest dimension of tumor deposit in lymph node - cm)
Extranodal extension	_____ (no, yes - number of lymph nodes involved)
Nipple and Skin Involvement:	_____ (tissue not present, absent, direct skin invasion, dermal lymphatic invasion, Paget's disease)
Chest Wall Involvement:	
Skeletal Muscle	_____ (tissue not present, absent, involved)
Abnormalities in non-neoplastic breast tissue:	_____ (absent, present - specify)
Hormone Receptors:	
Ordered:	_____ (not applicable, no, yes)
Result:	<input type="checkbox"/> <sup>6</sup> ER – negative <input type="checkbox"/> <sup>6</sup> ER – positive (_____% of cells) <input type="checkbox"/> <sup>6</sup> PR – negative <input type="checkbox"/> <sup>6</sup> PR – positive (_____% of cells) <input type="checkbox"/> controls: internal, external
HER2/neu IHC	<input type="checkbox"/> <sup>7</sup> (not determined, negative, equivocal or positive) <input type="checkbox"/> controls: external (TMA)
pTN Stage	_____ <sup>8</sup> pT ___ N ___

**TEMPLATE FOR MICROSCOPY OF  
IN SITU BREAST CARCINOMA - EXCISION**

Procedure:	—	(wide local excision/lumpectomy, mastectomy, wire localization excision, re-excision)
Axillary surgery:	—	(no, yes) – <i>specify procedure (axillary node dissection, sample of sentinel node biopsy)</i>
Side:	—	(right, left)
Tumor Location(s):	—	(not determined, central, UOQ, UIQ, LOQ, LIQ)
DCIS Architectural Type(s)	—	(cribriform, solid, micropapillary, papillary, comedo - <i>specify all that apply</i> )
DCIS Grade:	—	<sup>1</sup> (Low (I/III), Intermediate (II/III), High (III/III))
DCIS necrosis	—	(absent, present – <i>punctuate, comedo</i> )
Extent of DCIS	—	Size of largest focus ___ cm; # of blocks involved ___/total # of blocks ___ ( <i>specify tissue blocks with close and/or involved margins</i> )
Calcification:	—	(absent, in benign breast tissue, in in-situ component)
Resection Margins Involvement:	—	(not evaluable, absent, involved – <i>specify site/s</i> ) Distance to closest (specify) margin ___ cm.
Microinvasion (< 1 mm):	—	(present, absent)
Lymph Nodes:		( <i>if none present – delete this section</i> )
Involved:	—	( <i>number</i> )
Resected:	—	( <i>number</i> )
Size of nodal metastasis:	—	( <i>largest tumor deposit in lymph nodes - cm</i> )
Extranodal extension:	—	(no, yes – <i>number of lymph nodes involved</i> )
Nipple and Skin Involvement:	—	(tissue not present, absent, Paget's disease)
Abnormalities in non-neoplastic breast tissue:	—	(absent, present - <i>specify</i> )
pTN Stage	—	<sup>2</sup> pT ___ N ___

*pT is N?*

Correlation with previous relevant pathology report (if appropriate):  (not applicable, or – *previous surgical number and diagnosis*)

Pink Rose Information Package:  (no, yes)  
*send with all newly diagnosed malignancies; in dictation ask Secretary to send with report*

<sup>1</sup>See Attached.

<sup>2</sup> AJCC Cancer Staging Manual, 6<sup>th</sup> Edition. See attached.

## Appendix C

The College of American Pathologists cancer protocol checklists for invasive and non-invasive breast cancer are retrieved from <http://www.cap.org/>

<b>CAP Approved</b>	<b>Breast • DCIS</b> DCIS 3.0.0.1
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**Surgical Pathology Cancer Case Summary (Checklist)**

Protocol web posting date: October 2009

**DCIS OF THE BREAST: Complete Excision (Less Than Total Mastectomy, Including Specimens Designated Biopsy, Lumpectomy, Quadrantectomy, and Partial Mastectomy; With or Without Axillary Contents) and Mastectomy (Total, Modified Radical, Radical; With or Without Axillary Contents)**

**Select a single response unless otherwise indicated.**

**Specimen (Note A)**

Partial breast  
 Total breast (including nipple and skin)  
 Other (specify): \_\_\_\_\_  
 Not specified

**Procedure (Note A)**

Excision without wire-guided localization  
 Excision with wire-guided localization  
 Total mastectomy (including nipple and skin)  
 Other (specify): \_\_\_\_\_  
 Not specified

**Lymph Node Sampling (select all that apply) (Note B)**

No lymph nodes present  
 Sentinel lymph node(s)  
 Axillary dissection (partial or complete dissection)  
 Lymph nodes present within the breast specimen (ie, intramammary lymph nodes)  
 Other lymph nodes (eg, supraclavicular or location not identified)  
Specify location, if provided: \_\_\_\_\_

**Specimen Integrity**

Single intact specimen (margins can be evaluated)  
 Multiple designated specimens (eg, main excisions and identified margins)  
 Fragmented (margins cannot be evaluated with certainty)  
 Other (specify): \_\_\_\_\_

**Specimen Size (for excisions less than total mastectomy)**

Greatest dimension: \_\_\_ cm  
\*Additional dimensions: \_\_\_ x \_\_\_ cm  
 Cannot be determined

**Specimen Laterality**

Right  
 Left  
 Not specified

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

4

**\*Tumor Site (select all that apply)**

- \*  Upper outer quadrant
- \*  Lower outer quadrant
- \*  Upper inner quadrant
- \*  Lower inner quadrant
- \*  Central
- \*  Nipple
- \*Position:  o'clock
- \*  Other (specify):
- \*  Not specified

**Size (Extent) of DCIS (Note C and Figure)**

Estimated size (extent) of DCIS (greatest dimension using gross and microscopic evaluation): at least  cm

\*Additional dimensions  x  cm

\*Number of blocks with DCIS:

\*Number of blocks examined:

*Note: The size (extent) of DCIS is an estimation of the volume of breast tissue occupied by DCIS.*

**Histologic Type (Note D)**

Ductal carcinoma in situ. Classified as Tis (DCIS) or Tis (Paget)

**\*Architectural Patterns (select all that apply) (Note E)**

- \*  Comedo
- \*  Paget disease (DCIS involving nipple skin)
- \*  Cribriform
- \*  Micropapillary
- \*  Papillary
- \*  Solid
- \*  Other (specify: )

**Nuclear Grade (Note F)**

- Grade I (low)
- Grade II (intermediate)
- Grade III (high)

**Necrosis (Note G)**

- Not identified
- Present, focal (small foci or single cell necrosis)
- Present, central (expansive "comedo" necrosis)

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Margins (select all that apply) (Note H)**

- Margins cannot be assessed
- Margin(s) uninvolved by DCIS
  - Distance from closest margin: \_\_\_ mm
  - \*Specify margins:
    - \*Distance from superior margin: \_\_\_ mm
    - \*Distance from inferior margin: \_\_\_ mm
    - \*Distance from medial margin: \_\_\_ mm
    - \*Distance from lateral margin: \_\_\_ mm
    - \*Distance from anterior margin: \_\_\_ mm
    - \*Distance from posterior margin: \_\_\_ mm
    - \*Distance from other specified margin: \_\_\_ mm
    - \*Designation of margin: \_\_\_\_\_
- Margin(s) positive for DCIS
  - \*Specify which margin(s) and extent of involvement:
    - \*  Superior margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive
    - \*  Inferior margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive
    - \*  Medial margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive
    - \*  Lateral margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive
    - \*  Anterior margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive
    - \*  Posterior margin
      - \*  Focal
      - \*  Minimal/moderate
      - \*  Extensive

**\*Treatment Effect: Response to Presurgical (Neoadjuvant) Therapy (Note I)**

- \*  No known presurgical therapy
- \*  No definite response to presurgical therapy
- \*  Probable or definite response to presurgical therapy

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Lymph Nodes (required only if lymph nodes are present in the specimen) (Note J)**

Number of sentinel nodes examined: \_\_\_\_\_

Total number of nodes examined (sentinel and nonsentinel): \_\_\_\_\_

Number of lymph nodes with macrometastases (&gt;0.2 cm): \_\_\_\_\_

Number of lymph nodes with micrometastases (&gt;0.2 mm to 0.2 cm and/or &gt;200 cells): \_\_\_\_\_

Number of lymph nodes with isolated tumor cells ( $\leq 0.2$  mm and  $\leq 200$  cells): \_\_\_\_\_

Size of largest metastatic deposit (if present): \_\_\_\_\_

*Note: The sentinel node is usually the first involved lymph node. In the unusual situation in which a sentinel node is not involved by metastatic carcinoma, but a nonsentinel node is involved, this information should be included in a note.*

\*Extranodal extension:

- \* \_\_\_\_\_ Present
- \* \_\_\_\_\_ Not identified
- \* \_\_\_\_\_ Indeterminate

\*Method of Evaluation of Sentinel Lymph Nodes (select all that apply)

- \* \_\_\_\_\_ Hematoxylin and eosin (H&E), 1 level
- \* \_\_\_\_\_ H&E, multiple levels
- \* \_\_\_\_\_ Immunohistochemistry
- \* \_\_\_\_\_ Sentinel lymph node biopsy not performed
- \* \_\_\_\_\_ Other (specify): \_\_\_\_\_

**Pathologic Staging (pTNM) (Note K)**TNM Descriptors (required only if applicable) (select all that apply)

- \_\_\_\_\_ r (recurrent)
- \_\_\_\_\_ y (post-treatment)

Primary Tumor (pT)

- \_\_\_\_\_ pTis (DCIS): Ductal carcinoma in situ
- \_\_\_\_\_ pTis (Paget): Paget disease of the nipple *not* associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma.

*Note: If there has been a prior core needle biopsy, the pathologic findings from the core, if available, should be incorporated in the T classification. If invasive carcinoma or microinvasion were present on the core, the protocol for invasive carcinomas of the breast<sup>1</sup> should be used and should incorporate this information.*

Regional Lymph Nodes (pN) (choose a category based on lymph nodes received with the specimen; immunohistochemistry and/or molecular studies are not required)

Note: If internal mammary lymph nodes, infraclavicular nodes, or supraclavicular lymph nodes are included in the specimen, consult the *AJCC Staging Manual* for additional lymph node categories.

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

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*Modifier (required only if applicable)*

\_\_\_ (sn) Only sentinel node(s) evaluated. If 6 or more sentinel nodes and/or nonsentinel nodes are removed, this modifier should not be used.

*Category (pN)*

\_\_\_ pNX: Regional lymph nodes cannot be assessed (eg, previously removed, or not removed for pathologic study)

\_\_\_ pN0: No regional lymph node metastasis identified histologically  
*Note:* Isolated tumor cell clusters (ITC) are defined as small clusters of cells not greater than 0.2 mm or single tumor cells, or a cluster of fewer than 200 cells in a single histologic cross-section.<sup>#</sup> ITCs may be detected by routine histology or by immunohistochemical (IHC) methods. Nodes containing only ITCs are excluded from the total positive node count for purposes of N classification but should be included in the total number of nodes evaluated.

\_\_\_ pN0 (i-): No regional lymph node metastases histologically, negative IHC

\_\_\_ pN0 (i+): Malignant cells in regional lymph node(s) no greater than 0.2 mm and no more than 200 cells (detected by H&E or IHC including ITC)

\_\_\_ pN0 (mol-): No regional lymph node metastases histologically, negative molecular findings (reverse transcriptase polymerase chain reaction [RT-PCR])

\_\_\_ pN0 (mol+): Positive molecular findings (RT-PCR), but no regional lymph node metastases detected by histology or IHC

\_\_\_ pN1mi: Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm).

\_\_\_ pN1a: Metastases in 1 to 3 axillary lymph nodes, at least 1 metastasis greater than 2.0 mm

\_\_\_ pN2a: Metastases in 4 to 9 axillary lymph nodes (at least 1 tumor deposit greater than 2.0 mm)

\_\_\_ pN3a: Metastases in 10 or more axillary lymph nodes (at least 1 tumor deposit greater than 2.0 mm)

<sup>#</sup> *Approximately 1000 tumor cells are contained in a 3-dimensional 0.2-mm cluster. Thus, if more than 200 individual tumor cells are identified as single dispersed tumor cells or as a nearly confluent elliptical or spherical focus in a single histologic section of a lymph node, there is a high probability that more than 1000 cells are present in the lymph node. In these situations, the node should be classified as containing a micrometastasis (pN1mi). Cells in different lymph node cross-sections or longitudinal sections or levels of the block are not added together; the 200 cells must be in a single node profile even if the node has been thinly sectioned into multiple slices. It is recognized that there is substantial overlap between the upper limit of the ITC and the lower limit of the micrometastasis categories due to inherent limitations in pathologic nodal evaluation and detection of minimal tumor burden in lymph nodes. Thus, the threshold of 200 cells in a single cross-section is a guideline to help pathologists distinguish between these 2 categories. The pathologist should use judgment regarding whether it is likely that the cluster of cells represents a true micrometastasis or is simply a small group of isolated tumor cells.*

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.



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Distant Metastasis (M)

Not applicable

cM0(+): No clinical or radiographic evidence of distant metastasis, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow, or other nonregional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastasis

pM1: Distant detectable metastasis as determined by classic clinical and radiographic means and/or histologically proven larger than 0.2 mm

*Note: The presence of distant metastases in a case of DCIS would be very unusual. Additional sampling to identify invasive carcinoma in the breast or additional history to document a prior or synchronous invasive carcinoma is advised in the evaluation of such cases.*

**\*Additional Pathologic Findings (Note L)**

\*Specify: \_\_\_\_\_

**\*Ancillary Studies**

Estrogen Receptor (results of special studies performed on this specimen or a prior core needle biopsy) **(Note M)**

- \*  Immunoreactive tumor cells present
- \*  No immunoreactive tumor cells present
- \*  Pending
- \*  Not performed
- \*  Other (specify): \_\_\_\_\_

\*Name of antibody: \_\_\_\_\_

\*Name of vendor: \_\_\_\_\_

\*Type of fixative: \_\_\_\_\_

Progesterone Receptor (results of special studies performed on this specimen or a prior core needle biopsy) **(Note M)**

- \*  Immunoreactive tumor cells present
- \*  No immunoreactive tumor cells present
- \*  Pending
- \*  Not performed
- \*  Other (specify): \_\_\_\_\_

\*Name of antibody: \_\_\_\_\_

\*Name of vendor: \_\_\_\_\_

\*Type of fixative: \_\_\_\_\_

**\*Microcalcifications (select all that apply) (Note N)**

- \*  Not identified
- \*  Present in DCIS
- \*  Present in non-neoplastic tissue
- \*  Present in both DCIS and non-neoplastic tissue

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**\*Clinical History (select all that apply) (Note O)**

The current clinical/radiologic breast findings for which this surgery is performed include:

- \*  Palpable mass
- \*  Radiologic finding
  - \*  Mass or architectural distortion
  - \*  Calcifications
  - \*  Other (specify): \_\_\_\_\_
- \*  Nipple discharge
- \*  Other (specify): \_\_\_\_\_
  
- \*  Prior history of breast cancer
  - \*Specify site, diagnosis, and prior treatment: \_\_\_\_\_
- \*  Prior neoadjuvant treatment for this diagnosis of DCIS
  - \*Specify type: \_\_\_\_\_

**\*Comment(s)**

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Surgical Pathology Cancer Case Summary (Checklist)**

Protocol web posting date: October 2009

**INVASIVE CARCINOMA OF THE BREAST: Complete Excision (Less Than Total Mastectomy, Including Specimens Designated Biopsy, Lumpectomy, Quadrantectomy, and Partial Mastectomy With or Without Axillary Contents) and Mastectomy (Total, Modified Radical, Radical With or Without Axillary Contents)**

Select a single response unless otherwise indicated.

**Specimen (Note A)**

- Partial breast
- Total breast (including nipple and skin)
- Other (specify): \_\_\_\_\_
- Not specified

**Procedure (Note A)**

- Excision without wire-guided localization
- Excision with wire-guided localization
- Total mastectomy (including nipple and skin)
- Other (specify): \_\_\_\_\_
- Not specified

**Lymph Node Sampling (select all that apply) (Note B)**

- No lymph nodes present
  - Sentinel lymph node(s)
  - Axillary dissection (partial or complete dissection)
  - Lymph nodes present within the breast specimen (ie, intramammary lymph nodes)
  - Other lymph nodes (eg, supraclavicular or location not identified)
- Specify location, if provided: \_\_\_\_\_

**Specimen Integrity (Note C)**

- Single intact specimen (margins can be evaluated)
- Multiple designated specimens (eg, main excision and identified margins)
- Fragmented (margins cannot be evaluated with certainty)
- Other (specify): \_\_\_\_\_

**Specimen Size (for excisions less than total mastectomy) (Note C)**

- Greatest dimension: \_\_\_ cm
- \*Additional dimensions: \_\_\_ x \_\_\_ cm
- Cannot be determined

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Specimen Laterality**

- Right  
 Left  
 Not specified

**\*Tumor Site: Invasive Carcinoma (select all that apply) (Note D)**

- \*  Upper outer quadrant  
 \*  Lower outer quadrant  
 \*  Upper inner quadrant  
 \*  Lower inner quadrant  
 \*  Central  
 \*  Nipple  
 \* Position:  o'clock  
 \*  Other (specify): \_\_\_\_\_  
 \*  Not specified

**Tumor Size: Size of Largest Invasive Carcinoma (Note E)**

- Microinvasion only ( $\leq 0.1$  cm)  
 Greatest dimension of largest focus of invasion over 0.1 cm:  cm  
 \*Additional dimensions:  x  cm  
 No residual invasive carcinoma after presurgical (neoadjuvant) therapy  
 Cannot be determined (see Comment)

*Note: The size of the invasive carcinoma should take into consideration the gross findings correlated with the microscopic examination. In some cases, it may be helpful to use information about tumor size from imaging studies. If multiple foci of invasion are present, the size listed is the size of the largest contiguous area of invasion. The size of multiple invasive carcinomas should not be added together. The size does not include adjacent DCIS.*

*If there has been a prior core needle biopsy or incisional biopsy showing a larger area of invasion than in the excisional specimen, the largest dimension of the invasive carcinoma in the prior specimen should be used for T classification, if known.*

*If there has been prior treatment and no invasive carcinoma is present, the cancer is classified as Tis if there is residual DCIS and T0 if there is no remaining carcinoma.*

**Tumor Focality (Note F)**

- Single focus of invasive carcinoma  
 Multiple foci of invasive carcinoma  
 \*Number of foci: \_\_\_\_\_  
 \*Sizes of individual foci: \_\_\_\_\_  
 No residual invasive carcinoma after presurgical (neoadjuvant) therapy  
 Indeterminate

*Note: If there are multiple invasive carcinomas, size, grade, histologic type, and the results of studies for estrogen receptor (ER), progesterone receptor (PR), and HER2/neu should pertain to the largest invasive carcinoma. If smaller invasive carcinomas differ in any of these features, this information may be included in the "Comments" section.*

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Macroscopic and Microscopic Extent of Tumor (select all that apply) (Note G)**Skin

- Skin is not present
- Invasive carcinoma does not invade into the dermis or epidermis
- Invasive carcinoma directly invades into the dermis or epidermis without skin ulceration
- Invasive carcinoma directly invades into the dermis or epidermis with skin ulceration (classified as T4b)
- Satellite skin foci of invasive carcinoma are present (ie, not contiguous with the invasive carcinoma in the breast) (classified as T4b)

Nipple

- DCIS does not involve the nipple epidermis
- DCIS involves nipple epidermis (Paget disease of the nipple)

*Note: This finding does not change the T classification.*

Skeletal Muscle

- No skeletal muscle present
- Skeletal muscle is present and is free of carcinoma
- Carcinoma invades skeletal muscle
- Carcinoma invades into skeletal muscle and into the chest wall (classified as T4a)

*Note: Invasion into pectoralis muscle is not considered chest wall invasion, and cancers are not classified as T4a unless there is invasion deeper than this muscle.*

**Ductal Carcinoma In Situ (DCIS) (select all that apply) (Note G)**

- No DCIS is present
- DCIS is present
- Extensive intraductal component (EIC) negative
- EIC positive
- Only DCIS is present after presurgical (neoadjuvant) therapy

\*Size (Extent) of DCIS

\*Estimated size (extent) of DCIS (greatest dimension using gross and microscopic evaluation) is at least \_\_\_ cm

\*Additional dimensions: \_\_\_ x \_\_\_ cm

\*Number of blocks with DCIS: \_\_\_

\*Number of blocks examined: \_\_\_

*Note: The size (extent) of DCIS is an estimation of the volume of breast tissue occupied by DCIS. This information may be helpful for cases with a predominant component of DCIS (eg, DCIS with microinvasion) but may not be necessary for cases of EIC negative invasive carcinomas.*

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\*Architectural Patterns

- \*  Comedo
- \*  Paget disease (DCIS involving nipple skin)
- \*  Cribriform
- \*  Micropapillary
- \*  Papillary
- \*  Solid
- \*  Other (specify): \_\_\_\_\_

\*Nuclear Grade

- \*  Grade I (low)
- \*  Grade II (intermediate)
- \*  Grade III (high)

\*Necrosis

- \*  Not identified
- \*  Present, focal (small foci or single cell necrosis)
- \*  Present, central (expansive "comedo" necrosis)

**Lobular Carcinoma In Situ (LCIS)**

- Not identified
- Present

**Histologic Type of Invasive Carcinoma (Note H)**

- Ductal carcinoma in situ with microinvasion
- Lobular carcinoma in situ with microinvasion
- Ductal carcinoma in situ involving nipple skin (Paget disease) with microinvasion
- Invasive ductal carcinoma (no special type or not otherwise specified)
- Invasive lobular carcinoma
- Invasive carcinoma with ductal and lobular features ("mixed type carcinoma")
- Invasive mucinous carcinoma
- Invasive medullary carcinoma
- Invasive papillary carcinoma
- Invasive micropapillary carcinoma
- Invasive tubular carcinoma
- Invasive cribriform carcinoma
- Invasive carcinoma, type cannot be determined
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Other(s) (specify): \_\_\_\_\_

*Note: The histologic type corresponds to the largest area of invasion. If there are smaller foci of invasion of a different type, this information should be included under "Additional Pathologic Findings."*

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

**Histologic Grade: Nottingham Histologic Score (Note I)**Glandular (Acinar)/Tubular Differentiation

- Score 1: >75% of tumor area forming glandular/tubular structures
- Score 2: 10% to 75% of tumor area forming glandular/tubular structures
- Score 3: <10% of tumor area forming glandular/tubular structures
- Only microinvasion present (not graded)
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Score cannot be determined

Nuclear Pleomorphism

- Score 1: Nuclei small with little increase in size in comparison with normal breast epithelial cells, regular outlines, uniform nuclear chromatin, little variation in size
- Score 2: Cells larger than normal with open vesicular nuclei, visible nucleoli, and moderate variability in both size and shape
- Score 3: Vesicular nuclei, often with prominent nucleoli, exhibiting marked variation in size and shape, occasionally with very large and bizarre forms
- Only microinvasion present (not graded)
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Score cannot be determined

Mitotic Count

- Score 1 (see Table 2)
- Score 2 (see Table 2)
- Score 3 (see Table 2)
- Only microinvasion present (not graded)
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Score cannot be determined

\*Number of mitoses per 10 high-power fields: \_\_\_\_

\*Diameter of microscope field: \_\_\_\_ mm

Overall Grade

- Grade 1: scores of 3, 4, or 5
- Grade 2: scores of 6 or 7
- Grade 3: scores of 8 or 9
- Only microinvasion present (not graded)
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Score cannot be determined.

*Note: The grade corresponds to the largest area of invasion. If there are smaller foci of invasion of a different grade, this information should be included under "Additional Pathologic Findings."*

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**Margins (select all that apply) (Note J)**

\_\_\_ Margins cannot be assessed

\_\_\_ Margins uninvolved by invasive carcinoma

Distance from closest margin: \_\_\_ mm

\*Specify margins:

- \*Distance from superior margin: \_\_\_ mm
- \*Distance from inferior margin: \_\_\_ mm
- \*Distance from anterior margin: \_\_\_ mm
- \*Distance from posterior margin: \_\_\_ mm
- \*Distance from medial margin: \_\_\_ mm
- \*Distance from lateral margin: \_\_\_ mm
- \*Distance from other specified margin: \_\_\_ mm
- \*Designation of margin: \_\_\_\_\_

\_\_\_ Margins uninvolved by DCIS (if present)

Distance from closest margin: \_\_\_ mm

\*Specify margins:

- \*Distance from superior margin: \_\_\_ mm
- \*Distance from inferior margin: \_\_\_ mm
- \*Distance from anterior margin: \_\_\_ mm
- \*Distance from posterior margin: \_\_\_ mm
- \*Distance from medial margin: \_\_\_ mm
- \*Distance from lateral margin: \_\_\_ mm
- \*Distance from other specified margin: \_\_\_ mm
- \*Designation of margin: \_\_\_\_\_

\_\_\_ Margin(s) positive for invasive carcinoma

\*Specify margin(s): \_\_\_\_\_

\*Specify margin(s) and extent of involvement:

- \* \_\_\_ Superior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Inferior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Anterior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Posterior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive

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- \* \_\_\_ Medial margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Lateral margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive

\_\_\_ Margin(s) positive for DCIS

\*Specify margin(s): \_\_\_\_\_

\*Specify margin(s) and extent of involvement:

- \* \_\_\_ Superior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Inferior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Anterior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Posterior margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Medial margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive
- \* \_\_\_ Lateral margin
  - \* \_\_\_ Focal
  - \* \_\_\_ Minimal/moderate
  - \* \_\_\_ Extensive

**\*Treatment Effect: Response to Presurgical (Neoadjuvant) Therapy (Note K)**

**\*In the Breast**

- \* \_\_\_ No known presurgical therapy
- \* \_\_\_ No definite response to presurgical therapy in the invasive carcinoma
- \* \_\_\_ Probable or definite response to presurgical therapy in the invasive carcinoma
- \* \_\_\_ No residual invasive carcinoma is present in the breast after presurgical therapy

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

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**\*In the Lymph Nodes**

- \*  No known presurgical therapy
- \*  No lymph nodes removed
- \*  No definite response to presurgical therapy in metastatic carcinoma
- \*  Probable or definite response to presurgical therapy in metastatic carcinoma
- \*  No lymph node metastases. Fibrous scarring, possibly related to prior lymph node metastases with pathologic complete response
- \*  No lymph node metastases and no prominent fibrous scarring in the nodes

**\*Lymph-Vascular Invasion (Note L)**

- \*  Not identified
- \*  Present
- \*  Indeterminate

**\*Dermal Lymph-Vascular Invasion**

- \*  No skin present
- \*  Not identified
- \*  Present
- \*  Indeterminate

**Lymph Nodes (required only if lymph nodes are present in the specimen) (Note B)**

- Number of sentinel lymph nodes examined: \_\_\_\_
- Total number of lymph nodes examined (sentinel and nonsentinel): \_\_\_\_
- Number of lymph nodes with macrometastases (>0.2 cm): \_\_\_\_
- Number of lymph nodes with micrometastases (>0.2 mm to 0.2 cm and/or >200 cells): \_\_\_\_
- Number of lymph nodes with isolated tumor cells (≤0.2 mm and ≤200 cells): \_\_\_\_
- Size of largest metastatic deposit (if present): \_\_\_\_

*Note: The sentinel node is usually the first involved lymph node. In the unusual situation in which a sentinel node is not involved by metastatic carcinoma, but a nonsentinel node is involved, this information should be included in a note.*

**\*Extranodal Extension**

- \*  Present
- \*  Not identified
- \*  Indeterminate

**\*Method of Evaluation of Sentinel Lymph Nodes (select all that apply)**

- \*  Hematoxylin and eosin (H&E), one level
- \*  H&E, multiple levels
- \*  Immunohistochemistry
- \*  Sentinel lymph node biopsy not performed
- \*  Other (specify): \_\_\_\_\_

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**Pathologic Staging (based on information available to the pathologist) (pTNM)  
(Note M)**TNM Descriptors (required only if applicable) (select all that apply)

- m (multiple foci of invasive carcinoma)  
 r (recurrent)  
 y (posttreatment)

Primary Tumor (Invasive Carcinoma) (pT)

- pTX: Primary tumor cannot be assessed  
 pT0: No evidence of primary tumor<sup>#</sup>  
 pTis (DCIS): Ductal carcinoma in situ<sup>#</sup>  
 pTis (LCIS): Lobular carcinoma in situ<sup>#</sup>  
 pTis (Paget): Paget disease of the nipple *not* associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma<sup>#</sup>  
pT1: Tumor ≤20 mm in greatest dimension  
 pT1mi: Tumor ≤1 mm in greatest dimension (microinvasion)  
 pT1a: Tumor >1 mm but ≤5 mm in greatest dimension  
 pT1b: Tumor >5 mm but ≤10 mm in greatest dimension  
 pT1c: Tumor >10 mm but ≤20 mm in greatest dimension  
 pT2: Tumor >20 mm but ≤50 mm in greatest dimension  
 pT3: Tumor >50 mm in greatest dimension  
pT4: Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules). *Note:* Invasion of the dermis alone does not qualify as pT4.  
 pT4a: Extension to chest wall, not including only pectoralis muscle adherence/invasion  
 pT4b: Ulceration and/or ipsilateral satellite nodules and/or edema (including peau d'orange) of the skin which do not meet the criteria for inflammatory carcinoma  
 pT4c: Both T4a and T4b  
 pT4d: Inflammatory carcinoma<sup>\*\*</sup>

<sup>#</sup> For the purposes of this checklist, these categories should only be used in the setting of preoperative (neoadjuvant) therapy for which a previously diagnosed invasive carcinoma is no longer present after treatment.

<sup>\*\*</sup> Inflammatory carcinoma is a clinical-pathologic entity characterized by diffuse erythema and edema (peau d'orange) involving one-third or more of the skin of the breast. The skin changes are due to lymphedema caused by tumor emboli within dermal lymphatics, which may or may not be obvious in a small skin biopsy. However, a tissue diagnosis is still necessary to demonstrate an invasive carcinoma in the underlying breast parenchyma or at least in the dermal lymphatics, as well as to determine biological markers, such as ER, PR, and HER2 status. Tumor emboli in dermal lymphatics without the clinical skin changes described above do not qualify as inflammatory carcinoma. Locally advanced breast cancers directly invading the dermis or ulcerating the skin without the clinical skin changes and tumor emboli in dermal lymphatics also do not qualify as inflammatory carcinoma. Thus the term inflammatory carcinoma should not be applied to neglected locally advanced cancer of the breast presenting late in the course of a patient's disease. The rare case that exhibits all the features of inflammatory carcinoma, but in which skin changes involve less than one-third of the skin, should be classified by the size and extent of the underlying carcinoma.

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**Regional Lymph Nodes (pN)** (choose a category based on lymph nodes received with the specimen; immunohistochemistry and/or molecular studies are not required)

If internal mammary lymph nodes, infraclavicular nodes, or supraclavicular lymph nodes are included in the specimen, consult the *AJCC Cancer Staging Manual*<sup>1</sup> for additional lymph node categories.

**Modifier** (required only if applicable)

\_\_\_ (sn): Only sentinel node(s) evaluated. If 6 or more sentinel nodes and/or nonsentinel nodes are removed, this modifier should not be used.

**Category (pN)**

- \_\_\_ pNX: Regional lymph nodes cannot be assessed (eg, previously removed, or not removed for pathologic study)
- \_\_\_ pN0: No regional lymph node metastasis identified histologically  
*Note:* Isolated tumor cell (ITC) clusters are defined as small clusters of cells not greater than 0.2 mm or single tumor cells, or a cluster of fewer than 200 cells in a single histologic cross-section.<sup>#</sup> ITCs may be detected by routine histology or by immunohistochemical (IHC) methods. Nodes containing only ITCs are excluded from the total positive node count for purposes of N classification but should be included in the total number of nodes evaluated.
- \_\_\_ pN0 (i-): No regional lymph node metastases histologically, negative IHC
- \_\_\_ pN0 (i+): Malignant cells in regional lymph node(s) no greater than 0.2 mm and no more than 200 cells (detected by H&E or IHC including ITC)
- \_\_\_ pN0 (mol-): No regional lymph node metastases histologically, negative molecular findings (reverse transcriptase polymerase chain reaction [RT-PCR])
- \_\_\_ pN0 (mol+): Positive molecular findings (RT-PCR), but no regional lymph node metastases detected by histology or IHC
- \_\_\_ pN1mi: Micrometastases (greater than 0.2 mm and/or more than 200 cells, but none greater than 2.0 mm).
- \_\_\_ pN1a: Metastases in 1 to 3 axillary lymph nodes, at least 1 metastasis greater than 2.0 mm
- \_\_\_ pN2a: Metastases in 4 to 9 axillary lymph nodes (at least 1 tumor deposit greater than 2.0 mm)
- \_\_\_ pN3a: Metastases in 10 or more axillary lymph nodes (at least 1 tumor deposit greater than 2.0 mm)

<sup>#</sup> *Approximately 1000 tumor cells are contained in a 3-dimensional 0.2-mm cluster. Thus, if more than 200 individual tumor cells are identified as single dispersed tumor cells or as a nearly confluent elliptical or spherical focus in a single histologic section of a lymph node, there is a high probability that more than 1000 cells are present in the node. In these situations, the node should be classified as containing a micrometastasis (pN1mi). Cells in different lymph node cross-sections or longitudinal sections or levels of the block are not added together; the 200 cells must be in a single node profile even if the node has been thinly sectioned into multiple slices. It is recognized that there is substantial overlap between the upper limit of the ITC and the lower limit of the micrometastasis categories because of inherent limitations in pathologic nodal evaluation and detection of minimal tumor burden in lymph nodes. Thus, the threshold of 200 cells in a single cross-section is a guideline to help pathologists distinguish between these 2 categories.*

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*The pathologist should use judgment regarding whether it is likely that the cluster of cells represents a true micrometastasis or is simply a small group of isolated tumor cells.*

**Distant Metastasis (M)**

- Not applicable
- cM0(+): No clinical or radiographic evidence of distant metastasis, but deposits of molecularly or microscopically detected tumor cells in circulating blood, bone marrow, or other nonregional nodal tissue that are  $\leq 0.2$  mm in a patient without symptoms or signs of metastasis
- pM1: Distant detectable metastasis as determined by classic clinical and radiographic means and/or histologically proven  $>0.2$  mm

**\*Additional Pathologic Findings (Note N)**

\*Specify: \_\_\_\_\_

**Ancillary Studies (Note O)**

**Estrogen Receptor** (immunohistochemical results on invasive carcinoma performed on this specimen or a prior core needle biopsy or incisional biopsy)

- Performed on this specimen
- Performed on another specimen
  - \*Specify specimen (accession number): \_\_\_\_\_
- Pending
- Not performed
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Other (specify): \_\_\_\_\_

**Results:**

- Immunoreactive tumor cells present ( $\geq 1\%$ )
  - Quantitation: \_\_\_\_\_
- Less than 1% immunoreactive cells present
- No immunoreactive tumor cells present
- Results unknown
- Other (specify): \_\_\_\_\_

\*Antibody vendor and clone: \_\_\_\_\_

\*Type of fixative (if other than neutral buffered formalin): \_\_\_\_\_

**Progesterone Receptor** (immunohistochemical results for invasive carcinoma performed on this specimen or a prior core needle biopsy or incisional biopsy)

- Performed on this specimen
- Performed on another specimen
  - \*Specify specimen (accession number): \_\_\_\_\_
- Pending
- Not performed
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Other (specify): \_\_\_\_\_

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

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Results:

- Immunoreactive tumor cells present ( $\geq 1\%$ )  
    Quantitation: \_\_\_\_\_
- Less than 1% immunoreactive cells present
- No immunoreactive tumor cells present
- Results unknown
- Other (specify): \_\_\_\_\_

\*Antibody vendor and clone: \_\_\_\_\_

HER2/neu (results for invasive carcinoma performed on this specimen or a prior core needle biopsy or incisional biopsy)

*Immunoperoxidase Studies*

- Performed on this specimen
- Performed on another specimen  
    \*Specify specimen (accession number): \_\_\_\_\_
- Pending
- Not performed
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Other (specify): \_\_\_\_\_

Results:

- Negative (Score 0)
- Negative (Score 1+)
- Equivocal (Score 2+)
- Positive (Score 3+)
- Other  
    Specify: \_\_\_\_\_
- Results unknown

\*Antibody vendor and clone: \_\_\_\_\_

*Fluorescence In Situ Hybridization (FISH) for HER2/neu*

- Performed on this specimen
- Performed on another specimen  
    \*Specify specimen (accession number): \_\_\_\_\_
- Pending
- Not performed
- No residual invasive carcinoma after presurgical (neoadjuvant) therapy
- Other (specify): \_\_\_\_\_

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Results:

- Not amplified (HER2 gene copy <4.0 or ratio <1.8)
- Equivocal (HER2 gene copy 4.0 to 6.0 or ratio 1.8 to 2.2)
- Amplified (HER2 gene copy >6.0 or ratio >2.2)
  - \*Average number of HER2 gene copies per cell: \_\_\_\_
  - \*Average number of chromosome 17 per cell: \_\_\_\_
  - \*Ratio: \_\_\_\_
- Results unknown
- Other (specify): \_\_\_\_\_

\* Name of assay: \_\_\_\_\_

\*Other Ancillary Studies (results for invasive carcinoma performed on this specimen or a prior core needle biopsy or incisional biopsy)

- \*  Performed on this specimen
- \*  Performed on another specimen
  - \*Specify specimen (accession number): \_\_\_\_\_

\*Name of test: \_\_\_\_\_

\*Results: \_\_\_\_\_

**\*Microcalcifications (select all that apply) (Note P)**

- \*  Not identified
- \*  Present in DCIS
- \*  Present in invasive carcinoma
- \*  Present in non-neoplastic tissue
- \*  Present in both carcinoma and non-neoplastic tissue

**\*Clinical History (select all that apply) (Note Q)**

\*The current clinical/radiologic breast findings for which this surgery is performed include:

- \*  Palpable mass
- \*  Radiologic finding
  - \*  Mass or architectural distortion
  - \*  Calcifications
  - \*  Other (specify): \_\_\_\_\_
- \*  Nipple discharge
- \*  Other (specify): \_\_\_\_\_
- \*  Prior history of breast cancer
  - \*Specify site, diagnosis, and prior treatment: \_\_\_\_\_
- \*  Prior presurgical (neoadjuvant) therapy for this diagnosis of invasive carcinoma
  - \*Specify type: \_\_\_\_\_

**\*Comment(s)**

\* Data elements with asterisks are not required. However, these elements may be clinically important but are not yet validated or regularly used in patient management.

## Appendix D

Excel tables show the mapping between CAP breast cancer pathology checklists elements and Caisis Databases fields

NON INVASIVE CAP Checklist								
Label (CAP Page)	CAP Checklist		Required by pathologist	Mapped (yes/No)	Caisis DataDictionary			Comments
	Elements	Values			Table	Field	page #	
4	Specimen	Partial breast Total breast (including nipple and skin) Other (specify): Not specified	No					
4	Procedure	Excision without wire-guided localization Excision with wire-guided localization Total mastectomy Other (specify) Not specified	yes (choose any)	yes	Procedure	ProcName	158	
4	Lymph Node Sampling	No lymph nodes present Sentinel lymph node(s) Axillary dissection Lymph nodes present within the breast specimen Other lymph nodes Specify location, if provided	yes (choose any)	no				
4	Specimen Integrity	Single intact specimen Multiple designated specimens Fragmented Other (specify)	yes (choose one)	no				
4	Specimen Size	Greatest dimension: ___ cm Cannot be determined Additional dimensions: ___ x ___ cm	yes	yes No	NodePathFinding	PathFindMaxDim	117	
4	Specimen Laterality	Right Left Not specified	yes (choose one)	yes	Procedure	ProcSide	158	
5	Tumor Site	Upper outer quadrant Lower outer quadrant Upper inner quadrant Lower inner quadrant Central Nipple Position Other (specify) Not specified	yes (choose any)	no				
5	Size (Extent) of DCIS	Estimated size at least Additional dimensions Number of blocks with DCIS Number of blocks examined	yes	yes No	BreastPath	PathExtentInSitu	13	
5	Histologic Type	Ductal carcinoma in situ, Classified as Tis (DCIS) or Tis (Paget)	yes	yes	Pathology	PathHistology	125	
5	Architectural Patterns	Comedo Paget disease Cribriform Micropapillary Papillary Solid Other (specify)	yes (choose any)	yes	PathologyFinding	PathFindHistology	126	
5	Nuclear Grade	Grade I (low) Grade II (intermediate) Grade III (high)	yes (choose any)	yes	BreastPath	PathNuclearGrade	13	
5	Necrosis	Not identified Present, focal (small foci or single cell necrosis) Present, central	yes (choose one)	yes	BreastPath	PathInSituNecrosis	13	
6	Margins	Margins cannot be assessed Margin(s) uninvolved by DCIS Distance from closest margin Distance from superior margin Distance from inferior margin Distance from medial margin Distance from lateral margin Distance from anterior margin Distance from posterior margin Distance from other specified margin Designation of margin <b>Margin(s) positive for DCIS</b> <b>Specify which margin(s) and extent of involvement</b> Superior margin Inferior margin Medial margin Lateral margin Anterior margin Posterior margin Focal Minimal/moderate Extensive	yes (choose any)	no				



6	Treatment Effect	No known presurgical therapy No definite response to presurgical therapy Probable or definite response to presurgical therapy	yes (choose one)	no				
7	Lymph Nodes	Number of sentinel nodes examined Total number of nodes examined (sentinel and nonsentinel) Number of lymph nodes with macrometastases Number of lymph nodes with micrometastases Number of lymph nodes with isolated tumor cells Size of largest metastatic deposit (if present) <b>Extranodal extension:</b> Present Not identified Indeterminate <b>Method of Evaluation of Sentinel Lymph Nodes:</b> Hematoxylin and eosin H&E, multiple levels Immunohistochemistry Sentinel lymph node biopsy not performed Other (specify)	yes (choose one)	no				
7	Pathologic Staging	<b>TNM Descriptors</b> r (recurrent) y (post-treatment) <b>Primary Tumor (pT)</b> pTis (DCIS) pTis (Paget)	yes (choose any)	yes	PathologyStageGrade	PathStageSystem	127	
8		<b>Regional Lymph Nodes (pN)</b> Modifier Only sentinel node(s) evaluated <b>Category (pN)</b> Regional lymph nodes cannot be assessed No regional lymph node metastasis identified histologically..... No regional lymph node metastases histologically, negative IHC Malignant cells in regional lymph node(s) No regional lymph node metastases histologically, negative molec Positive molecular findings (RT-PCR), but no regional lymph node Micrometastases Metastases in 1 to 3 axillary lymph nodes Metastases in 4 to 9 axillary lymph nodes Metastases in 10 or more axillary lymph nodes	yes (choose one)	yes	PathologyStageGrade	PathStageN	127	
9		<b>Distant Metastasis (M)</b> Not applicable Distant detectable metastasis No clinical or radiographic evidence of distant metastasis.....	yes (choose one)	yes	PathologyStageGrade	PathStageM	127	
9	Additional Pathologic Findings	Specify	yes	yes	PathologyFinding	PathFindNotes	126	
9	Ancillary Studies	<b>Estrogen Receptor</b> Immunoreactive tumor cells present No immunoreactive tumor cells present Pending Not performed Other (specify) <u>Name of antibody</u> <u>Name of vendor</u> <u>Type of fixative</u> <b>Progesterone Receptor</b> SAME AS PREVIOUS	yes (choose one)	yes	PathTest	PathTest	124	
9	Microcalcifications	Not identified Present in DCIS Present in non-neoplastic tissue Present in both DCIS and non-neoplastic tissue	yes (choose one)	yes	BreastPath	PathCalcifications	13	
10	Clinical History	Palpable mass Radiologic finding Mass or architectural distortion Calcifications Other (specify) Nipple discharge Prior history of breast cancer Specify site, diagnosis, and prior treatment Prior neoadjuvant treatment for this diagnosis of DCIS Specify type	yes (choose any or none)	no				
	Comment(s)		yes	yes	PathTest	PathNotes	124	

**INVASIVE (Additional Elements)**

5	Tumor Size: Size of Largest Invasive Carcinoma	Microinvasion >0.1 Greatest dimension of largest focus of invasion over 0.1 cm: ___ Additional dimensions: ___ x ___ cm No residual invasive carcinoma after presurgical (neoadjuvant) therapy Cannot be determined	yes	yes	BreastPath	PathTumorMaxDim	13	
5	Tumor Focality	Single focus of invasive carcinoma Multiple foci of invasive carcinoma Number of foci: (Got the count) Sizes of individual foci: No residual invasive carcinoma after presurgical (neoadjuvant) therapy Indeterminate	yes	yes	BreastPath	PathMultifocal	13	
6	Macroscopic and Microscopic Extent of Tumor	<b>Skin</b> Skin is not present Invasive carcinoma does not invade into the dermis or epidermis Invasive carcinoma directly invades into the dermis or epidermis Invasive carcinoma directly invades into the dermis or epidermis Satellite skin foci of invasive carcinoma are present <b>Nipple</b> DCIS does not involve the nipple epidermis DCIS involves nipple epidermis <b>Skeletal Muscle</b> No skeletal muscle present Skeletal muscle is present and is free of carcinoma Carcinoma invades skeletal muscle Carcinoma invades into skeletal muscle and into the chest wall	yes (choose any)	no				
6	Ductal Carcinoma In Situ (DCIS)	<b>No DCIS is present</b> <b>DCIS is present</b> Extensive intraductal component (EIC) negative EIC positive Only DCIS is present after presurgical (neoadjuvant) therapy	yes (choose one)	yes	BreastPathFinding	PathFindInsitu	14	
7	Lobular Carcinoma In Situ (LCIS)	Not identified Present	yes	no				

8	Histologic Grade: Nottingham Histologic Score	<b>Glandular (Acinar)/Tubular Differentiation</b> Score 1: >75% of tumor area forming glandular/tubular structures Score 2: 10% to 75% of tumor area forming glandular/tubular structures Score 3: <10% of tumor area forming glandular/tubular structures Only microinvasion present (not graded) No residual invasive carcinoma after presurgical (neoadjuvant) therapy Score cannot be determined	yes (choose one)	yes	BreastPath	PathTubForm	13		
		<b>Nuclear Pleomorphism</b> Score 1: Nuclei small with little increase in size in comparison with epithelial cells, regular outlines, uniform nuclear chromatin, little variation in size and shape Score 2: Cells larger than normal with open vesicular nuclei, visible moderate variability in both size and shape Score 3: Vesicular nuclei, often with prominent nucleoli, exhibiting in size and shape, occasionally with very large and bizarre forms Only microinvasion present (not graded) No residual invasive carcinoma after presurgical (neoadjuvant) therapy Score cannot be determined	yes (choose one)	yes	BreastPath	PathNucPleo	13		
		<b>Mitotic Count</b> Score 1 (see Table 2) Score 2 (see Table 2) Score 3 (see Table 2) Only microinvasion present (not graded) No residual invasive carcinoma after presurgical (neoadjuvant) therapy Score cannot be determined  *Number of mitoses per 10 high-power fields: ____ *Diameter of microscope field: ____ mm	yes (choose one)	yes	BreastPath	PathMitdx	13		
		<b>Overall Grade</b> Grade 1: scores of 3, 4, or 5 Grade 2: scores of 6 or 7 Grade 3: scores of 8 or 9 Only microinvasion present (not graded) No residual invasive carcinoma after presurgical (neoadjuvant) therapy Score cannot be determined	yes (choose one)	yes	PathologyFinding	PathFindGrade	126		
10 - 11	Treatment Effect: Response to Presurgical	<b>In the Breast</b> No known presurgical therapy No definite response to presurgical therapy in the invasive carcinoma Probable or definite response to presurgical therapy in the invasive carcinoma No residual invasive carcinoma is present in the breast after presurgical therapy  <b>In the Lymph Nodes</b> No known presurgical therapy No lymph nodes removed No definite response to presurgical therapy in metastatic carcinoma Probable or definite response to presurgical therapy in metastatic carcinoma No lymph node metastases. Fibrous scarring, possibly related to metastases with pathologic complete response No lymph node metastases and no prominent fibrous scarring in the lymph nodes	yes (choose one)	no					
11	*Lymph-Vascular Invasion	Not identified Present Indeterminate  <b>Dermal Lymph-Vascular Invasion</b> No skin present Not identified Present Indeterminate	yes (choose one)	yes	BiopsyPath	PathVascularInv	10		
15	Ancillary Studies	<b>HER2/neu</b> Immunoperoxidase Studies Performed on this specimen Performed on another specimen Specify specimen (accession number): Pending Not performed No residual invasive carcinoma after presurgical (neoadjuvant) therapy Other (specify):  Results: Negative (Score 0) Negative (Score 1+) Equivocal (Score 2+) Positive (Score 3+) Other Specify: Results unknown Antibody vendor and clone:	yes (choose one)	yes	PathTest	PathTest	124		
		Fluorescence In Situ Hybridization (FISH) for HER2/neu Performed on this specimen Performed on another specimen Specify specimen (accession number): Pending Not performed No residual invasive carcinoma after presurgical (neoadjuvant) therapy Other (specify):  Results: Not amplified (HER2 gene copy <4.0 or ratio <1.8) Equivocal (HER2 gene copy 4.0 to 6.0 or ratio 1.8 to 2.2) Amplified (HER2 gene copy >6.0 or ratio >2.2) Average number of HER2 gene copies per cell: Average number of chromosome 17 per cell: Ratio: Results unknown Other (specify) Name of assay	yes (choose one)	yes	PathTest	PathTest	124		
		Other Ancillary Studies (results for invasive carcinoma performed prior core needle biopsy or incisional biopsy) Performed on this specimen Performed on another specimen Specify specimen (accession number): Name of test: Results:	yes (low Priority)	no					
			yes	yes	PathTest	PathResult	124		
			yes	no					
			yes	yes	PathTest	PathResult	124		
			yes	no					
<b>Color Scheme</b>									
		Elements that could not be mapped							
		Elements that may have more than one value							

## Appendix E

### Screenshots for In Situ Breast Carcinoma – eforms checklists implemented in the Caisis platform

The screenshot displays the 'In Situ Breast Carcinoma- Checklist' form in the Caisis platform. The left sidebar shows the 'Enter Data test5' menu with 'Specimen' selected. The main content area is divided into sections: 'Procedure', 'Lymph Node Sampling', 'Specimen Integrity', and 'Specimen Size'. Each section contains a table with an 'Add Row' button. The 'Specimen Size' section includes input fields for 'Greatest Dimension (cm)', 'Additional Dimensions (\_ x \_ cm)', and a checkbox for 'Cannot be determined'.

The screenshot displays the 'In Situ Breast Carcinoma- Checklist' form in the Caisis platform. The left sidebar shows the 'Enter Data test5' menu with 'Tumor' selected. The main content area is divided into sections: 'Tumor Site' and 'Tumor Size'. The 'Tumor Site' section contains a dropdown menu and an 'Add Row' button. The 'Tumor Size' section includes input fields for 'Estimated size at least', 'Additional dimensions (\_ x \_ cm)', 'Number of blocks with DCIS', and 'Number of blocks examined'.

test5 55 DOB: [dropdown] Find A Patient [dropdown] by Last Name or MRN [input] [search] Help Log Out (s) Disease View: All [dropdown]

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE [dropdown]

Browse Eforms [dropdown] By Clinic My EForms By Patient Current User [dropdown] Lock System / Change U [dropdown]

Enter Data test5

- Specimen
- Tumor
- Histology**
  - Histologic Type
  - Architectural Patterns
  - Nuclear Grade
  - Necrosis
  - Microcalcifications
- Margins
- Presurgical
- Lymph Nodes
- Pathologic Staging
- Ancillary Studies
- Clinical History

HIDE PAGES [dropdown]

### In Situ Breast Carcinoma- Checklist

Enter Data [button] Review for Approval [button]

**Histologic Type**

[input] [dropdown] [x]

**Architectural Patterns**

[input] [dropdown] [x]

Add Row [button]

**Nuclear Grade**

[input] [dropdown] [x]

Add Row [button]

**Necrosis**

[input] [dropdown] [x]

Add Row [button]

test5 55 DOB: [dropdown] Find A Patient [dropdown] by Last Name or MRN [input] [search] Help Log Out (s) Disease View: All [dropdown]

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE [dropdown]

Browse Eforms [dropdown] By Clinic My EForms By Patient Current User [dropdown] Lock System / Change U [dropdown]

Enter Data test5

- Specimen
- Tumor
- Histology
- Margins**
  - Margins
- Presurgical
- Lymph Nodes
- Pathologic Staging
- Ancillary Studies
- Clinical History

HIDE PAGES [dropdown]

### In Situ Breast Carcinoma- Checklist

Enter Data [button] Review for Approval [button]

**Margins**

[input] [dropdown] [x]

Distance from closest margin (mm): [input]

Specify closest margin:

Distance from superior margin: [input]

Distance from inferior margin: [input]

Distance from medial margin: [input]

Distance from lateral margin: [input]

Distance from anterior margin: [input]

Distance from posterior margin: [input]

Distance from other specified margin: [input]

[view xml](#)

test5 55 DOB: [dropdown] Find A Patient [dropdown] by Last Name or MRN [search] Help Log Out (s) Disease View: All [dropdown]

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE [dropdown]

Browse EForms [dropdown] By Clinic My EForms By Patient Current User [dropdown] Lock System / Change U

Enter Data test5

Specimen

Tumor

Histology

Margins

**Presurgical**

Treatment Effect

Lymph Nodes

Pathologic Staging

Ancillary Studies

Clinical History

view xml

### In Situ Breast Carcinoma- Checklist

Enter Data Review for Approval [dropdown]

#### Treatment Effect

[input] ...

Add Row

test5 55 DOB: [dropdown] Find A Patient [dropdown] by Last Name or MRN [search] Help Log Out (s) Disease View: All [dropdown]

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE [dropdown]

Browse EForms [dropdown] By Clinic My EForms By Patient Current User [dropdown] Lock System / Change U

Enter Data test5

Specimen

Tumor

Histology

Margins

Presurgical

**Lymph Nodes**

Lymph Nodes

Pathologic Staging

Ancillary Studies

Clinical History

view xml

### In Situ Breast Carcinoma- Checklist

Enter Data Review for Approval [dropdown]

#### Lymph Nodes

Number of sentinel nodes examined: [input]

Total number of nodes examined (sentinel and nonsentinel): [input]

Number of lymph nodes with macrometastases (>0.2 cm): [input]

Number of lymph nodes with micrometastases (>0.2 mm to 0.2 cm and/or ≥200 cells): [input]

Number of lymph nodes with isolated tumor cells (<0.2 mm and ≤200 cells): [input]

Size of largest metastatic deposit (if present): [input]

Extranodal extension:

[input] ...

Add Row

Method of Evaluation of Sentinel Lymph Nodes

[input] ...

Add Row

test5 55 DOB: Find A Patient by Last Name or MRN Help Log Out Disease View: All

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE

Browse EForms By Clinic My EForms By Patient Current User Lock System / Change U

Enter Data test5

Specimen

Tumor

Histology

Margins

Presurgical

Lymph Nodes

**Pathologic Staging**

Staging

Ancillary Studies

Clinical History

view.xml

### In Situ Breast Carcinoma- Checklist

Enter Data Review for Approval

**Staging**

**TNM Descriptors**

Add Row

**Primary Tumor (pT)**

Add Row

**Regional Lymph Nodes (pN)**

**Modifier**  Only sentinel node(s) evaluated. If 6 or more nodes (sentinel or nonsentinel) are removed, this modifier should not be used.

**Category (pN)**

Add Row

**Distant Metastasis (pM)**

Add Row

test5 55 DOB: Find A Patient by Last Name or MRN Help Log Out Disease View: All

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE

Browse EForms By Clinic My EForms By Patient Current User Lock System / Change U

Enter Data test5

Specimen

Tumor

Histology

Margins

Presurgical

Lymph Nodes

Pathologic Staging

**Ancillary Studies**

Ancillary Studies

Clinical History

view.xml

### In Situ Breast Carcinoma- Checklist

Enter Data Review for Approval

**Ancillary Studies**

Test	Result	Name of antibody	Name of vendor	Name of fixative

Add Row

test5 55 DOB: Find A Patient by Last Name or MRN Help Log Out (a) Disease View: All

PATIENT LISTS PATIENT DATA FORMS EFORMS DATA ANALYSIS MORE

Browse Eforms By Clinic My EForms By Patient Current User Lock System / Change U

Enter Data test5

- Specimen
- Tumor
- Histology
- Margins
- Presurgical
- Lymph Nodes
- Pathologic Staging
- Ancillary Studies
- Clinical History**  
Clinical History

[view xml](#)

### In Situ Breast Carcinoma- Checklist

Enter Data Review for Approval

#### Clinical History

The current clinical/radiologic breast findings for which this surgery is performed include:

Add Row

## Appendix F

The Gantt Charts used to illustrate the internship work and develop a plan and timeline for each task.

