Demonstrating the Feasibility of Statistical Process Control Charts as a Surveillance and Decision Tool for Breast Screening Utilizing Open Source Solutions

by

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Abstract

Healthcare organizations typically suffer from the Data Rich, Information Poor (DRIP) syndrome, which has a direct impact on the ability of organizations to monitor processes which is the basis of surveillance activities. The objectives of this research were to demonstrate the feasibility of Statistical Process Control Charts (SPC) as a surveillance and decision tool, and to identify a data collection framework that satisfies the key quality factors of completeness, accuracy, comparability, usability and timeliness criteria. SPC charts were developed and customized using Open Source Software (OSS). A survey was developed and executed to identify breast pathologists' familiarity with synoptic reporting elements and their reporting habits. Results showed that SPC charts successfully identified developing trends in monitored processes and correctly isolated special causes from common causes. Perl was identified as an OSS solution for parsing templated pathology reports to populate the relational database. The R language for statistical computing provided an OSS solution for implementing SPC charts. Pathologists' responses did not correspond with respect to their ratings of reporting elements.

List of Abbreviations Used

SPC	Statistical Process Control
DRIP	Data Rich Information Poor
NSBSP	Nova Scotia Breast Screening Program
QEII	Queen Elizabeth II Health Sciences Centre
OSS	Open Source Systems
GPL	General Public License
CAP	College of American Pathologists
KSU	King Saud University
UCL	Upper Control Limit
LCL	Lower Control Limit
SR	Specific Range
LS	Length of Stay
KPI	Key Performance Indicators
CDHA	Capital Health Authority
ODBC	Open Database Connectivity
RODBC	R Open Database Connectivity

Acknowledgements

Chapter 1   Introduction

Healthcare organizations have amassed an abundant amount of data, collected through varying processes over the years. Unfortunately the amount of information which is extracted from the collected data to support effective surveillance tools is often limited, therefore making development of effective surveillance tools difficult or impossible to implement. This condition is identified as the Data Rich, Information Poor (DRIP) syndrome (1).

Pathology is one of the fundamental components of data collection for breast cancer diagnostic procedures. Collected data are being used by breast screening programs at national and international levels for reporting and performance surveillance.   Current breast cancer pathology data collection practices generally do not fully satisfy the evaluation criteria for pathology clinical reporting. This lack of both breadth and depth in data collection has an impact on the ability to act on the data collected by both clinicians, through clear communication of pathology results, and by program managers, who seek to improve clinical and managerial processes by evaluating developing trends that reflect processes in breast cancer pathology reports. This deficit hampers the ability to measure performance associated with pathology reporting and related patient care. To monitor performance at clinical and managerial levels, surveillance tools are required. Effective surveillance tools depend upon high quality information sources.

One solution to DRIP is health informatics technologies to ensure high quality data collection that facilitate reliable information production. Typically, quality factors are

used to ensure optimal and effective use of data for performance improvement and surveillance purposes (2).

In the field of pathology reporting, Srigley and colleagues managed to identified four important factors that determine the quality of pathology clinical reports: timeliness, accuracy, usability and completeness (2). Comparability is another factor that can be considered to avoid diversity among pathology reports (3,4,5). Considering this factor in addition to the four factors by Srigley will ensure that health care information based on breast pathology reports is optimal for all patients.

1.1 Research Question and Problem Statement

What is the feasibility of the application of Statistical Process Control charts as a decision tool at Nova Scotia Breast Screening Program (NSBSP) for monitoring breast-screening pathology reports and key performance indicators? What is a framework for data collection in pathology reporting that supports the use of SPC charts as a decision tool?

A real time surveillance tool at NSBSP Program is needed to assist clinicians and decision makers to monitor performance at managerial and clinical levels. Information flow within and between NSBSP and other clinical entities do not easily facilitate the systematic information flow required to support a timely surveillance tool. Pathology reports are one of the main sources of information at NSBSP. Currently the pathology reports for breast screening participants does not satisfy the quality factors for pathology reporting, due to the low reporting level based on synoptic scale (2). Furthermore, the current pathology reporting interface is not flexible and dynamic enough to meet the

requirement of pathologists for a user-friendly interface. Every pathologist has his/her own reporting template due to unavailability of standard reporting template. The results of the drawbacks previously mentioned have a direct effect on the collected data and decision-making mechanisms. Data repositories contain data in a non-usable form and decisions based on trends are made in an ad-hoc fashion without following any systematic approach.

1.2 Research Area

Interdisciplinary research is defined as the conceptualization of solutions from two or more research areas (6). As such, this thesis is interdisciplinary, encompassing research areas that include:

    a. Health Informatics (Public Health Informatics)

According to Wyatt and colleagues health informatics is "The study and application of methods to improve the management of *patient data, medical knowledge,* population data and other *information* relevant to patient care and community health" (7). Health informatics domain consists of four branches; public health informatics, bioinformatics, clinical informatics, and consumer health informatics (7). The focus of this thesis is public health informatics, which is defined as "The use of *medical informatics* methods to promote public health practice, research, and learning, using an interdisciplinary approach, including the public health sciences, for example, epidemiology and health services research, and the information sciences, for example, computing science and

technology" (7). Public health informatics includes many sub-domains. In this research the focus will be on two sub-domains, Biostatistics and Epidemiology.

Biostatistics defined as "The field involves the development and application of statistical methods to scientific research in areas such as medicine, epidemiology, environmental health, genetics, and ecology." (8). The researcher considered biostatistics principles when developing and customizing the surveillance decision tool.

Epidemiology is a branch of public health science that plays a major role in public health informatics research field (7). According to the World Health Organization epidemiology is "the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems." (9). The researcher used epidemiology to identify and define valid and reliable key performance indicators that are recognized by local users and literature for performance comparison.

> b. Medicine (Pathology)

Pathology is "the branch of medicine that deals with the laboratory examination of samples of body tissue for diagnostic" (10). The researcher particularly focused on pathology reporting standards to drive information flow solution.

1.3 Purpose and Objectives

The purpose of this research was to develop a new framework for the collection of breast cancer pathology data for transfer of relevant data to the NSBSP for incorporation into

surveillance tool to monitor developing trends in key performance indicators at NSBSP and pathology reports. The specific objectives of this research were:

a.   To identify decision makers' needs, that will assist in the establishment of a surveillance decision tool for the early detection of developing trends in breast-screening pathology reports and key performance indicators,

b.   To map the current flow of pathology information to the NSBSP,

c.   To identify the impact of the drawbacks of these reporting protocols on the data quality and information management,

d.   To suggest a new reporting framework/solution that overcomes the identified drawbacks in the current pathology reporting protocols that feed data to the NSBSP.

1.4 Approach (SSS)

The research steps that were taken to approach these objectives are based upon a three-phases:

a.   **S**ynoptic Pathology Reporting: identify the current reporting level at the pathology lab and to identify how familiar pathologists are with synoptic standards that are currently recommended and recognized by certified Boards such as the College of American Pathologists (CAP), and

b. **S**emantic Interoperability and Openness: suggest a solution that achieves a high level of interoperability between the involved systems and considers an open-source solution that factors in the financial resource constraints that exist, and

c. **S**urveillance and Knowledge Discovery: demonstrate the utility of having a surveillance tool to assist decision makers.

1.5 Challenges and Assumption

The major challenges to this research are expected to be related to users' degree of acceptance of the new tool, which can be identified by demonstrating the tool's abilities based on historical events. Users were identified as front users such as pathologists, radiologists, data entry clerks and managers at NSBSP. The degree of engagement by the clinicians in cooperation with the research is a challenge, as the stakeholders are highly engrossed with their daily tasks and finding time to provide feedback on a regular basis may be difficult. In addition, legacy systems and practices might impose financial and political resistance due to additional resource requirements and to the behavioral change required. However, it is assumed that the feasibility demonstration of the surveillance tool will motivate clinicians and decision makers to consider using the proposed solution in future system updates.

Chapter 2   Background

2.1 Surveillance and Knowledge Discovery

Knowledge Discovery is "the nontrivial extraction of implicit, previously unknown, and potentially useful information from data" (11). Surveillance in its general form is defined as "ongoing systematic collection, analysis, and interpretation of health-related data for use in planning, implementing, and evaluating public health practice" (12). Both knowledge discovery and surveillance require good sources of information to achieve their goals. Within the framework of public health informatics, information sources must meet three quality factors: reliability, accuracy and timeliness (13). To ensure high efficiency of the results from surveillance process, data collected from information sources is expected to transition through three states: data, information and knowledge. Progression through these states can be achieved by applying specific processes and analysis that are determined by users. Data are necessary but not sufficient for surveillance and knowledge discovery. In addition, data contain rich information but cannot be used until processed. The main focus at the first phase is to transform data into information based on rules determined by decision makers. The second phase focuses on applying rules that compare the resulting information to experts' insight to generate knowledge (13).

The implementation of decision tools in a public health surveillance framework helps healthcare organizations to measure and analyze the process in order to improve the quality and delivery of care. Improvement initiatives require change in processes. To ensure the success of the intervention, it is important to measure and monitor the

processes in real time fashion. It is common among decision makers to arrive at false conclusions because they compare numerical values, rather than processed information, of current versus past performance measures that can often lead them to false or invalid decisions (14). This can be avoided if the context behind the numerical values is appropriately understood and analyzed.

2.1.1 Statistical Process Control (SPC)

Statistical Process Control utilizes graphical charts and statistical concepts to identify the variation in pre-identified processes (15,16). Processes are monitored to ensure that performance is under control and outcomes are meeting acceptable standard. SPC provides its users with ability to monitor developing trends that indicate positive or negative change in stable processes (15). This statistical tool was invented in the early twentieth century by Walter A. Shewhart (17).

As part of any process it is natural to have fluctuating outcomes that vary due to different causes. However, the variation should be kept within acceptable limits while considering continuous improvement to avoid undesirable results. The outcomes associated with processes are subject to the laws of probability theory. Many processes can be explained by the Gaussian curve (15). The middle point of the Gaussian curve represents the mean value of a selected sample, which can be calculated based on the history of the monitored process. Users are recommended to collect data over a period of 12-24 months of a continuous process and calculate the mean (16). For example, plus or minus 3 standard deviation on either side of the mean value can be used to determine the Upper Control

Limit (UCL) and the lower Control Limit (LCL). The range located between the limits represents the acceptable variation of the process, which is called the Specific Range (SR) (15).

Identifying the cause behind performance variation is the starting point for leaders to take action. It is essential to understand the main cause that led to the change to avoid it in the future and to keep it within the acceptable control limits (15). Two types of variation exist in every process: common and special causes. Common cause variation is a natural part of any process and usually does not require any intervention by decision makers. Special cause variation is associated with unique events that can lead to significant failure, which requires immediate correction (18). At NSBSP normal variation is the natural variability that could be caused by slight change in clinicians' performance scanning time, whereas special cause variation may be if a machine goes down unexpectedly for servicing reducing the capacity and leading to an increase in wait times.

2.1.2 Medical Applications of Statistical Process Control Charts

In the past, quality monitoring at healthcare organizations used to be achieved by statistical hypothesis testing, which can be done by applying multiple tests on collected data and identifying the differences in the results (16). This process is an onerous task for clinical decision makers, as it requires data collection to create samples for hypothesis

testing and does not reveal any developing trends at accumulated events (16). Although quality control has been regularly used in the engineering and food industries, it is a relatively new concept in healthcare. For many years quality monitoring techniques that are used for industrial purposes faced strong resistance by clinicians (15). The involvement of patient care was the barrier to introduce quality control concepts; clinicians claimed that the use of industrial concepts in patient care was inappropriate (15). However, due to increases in reported medical errors and undesired performance levels of clinicians and processes along information flow, decision makers in the healthcare industry have introduced quality monitoring concepts to their organizations but with few modifications to surveillance tools that have been used in other industries to become more suitable in the healthcare context (15).

Healthcare and industry have common standards to maintain quality of services they provide, these standards aim to reduce variability among the outcomes of any process (15). Decision makers and clinicians in health care organizations are doing their utmost to provide standard medical care with minimum variation possible among treated patients. The barrier to reach a consistent outcome is the high level of variability among inputs such as, patients conditions, clinicians work load, amount of available resources and type of medications (15). Consequently, a tool that considers variation in processes is needed to monitor performance in healthcare organizations.

A study by Mertens and colleagues to test the utility and feasibility of SPC was performed on admissions to Visiting Nurse Association and Hospice of Western New England; a total of 2126 of cancer admissions between 1996 and 2001 were tested (19).

Three objectives were identified for the study. Firstly, test the ability of SPC to monitor the changes in Length of Stay (LOS). Secondly, identify the special causes that affect LOS. Finally, to monitor the relationship between LOS and date of admission to hospice. LOS is a good indicator as it changes over time and the degree of variability is dependent on different factors. The study showed that SPC charts developed to monitor performance are effective tools to monitor variability over the time. Observations from this study are as follows:

a- LOS is associated with date of admission; however, the decrease is not constant.

b- The improvement (decrease) in LOS is associated with the degree of awareness about post-cancer care among patients and clinicians.

SPC charts demonstrated their efficiency as a monitoring tool and as an early alert system in industry. Unfortunately, they are still waiting for more widespread adoption in the healthcare environment (20). A study by Larsson and colleagues was performed to assess the utility of SPC as an early alert tool and to develop an out-of-control action plan based on information from SPC charts at a seniors' care institute and a continuing education organization in Sweden. Two indicators were selected for the study; number of episodes of illness per employee and self-evaluated health condition (20). The results showed that SPC is an effective and accurate tool that provides decision makers with facts based on the real situation in the organization to take corrective actions. Health outcomes at both organizations were significantly improved. Furthermore, SPC provided leaders with a timely monitoring tool. The clarity and simplicity of SPC have encouraged leaders to use the charts on daily bases. In addition, the ease of use was the driving engine to implement

new indicators that represent different dimensions at the organizations. Researchers noticed a high level of integration was achieved between indicators from two dimensions; work place and health status. This integration opened new attributes for leaders to improve performance in untraditional style at their organizations (20).

2.1.3 Considerations

Leaders and clinicians at healthcare organizations are required to consider the following while implementing and using SPC:

a- SPC is a tool that provides timely alerts only without providing any explanations about the causes that trigger the alarm. Leaders are expected to start immediate systematic investigations to identify the cause, normal or special, of the alarm. In addition, it is recommended to prepare an Out-of-Control Action Plan to be used as a guideline if the alarm is triggered. The plan is a framework that will assist leaders to identify the causes and what actions to be taken to correct the situation (20).

b- An SPC alert does not occur if all values of causes are within the UCL and LCL. Consequently, the charts will assume that all indicators are under complete control and all processes are performing as they should. This phenomena might deceive decision makers, as values close to the mean are representing the most controlled processes (15).

c- All values that represent different processes within UCL and LCL might discourage leaders from continuing to improve. It is recommended that attention be paid even to controlled processes, as SPC cannot be used as an effective tool to monitor small variations in overall performance. Leaders might find themselves dealing with an out-of-control process that did not draw the attention significantly (15).

2.2 Open-Source Software

Open-Source Software (OSS) refers to software that meets the requirements of the Open Source Initiative and Open Source Definition (21). There is a common and inaccurate understanding of OSS that limits the definition to the accessibility to software's source code to perform adaptations. According to Lauri and Salmivalli OSS is more than that. They stated that "The licensing terms do more: they allow the free use, redistribution and modification of the software. The copyright owner holds the moral rights and some economic rights to the software, but transfers many important rights to the users and developers of the software, in order to enable the development of the software and to increase its adoption" (21). In the following sections the benefits, drawbacks and the application in healthcare of OSS will be discussed in detail.

2.2.1 Adoption of Open Source Software

The adoption of OSS is a controversial issue that splits the software community into two groups (22,23). A study by Lorraine and Morgan identified the impact of drawbacks and

benefits of OSS on the adoption rate in 13 organizations (23). This study was the first study to focus on the drawbacks and benefits of adoption of policies of OSS in European software firms (23). The study itemized a list of drawbacks and benefits under two categories; business perspectives such as cost, flexibility and collaboration and technology perspectives such as security, compatibility and ease of use. As mentioned before the adoption of OSS is controversial and there are many benefits that will increase the adoption rate among organizations. On the other hand the drawbacks could decrease the adoption rate among organizations according to their objectives and goals (23).

2.2.2 Open-Source Software Applications in Healthcare Field

The current information systems at healthcare organization are legacy systems that were built and designed to serve an independent specific purpose inside each entity of the healthcare organization (21). This isolated state of each information system with the absolute control of the developers are now the main barriers toward fully integrated health information systems within an institution, much less nationally or internationally. Healthcare organizations would benefit from considering OSS in their future plans due to the ability to save resources and to integrate systems within an institution (21).

There are other advantages that could benefit the healthcare industry. Firstly, the source codes that are used to design the software are freely available for developers. Consequently, users in medical organizations can customize the code according to their needs and the standard they follow (24). Furthermore, the availability of the software's

source code enables health care stakeholders to promote standards among their peers (25). Secondly, OSS is affordable which means that organizations can redirect the funding to improve the hardware or any components of the information system. Finally, OSS is not vendor dependent, so the organization will not have to rely on a specific vendor for support and maintenance (24). In addition, health care systems hold sensitive information where security is a top priority of stakeholders. OSS will assist in maintaining security measures at high level by allowing healthcare providers to store information within the facility under their complete control and supervision. Provider continuity is an important factor that should be taken into consideration, which can be solved by adopting OSS due to the independency on a sole service provider (25). However, there are important factors that should be considered regarding the continuity of OSS such as the maturity of the system, the adoption rate among users and system lifespan in the market (26).

2.2.3 Caisis Open-Source Cancer Management System

Caisis is an open source web based data base management system under the licenses of General Public Licenses (GPL) (27,28). The first version of the software was developed in 1991 as a research data base management system for urologic oncology, through the years and due to the wide spread among medical community Caisis became an integrated clinical and research system (28). The clinical and research features provided by Caisis include but are not limited to the following (27,28):

a- Interface dedicated for patient clinical history,

b- Flexible tool to facilitate building data capture templates,

c- Dynamic protocol to build modules to update the system to include new diseases,

d- Pre-integrated modules such as specimen banking and project tracking,

e- Dynamic plug-in tools to add new features if needed, and

f- Compatibility with the US Health Insurance Portability and Accountability Act (HIPAA) standards for the security of electronic health information systems

Some clinical research data repositories suffer from a high level of fragmentation, where there is a dedicated independent repository for each disease in medical organizations. This phenomenon has created barriers for collaboration among researchers. In addition, many of the repositories lack adequate documentation pertaining to data definitions and dictionaries. On the other hand, the main idea behind building the system was to design a system that receives data from multiple sources that represent multiple diseases in medical organizations. Caisis provides an organized data set in temporal fashion that can be used for different disease. It also provides dynamic modules to update the disease list if needed. This flexibility and versatility has significantly decreased the learning curve for new researchers to learn interacting and searching the database (28).

The availability of transparent and direct communication channels among developers and medical communities has led to a significant improvement in Caisis over the recent years.

Every release of the software shows an improvement in security measures and new features are added based on users feedback (27). Caisis developers recommend performing pilot studies at local medical organizations and publishing the results among the medical communities (28). The unrestrained feedback and communication channels will keep the development cycle in a continuous state of improvement.

2.3 Cancer Pathology Reporting

Pathology reports are medical documents produced by pathologists after examining pathological tissues that can be obtained in three different ways: surgery, biopsy and endoscopic procedures. For cancer patients, cancer staging and diagnosis are primarily based on pathology reports (29).

2.3.1 Quality of Pathology Reports

The lack of the adoption of standard pathology reporting templates by pathologists and the tendency to create individualized templates has led to a high degree of variability between the reporting templates (30).

 A 2011 study by Verleye and colleagues was performed to evaluate ovarian cancer pathology reports and revealed incompleteness in the reports at eleven medical institutes (31). The study shows that 20.5% of the reports were missing the description of tumor origin, 7.7% were missing the microscopic description and 40.1% were missing the samples measurement and weight (31,32).

The process of cancer diagnosis is highly dependent on two types of medical documents: the pathology and operative reports (2). A study on in 2012 by Donahoe and colleagues showed a significant incompleteness in breast cancer operative reports. One hundred reports were examined to evaluate the completeness of reporting elements. The results show that 84% of the reports were missing major diagnosis reporting elements (33).

Pathology reports are interdisciplinary medical documents (32). Completeness is not the only quality factor that is needed to maintain high level of patient care. A wide range of stakeholders requires access to pathology report data. Clinicians require an easy and direct access to plan patient treatment. Researchers require access to evaluate services and develop solutions. Decision makers and managers are expected to perform systematic resource planning and performance monitoring to make decisions based on data that reflects the real situation at their organizations. Thus pathology reports are not isolated and built solely for pathologists; complete and well-structured reports are a necessity for stakeholders (32). The majority of evaluation studies focus on completeness as a factor to measure quality of pathology reports. In the following section recommended quality factors will be discussed in details.

2.3.2 Quality Factors for Pathology Reports

Pathology and cancer operative reports contain valuable information that plays a major role in the following areas (2):

a- Patient and care management: Pathology reports contain information and data elements that have a direct impact on patient management. Demographic

information, tumor measurements and diagnosis are examples of the essential information for patient management. Slight changes in reporting elements preferences such as terminal digit preferences might lead to unidentified errors by pathologists and decision makers (34).

b- Cancer trends monitoring: Pathology reports if collected and monitored using pre identified data elements, will facilitate monitoring developing trends at different dimensions such as time and place. Clinicians can identify irregularity in cancer incidents at specific locations.

c- Resource management: Monitoring trends associated with pathology wait times, patient wait times and locations will assist decision makers in evaluating and managing resources. Increased wait times might indicate a deficiency in equipment or number of clinicians at specific sites compared to others.

Pathology reports are vital medical documents for key information but this cannot be achieved without addressing certain evaluation criteria. Srigley and colleagues identified four essential factors that determine the quality of pathology reports: completeness, accuracy, timeliness and usability (2). These four factors by Srigley intersect with the data quality dimensions outlined by the Canadian Institute for Health Information, which include accuracy, timeliness, relevance, comparability and usability (4).

The literature indicates that pathology reports suffer from incomplete reporting elements that lead to inaccurate and variable cancer diagnosis (31,32). The World Health Organization in South East Asia Region (WHO-SEARO) identified a list of factors that

help ensure the completeness of medical document (35). The following subset are the focus of this research:

a- Meaningful information,

b- Avoid duplicates,

c- Avoid abbreviations,

d- Permanent information, and

e- Detailed and comprehensive, but well structured and standardized.

Three completeness dimensions were identified by Pipino and colleagues: schema completeness, population completeness and column completeness (36). The focus in this research is on schema completeness defined as "the degree to which entities and attributes are not missing from the schema" (36).

Managers and decision makers require access to pathology reports to retrieve data elements that assist them in making decisions. Accuracy of information is used to describe how precisely the available information reflects the real situation (37). Decisions should be made based on truthful and accurate information that reflects the real situation at the medical organization.

Pathology reports are interdisciplinary medical documents (32) where all stakeholders require easy access to the reports. The factor 'usability' refers to the ability to access and

use the data on the reports. The ability to produce information by processing data is highly dependent on data's format. Surveillance tools used by decision makers, cancer registries and researchers require data sources in usable form that can be analyzed and interpreted (2).

The factor 'timeliness' refers to the ability to gather data from their sources to produce processed dependable information in rapid and timely fashion (38). It is unfortunate that government agencies have to wait for annual reports to evaluate the performance at cancer medical institutes. Decision makers need systems that reduce turnaround time to reach real time state.

The factor 'comparability' refers to the consistency among data elements and standards in a way that all data sources are comparable and similar (4). In addition to consistency accuracy is required to achieve comparability (3).

2.4 Synoptic Pathology Reporting

Advancements in health information technologies and applications have led to major positive changes in the field of medical reporting. These advancements have established a strong basis for a new pathology reporting system that overcomes all the obstacles to achieving high quality reports. According to Cancer Care Ontario, synoptic pathology reporting "uses an electronic report in discrete data field format (i.e., each type of information has a specific place and format in the report) that allows for the standardized collection, transmission, storage, retrieval and sharing of data between clinical information systems"(39). The synoptic report is based on the reporting elements in the

traditional reports, the main difference is how the report is structured and built. The synoptic format is a restructured traditional report in a form of discrete independent data fields that are used to build checklists and drop down menus (40). Due to the variability among pathology cases, synoptic reports designers have considered the inclusion of free text comment boxes to add additional comment by pathologists if needed (40).

2.4.1 Why Synoptic Reporting?

Evaluation studies were performed to evaluate the synoptic report in regards to the five quality factors (completeness, accuracy, usability, timeliness and comparability) and to address the issues with traditional reporting method (41,42). In the following sections, the advantages of synoptic reporting will be reviewed and how it meet the quality factors.

2.4.1.1 Completeness and Accuracy

A comparison between web-based reporting systems and traditional dictation systems by Chambers and colleagues were performed following the implementation of a the Alberta WebSMR system in Cancer Surgery Alberta. The results showed the abilities and features of the new system that replaced traditional dictation system, has elevated the data capture rate of colorectal cancer from 46% to 99% (40).

Furthermore, an evaluation study by Gur and colleagues compared 60 traditional breast cancer reports with computerized synoptic reports (42). The evaluation team has selected 36 data elements as comparison criteria. Results showed a significant gap between the

two reporting methods, where 94.7% of the synoptic reports were complete versus 66% of the traditional narrative reports (42).

The same study revealed that traditional reports suffer from redundancy and non-essential data that consume physicians' time during interpretation (42). There are no doubts about traditional reporting having more details compared to synoptic reporting, but the degree of essential information is questionable. Clinicians want clear and easy-to-read, yet comprehensive, reports with essential details that improve the quality of interpretation of the reports. This could be achieved by following the synoptic format that has a predetermined structure to lead the pathologist while filling the report (40,42).

2.4.1.2 Timeliness

Clinicians and decision makers demand that medical information be available within acceptable period of time. Synoptic reporting shows a significant reduction in retrieval time. The medical reports delivery process involves many different destinations, with the traditional reporting method requiring transcription which exceeds the acceptable time frame. Fortunately with synoptic reporting information, neither retrieval nor delivery is an issue. Clinicians at Cancer Surgery Alberta are able to complete the delivery process within a short period of time. As Chamber stated "At our institution, this process of distribution is achieved within 24 hours in 97% of patients" (40). In addition, data are much easier and faster to interpret compared to traditional reports with long paragraphs of free narrative text, as data are available in lists that have unique identifiable headers (2).

2.4.1.3 Usability

Pathology reports contain valuable data that benefit a wide range of stakeholders. Data can be considered useless unless they are analyzed to extract information that yield the necessary knowledge. The ability of processing data on medical reports is totally dependent on the ability to retrieve the data in a usable form that can be interpreted by surveillance tools and information systems. The synoptic format provides a solution to address these usability issues. As mentioned above, synoptic reports are composed of discrete independent data fields that are used to build checklists and drop down menus (40). The availability of discrete data fields offers a high level of versatility that serves different systems' standards and formats. Thus, knowledge discovery and translation can be performed in real-time fashion to assist decision makers (43).

2.4.1.4 Comparability

Pathology reports contain clinical data, which can be considered as a main source of data for diagnosis. The sensitivity of such data imposes a direct effect on the quality of healthcare provided to patients (44). One solution to this issue is using structured and standardized reporting method, which can be used to avoid diversity among pathology reports produced by different pathologists (3).

2.5 Levels of Reporting

The College of American Pathologists has defined six reporting levels to describe the reporting method at pathology laboratories (2). The levels of reporting will be used to evaluate the reporting method at Queen Elizabeth II Health Sciences Centre, Halifax,

Nova Scotia. This laboratory is the only lab that performs breast pathology exams across Capital Health District Authority (CDHA).

2.6 Nova Scotia Breast Screening Program and Queen Elizabeth II Health Sciences Centre

The Nova Scotia Breast Screening Program was established and funded by the Nova Scotia Department of Health in 1991. The main goal of the program is to reduce the mortality rate due to breast cancer in Nova Scotia women aged between 50 to 69 years by thirty percent. The program aimed to achieve better breast health in a period of ten years after establishing a screening program across the province (45). The program offers preventive health care to asymptomatic Nova Scotia women through regular breast screening and facilitates timely follow-ups for abnormal results. The program services are provided through 11 fixed sites across the province and three mobile units that reach the areas not covered by the fixed sites (46).

The Queen Elizabeth II Health Sciences Centre (QEII) has the largest pathology department in the province and contributes a substantial amount of breast tissue pathology data to the NSBSP.

Chapter 3 Research Approach

In this chapter the approach that was followed to answer the research question is discussed. As mentioned earlier, a real time surveillance tool at the NSBSP would assist clinicians and decision makers to monitor performance related to pathology at managerial and clinical levels. The researcher chose SPC charts as a potential surveillance tool for reasons that were discussed in Chapter two. A review of the literature reveals no prior work specifically targeted at evaluating the utility and feasibility of SPC charts for trend detection in breast cancer pathology. Through this research, we hope to see SPC charts adopted as decision tools by the NSBSP.

This research will involve several steps:

a. A review of current breast cancer pathology data collection practices at various DHA sites as well as suggestions for expansion of current data collection.

b. The development and demonstration of a surveillance tool to monitor developing trends in breast cancer pathology.

c. The identification of a solution to help improve the quality, timeliness and usability of pathology data flow from the hospital departments to the NSBSP.

The approach that was followed in this research was broken down into two main phases, with a major consideration being the interoperability between involved systems and software:

Phase I

This phase of the research involved consultation with breast pathology pathologists in CDHA to understand current practices for the capture of pathology data for breast diagnostic procedures.

Phase II

SPC charts were used to generate reports of pathology trends relating to wait times and nationally set performance indicators. Data extracted from the NSBSP was used to demonstrate the utility of SPC charts for the purposes of early trend identification.

3.1 Ethics

SPC were used to generate reports of pathology time trends related to both wait times and national breast screening performance indicators. The generation of the SPC charts required the use of aggregate data extracted from NSBSP. This approach was reviewed by the Research Ethics Board of the Capital District Health Authority of Nova Scotia (submission date of proposal 18 April 2012) and the proposal received a waiver on the grounds of quality assurance (waiver received 19 April 2012).

3.2 Statistical Process Control Plan

An adapted plan from Mertens and colleagues (19) and Doty (47) to match the thesis objectives were used to guide the demonstration of utility of the SPC charts. The plan was used as a framework to create the charts for a group of selected key performance indicators (see Table 1).

Statistical Process Control Plan	
1. Key performance indicators selection and definition.	• The concurrence among stakeholders on a selected set of indicators. • The availability of required raw data, which are used to measure and calculate the indicator in the NSBSP database. • The agreement between the selected indicators that represent local needs and indicators at the national level.
2. Determine variables (Special-cause variation).	• Variables that might trigger Special-cause variation were identified through discussions with experts and decision makers at the NSBSP.
3. Control charts selection and considerations.	• X-Bar and R Charts were used to analyze and plot continuous variables (interval data) such as wait times.
4. Select a study sample and locations.	• The age group between 50 and 69 was represented in the data. • Data consisted of results of mammography screening visits between 2009 and 2012. • Data included results from each the NSBSP site (excluding mobile sites) and for Nova Scotia as a whole.
5. Data extraction and preprocessing.	• Data extraction was requested and regulated based on the NSBSP guidelines.
6. Determine chart's characteristics.	• Charts consist of 12 quarterly samples. • Upper Control Limits (UCL) and Lower Control Limits (LCL) were set based on decision makers' needs. The main factor in determining both values was the desired degree of sensitivity of the surveillance tool. • Run length was set based on decision makers' desired degree of sensitivity of the surveillance tool. • Centerline was calculated based on mean value of each key performance indicator.
7. Determine control behavior through tests.	• Control tests were determined empirically based on decision makers' needs. Out of Control status for each key performance indicator was identified based on the control tests.
8. Charts analysis.	• Analyze retrospective charts with decision makers see Chapter 4.
9. Decision makers and continuity of use.	• Users were provided with the SPC plan for continuity of use. • Integration between Caisis and R (see Chapter 4).

Table 1: SPC Plan, adapted from (19,47)

3.2.1 Indicators Selection and Definition

Indicators selection and definition is an essential part of performance monitoring. Decision makers are required to determine what processes they want to monitor in their organizations. The process of indicators selection should not be an individual decision. A group of front-end decision makers, data collectors, and back-end decision makers, data analysts, are expected to share views and participation in this process.

The purpose of this research is to develop a tool that provides decision makers with a means of real-time surveillance, specifically to monitor and detect trends in breast cancer screening processes and other processes parallel to pathology. According to the Royal College of Pathologists "A key performance indicator should be defensible, credible, supported by body of evidence in the literature, feasible and acceptable to all stakeholders." (48). While selecting and defining the indicators we considered the following:

a. The agreement among stakeholders on the selected indicators. To overcome this challenge we had to arrange meetings with all stakeholders. We engaged different decision makers from different backgrounds such as pathologists, radiologists, program managers, epidemiologists, health informaticians, biostatisticians and research managers.

b. The availability of required raw data, used to measure and calculate the indicator in the NSBSP database. This imposes the importance of data collection at the NSBSP. We noticed a shortage in collected data such as wait times, due to

information management and flow. We managed to select a wide variety of indicators from the available data in the NSBSP database.

c. The accordance between the selected indicators that represent local needs and indicators at the national level. At the selection phase, a subset of national key performance indicators for organized breast cancer screening programs across Canada was considered (45,49).

A final list of national breast screening performance indicators that were selected by stakeholders as follows:

a. Abnormal Detection Rate (based on radiologists' reports)

Computation formula (number of abnormal screens / total screens)*100

b. Invasive Cancer Detection Rate

Computation formula (number of invasive cancers / total screens)*100

c. In Situ Cancer Detection Rate

Computation formula (number of in situ cancers / total screens)*1000

d. Cancer Detection Rate

Computation formula ((number of invasive cancer + number of in situ cancer) / total screens) *1000

e. Positive Predictive Value Rate

Computation formula ((number of invasive cancer + number of in situ cancer) / total abnormal screens)*1000

A final list of provincial wait time performance indicators that were selected by stakeholders as follows (see Figure 1):
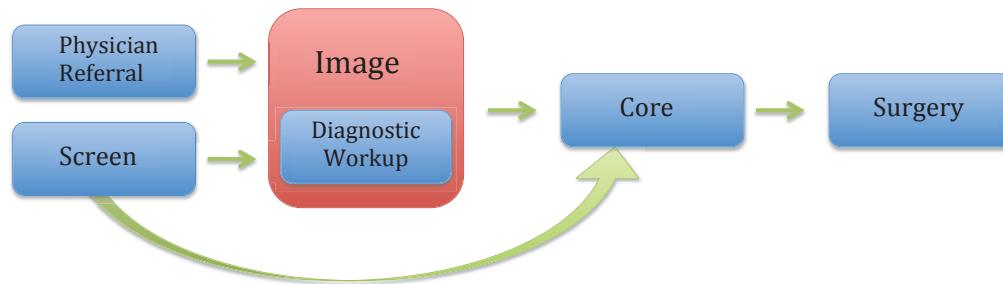
Figure 1: Wait Times

a. Screen-workup: Time in days between date of the screen to date of the diagnostic workup. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter year.

b. Screen to first core biopsy: Time from date of first screen to date of first core biopsy. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter year.

c. Workup-core: Time from date of diagnostic workup to date of first core biopsy. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter year.

d. Image-core: Time from date of most recent investigative image in diagnostic radiology to date of first surgery. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter year.

3.2.2 Determine Variables (Special–Cause Variation)

Variables that might trigger special-cause variation were identified empirically through discussions with experts and decision makers at the NSBSP (see Table 2).

Screen – Workup Wait Time
- Equipment failure time.   - Radiologists reporting time, highly dependent on radiologists' capacity.   - Screening site capacity (technician availability, appointment slot availability, screening room availability, and radiologist availability).   - Demand.   - Resource availability.   - Radiologists' experience, new radiologists show higher learning curve (longer time).   - Clinical practice variation, such as using ultrasound as an alternative.
Screen - First core biopsy Wait Time
- Equipment failure time.   - Radiologists reporting time, highly dependent on radiologists' capacity.   - Screening site capacity (technician availability, appointment slot availability, screening room availability, and radiologist availability).   - Resource availability.   - Demand.   - Radiologists' experience, new radiologists show higher learning curve (longer time).   - Clinical practice variation, such as using ultrasound as an alternative.

Table 2: Special Cause Variables

Workup - Core Wait Time
- Equipment failure time.   - Radiologists reporting time, highly dependent on radiologists' capacity.   - Screening site capacity (technician availability, appointment slot availability, screening room availability, and radiologist availability).   - Demand.   - Resource availability.   - Radiologists' experience, new radiologists show higher learning curve (longer time).   - Clinical practice variation, such as using ultrasound as an alternative.
Image - Core Wait Time
- Equipment failure time.   - Public awareness.   - Primary care practitioner referral patterns.
Abnormal Detection Rate
- Demographic variation (age dependent risk, risk profile of women entering)   - Radiologists' experience (new radiologists show higher learning curve, longer time).   - Changing technology (new machines, radiologists' behavior).   - Clinical practice guidelines.   - Radiologists' Report Cards (feedback on overall performance compared to other radiologists).

Table 2 ctd: Special Cause Variables

3.2.3 Control Charts Selection and Considerations

Wachs listed five factors to consider while choosing the proper control chart for each key performance indicator (50):

a. Type of data that are used to build the charts.

b. The surveillance tool degree of sensitivity required by decision makers.

c. Data if they were collected from a single site or multiple sites.

d. Flexibility and ease of use.

e. Amount of data.

X-Bar and R Charts were selected to monitor wait times since wait times are classified as interval data and are interpreted as normally distributed data (16).

3.2.4 Data Extraction and Pre-processing

The NSBSP provided aggregate data for use in surveillance tool development and analysis. Several considerations were taken into account to extract the data:

a. In order to import usable raw data into the R language for statistical computing, Comma-Separated Values (CSV) format files were provided by the NSBSP.

b. Data were extracted for the 50 – 69 year old age group to be consistent with the national target age group.

c. Data consisted of results of screens between 2009 and 2012

d. Data included results for each of the NSBSP fixed sites.

3.2.5 Charts Characteristics

Characteristics such as Upper Control Limits (UCL), Lower Control Limits (LCL), Centerline, and number of samples were used to determine the sensitivity of charts in detecting out of control trends and the way that decision makers requested to present the charts. The following characteristics were considered while developing the charts:

a. Charts were built based on 12 quarterly samples that represent data collected between 2009 and 2012. This number of samples was considered to make the

charts practically meaningful to the NSBSP and easier to interpret. However, the number of samples can be adjusted according to users' needs.

b. The centerline was identified by calculating the mean value in the period from 2009 to 2012. There is no concurrence in the literature about the number of intervals that should be used to calculate the mean; however, Sellick recommended using 12 to 24 months and that data should be collected from the same locations throughout the period under observation (16).

c. Two considerations were taken while defining UCL and LCL: Type I and II Errors. According to Noyez, the range above and below the centerline has a direct effect on chart accuracy (15). Defining a small range between limits will increase the chance of detecting in-control-processes as out-of statistical-control processes. Shewhart recommended using a minimum of three-standard errors above and below the centerline. He based this conclusion based on complex statistical theories that are beyond the scope of this thesis and therefore are not discussed here (17). Basically, the chance of making a false positive decision rises to 5% if a less than three standard errors is used to define limits (15). On the other hand a false negative decision will be made if the process were not recognized as an out-of-statistical control process, this error might occur if the limits are greater than three standard errors (15,17). Although Shewhart recommended choosing three standard errors, he stated "the fact that the criterion which we happen to use has a fine ancestry in highbrow statistical theorems does not justify its use. Such justification must come from empirical evidence that it works" (17). Consequently, the decision was made to define limits empirically guided by the

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needs of the NSBSP. Stakeholders wanted to maintain relatively narrow limits for wait-times indicators.

3.2.6 Charts Behavior (Control Tests/Patterns)

Control tests were developed and provided to users and decision makers at the NSBSP to be used as a reference guide to monitor processes within UCL and LCL (see Table 3). As mentioned before, processes might stay within the limits, giving the impression that they are under control and meeting all users' needs. Processes within limits are described as under statistical control and charts will not trigger the alert. However, processes under statistical control still require special attention for continuous performance improvement. To reflect on this phenomenon, Sellick stated, "if no tests are met the process is in control. This refers only to the statistical analysis, not the clinical appropriateness of the value" (16). The charts' tests are mainly used to identify (16):

a. The distance between value samples and mean value of each key performance indicator.

b. The patterns that were defined by users within the control limits and require special attention before reaching the out-of-statistical control status.

Control Tests/Patterns
1. A sample located beyond UCL or LCL
2. Three out of four samples form a continues pattern above or below the centerline but within UCL and LCL.
3. Three samples form a continuous pattern on one side of the centerline.
4. Four samples within 1 sigma above or below the centerline

Table 3: Control Tests, adapted from (16, 19 and 47)

If data samples on the charts matched the pre-determined patterns, users can reach the conclusion that processes are out of statistical control and require to take corrective measures (16,47). Corrective measures can be applied by identifying and eliminating special causes that influence the process (47). Process correction is defined as "use of control charts to identify and correct assignable causes so that the process can be brought back into statistical control"(47). In addition, the same patterns are used to apply improvement measures, which can be done by refining the common causes that influence the process (47). Improvement measures defined as "activities that concentrate on changing the process parameters so that the process can be made better than it was" (47). The pre-determined patterns also can be used as a reference guide to train new users to use control charts.

3.3 "R" for Statistical Computing

R serves two major functions in statistical computing. It serves both as a language that can be used to perform statistical analysis and as a graphical environment for plotting

graphs. R was developed as OSS under the GPL by John Chambers and colleagues at Bell Laboratories, which is now known as Lucent Technologies (51).

R was selected to develop and present the utility of SPC charts as a surveillance tool for the NSBSP. The main reason behind this choice is the interoperability between R and Caisis (the platform for development of the Breast Imaging EMR that the NSBSP will be using). The 2012 Caisis 6.0 release has the ability to host peripheral software as plug-ins (27); R has been integrated in this way as part of the core Caisis installation. Another reason we chose R is its ease of use, not requiring a high level of experience with statistical software to generate SPC charts. Furthermore, R provides a complete solution that facilitates data collection, editing, analysis, and graphical presentation (51).

3.4 Synoptic Reporting Survey

A survey was developed and distributed among senior pathologists at the QEII pathology laboratory. The survey had two goals: to determine how familiar pathologists are with the CAP checklist and to identify the concurrence on reporting elements among pathologists (see Appendix 1).

The survey was developed and published using Opinio online survey software. Opinio is available for free to Dalhousie faculty, staff and students under supervision terms. The service can be accessed through a secure web server at https://surveys.dal.ca/opinio/admin/folder.do. All data and results were stored on the web server and access was granted to the main researcher only. Questions were sent using an

email invitation-link that can be accessed and answered by the invitee only. A nominal scale was used to acquire the participants' responses.

3.4.1 Cohen's Kappa Analysis (Inter-rater reliability)

To analyze results gathered from the survey, Cohen's Kappa Analysis was selected. The Kappa or inter-rater reliability method is the most popular and trusted method among researchers for the analysis of nominal scale surveys (52). In addition, it provides a solid framework to measure scores' reliability without relying on qualitative measures that fail to determine scores' reliability precisely (53). The main goal was to determine if selected questions and related answers from the survey are coherent and consistent across all participants.

R software was selected to perform the Kappa analysis due to the availability of the Kappa statistical package in R environment. Results from Opinio were extracted and entered manually into a Microsoft Office Excel spreadsheet, which was then converted into Comma Separated Values file (CSV) that can be used in R software.

Chapter 4 Results and Discussion

This chapter presents and discusses the following:

a. Results from the Cohen's Kappa analysis that was performed to determine the degree of agreement on synoptic pathology reporting elements among clinicians.

b. Information flow analysis at NSBSP and QEII pathology laboratory.

c. Results from the control charts based on the SPC plan outlined in Chapter 3.

d. An integration solution between "R" and Caisis.

The main objective is to determine if the control charts are able to detect special causes that influence the processes being monitored. This can be achieved by applying the control tests/patterns to identify developing trends. All results were reviewed and confirmed by matching the interpretations of decision makers at the NSBSP with the retrospective patterns that were identified on the control charts.

4.1 Pathology Laboratory at QEII and NSBSP

A system analysis was performed by the researcher and Dr. Penny Barnes, a senior pathologist at QEII, to identify the information flow between the pathology lab and NSBSP. The goal of the information analysis was to determine the reporting level at the QEII based on CAP synoptic levels and to identify any potential drawbacks that might affect data flow to the surveillance tool. The investigation revealed the following (see Figure 2):

a- The current reporting method does not satisfy the quality reporting factors and recommended standards by CAP.

b- Based on the six synoptic reporting levels by CAP, the reporting level at QEII is equivalent to level three. Level three lacks drop down menus and standard templates that can be used by all pathologists at the laboratory.

c- Each pathologist has an individual customized template that can be assigned to a shortcut key or hot key to import the template.

d- Final reports do not meet CAP standards for quick review and interpretations.

e- Data elements on pathology reports are not in a usable form that supports surveillance tools. Data in discrete usable form are essential to support real time surveillance tools.

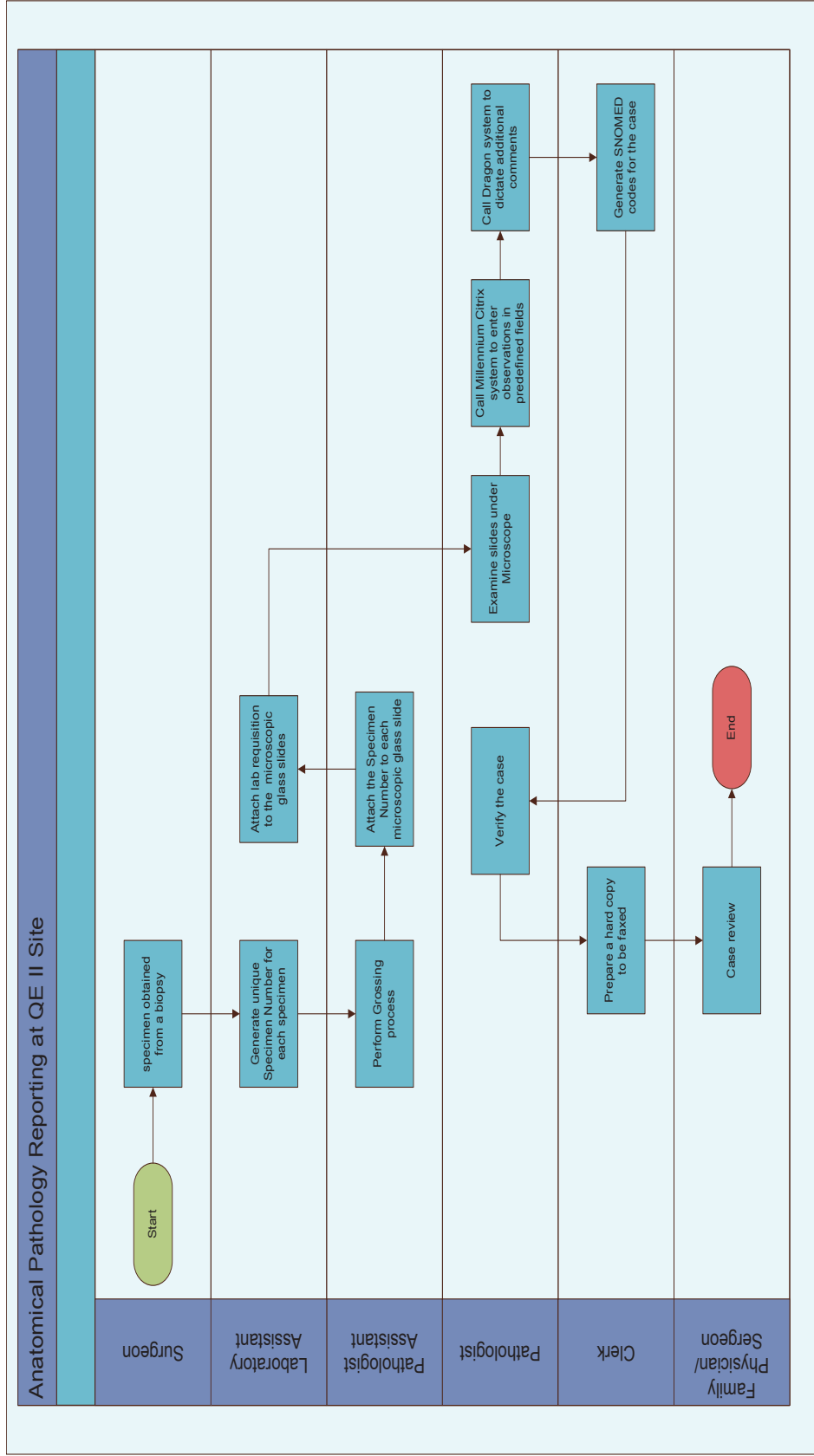f- Paper based communication channels between the laboratory at QEII and NSBSP.

Figure 2: Information Flow at QEII Lab

4.2 Cohen's Kappa Analysis Results

Kappa analysis was performed on the results gathered from the synoptic reporting survey. The Kappa statistic is a measure of the agreement above and beyond the agreement expected by chance. The analysis showed interesting results, where clinicians' responses did not correspond on reporting elements. A scale of Kappa values was used to determine the level of agreement among raters (see Table 4).

K-Value	Level of agreement
< 0.00	Poor
0.00 – 0.2	Slight
0.21 – 0.4	Fair
0.41 – 0.6	Moderate
0.61 – 0.8	Substantial
0.81 – 1.0	Perfect

Table 4: Kappa Scale, Adapted From (54,55)

Results based on level of agreement are as follows:

a. Question one: This question was used to determine if the clinician is familiar with CAP checklist and Synoptic Reporting. The k value for this question is 0.467, which is Fair according to the Kappa scale.

b. Question two: CAP reporting elements that represent the minimum required reporting elements for patients without invasive carcinoma or micro-invasion, were listed and clinicians were asked to rate each element according to how useful they feel the element is for patient care. The k value for this question is < 0, which is Poor according to the Kappa scale.

c. Question three: CAP reporting elements that represent the minimum required reporting elements for patients without invasive carcinoma or micro-invasion, were listed and clinicians were asked to select the element that they currently report. The k value for this question is 0.309, which is Fair according to the Kappa scale.

d. Question four: CAP reporting elements that represent the minimum required reporting elements for patients with invasive carcinoma or micro-invasion, were listed and clinicians were asked to rate each element according to how useful they feel the element is for patient care. The k value for this question is < 0, which is Poor according to the Kappa scale.

e. Question five: CAP reporting elements that represent the minimum required reporting elements for patients with invasive carcinoma or micro-invasion, were listed and clinicians were asked to select the element that they currently report. The k value for this question is < 0, which is Poor according to the Kappa scale.

Based on Kappa values, there is a substantial amount of disagreement among clinicians. In addition, Kappa values confirm what was observed on a sample of pathology reports that were produced by a group of pathologists at QEII (See Appendix 2 and Appendix 3). Reports show a high level of variability on how pathologists report their cases. An on site investigation was initiated to identify the cause behind this variation. The investigation showed that each senior pathologist has an individual reporting template. This discrepancy among reporting templates has a direct effect on the information flow. Specifically patient navigators who are responsible of scanning and extracting the data

from reports are facing difficulties due to the variation among reports. Furthermore, without having a reporting template that guarantee the five quality factors, timeliness, completeness, accuracy, comparability and usability it is impossible to implement an accurate surveillance system. Surveillance tool such as SPC requires a reliable source of data to achieve its objectives.

4.3 NSBSP Data Flow Analysis

An information flow analysis was performed at NSBSP to identify the borders between the screening program and pathology laps at QEII (See Figure 3). In addition, the analysis helped in understanding the current situation on how decision makers at the program are using data from pathology reports to evaluate and monitor key performance indicators. Information flow steps are as follows:

a- A NSBSP patient navigator is assigned to reenter pathology reports to Mammography Information System (MIS). Which is achieved by skimming the reports and pre-identified data elements are entered based on the program needs.

b- Decision maker run multiple queries in set screens.

c- Each query produces a .dbf file, which is imported into SAS program for statistical analysis.

d- SAS is used to export processed statistics into CSVs files.

e- CSVs files imported into 'Numbers', Apple's software, to produce key performance indicators charts.

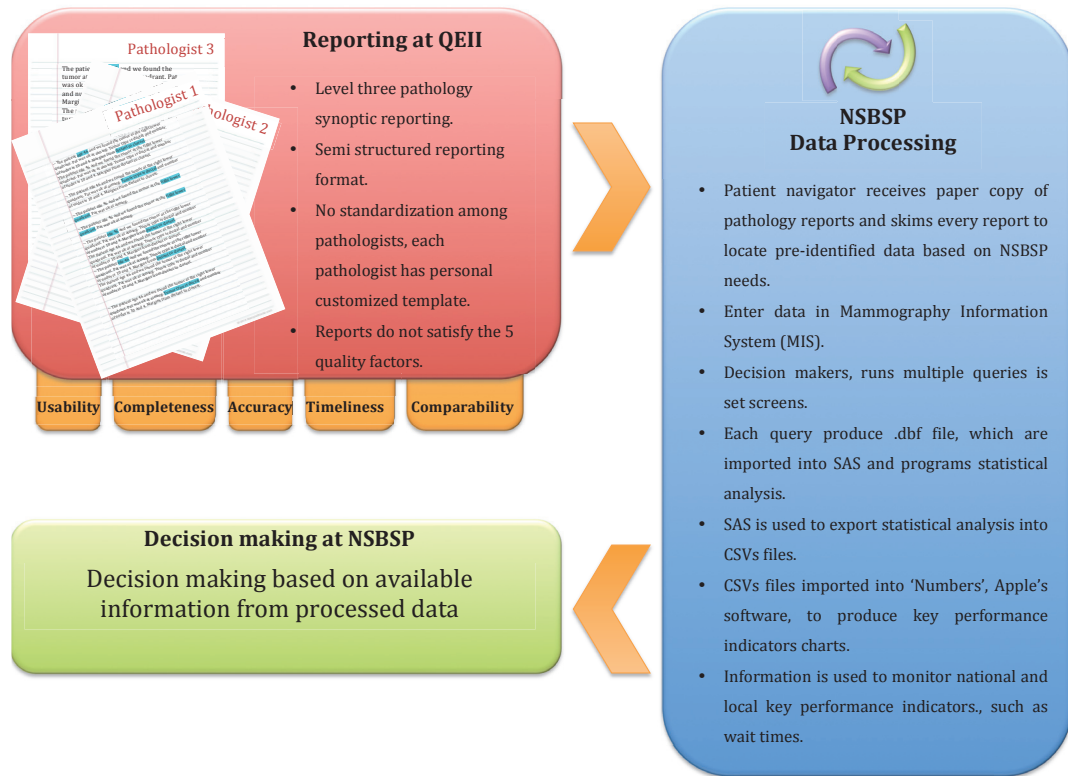f- Information is used to monitor national and local key performance indicators, such as wait times.

Figure 3: Current Information Cycle at NSBSP and QEII

4.4 "R" and Caisis Integration Solution

The main consideration when identifying an integration framework between R and Caisis to produce SPC charts was the ease of use and flexibility. The following framework was revised and confirmed by Caisis developers:

1. Printed reports at NSBSP are saved as ASCII files on Caisis server. Parsing process, using Perl programming language, to extract and format, discrete usable form, the relevant pathology data from the report for

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importing into Caisis.

2. R scripts are executed through the Caisis interface, as it allows using R as a plug-in.

3. Data that is stored in the Caisis MS SQL server is imported into R using the R Open Database Connectivity (RODBC) package and SQL queries that are written in R. The Open Database Connectivity (ODBC) package that was developed as a universal database access scheme enables data retrieval from any database through an ODBC interface and the storage of data in R (56). Another approach is to import CSV files containing the data into R to create the data frame objects that are used for analysis.

4. The Quality Control Charts (QCC) package in R is used to generate customizable SPC charts using the data frame objects imported into R.

5. All summary statistics and SPC chart plots are generated in R and directed outside of Caisis to files explicitly specified in the R scripts by a path to a particular filename in a particular folder.

6. To fulfill ease of use for non-programmer users, all R scripts containing R code can be saved and triggered through Caisis menu items to generate charts as needed.

The proposed solution minimizes the number of user interfaces required. All processing can be achieved through Caisis interface only, which will provide easy and flexible information flow (see Figure 4). The current framework requires decision makers to interact with three different interfaces; MIS, Numbers and SAS (see Figure 3). In addition, the current information processing is based on non-reliable data that do not

satisfy the five quality factors: timeliness, usability, accuracy, comparability and completeness (2)
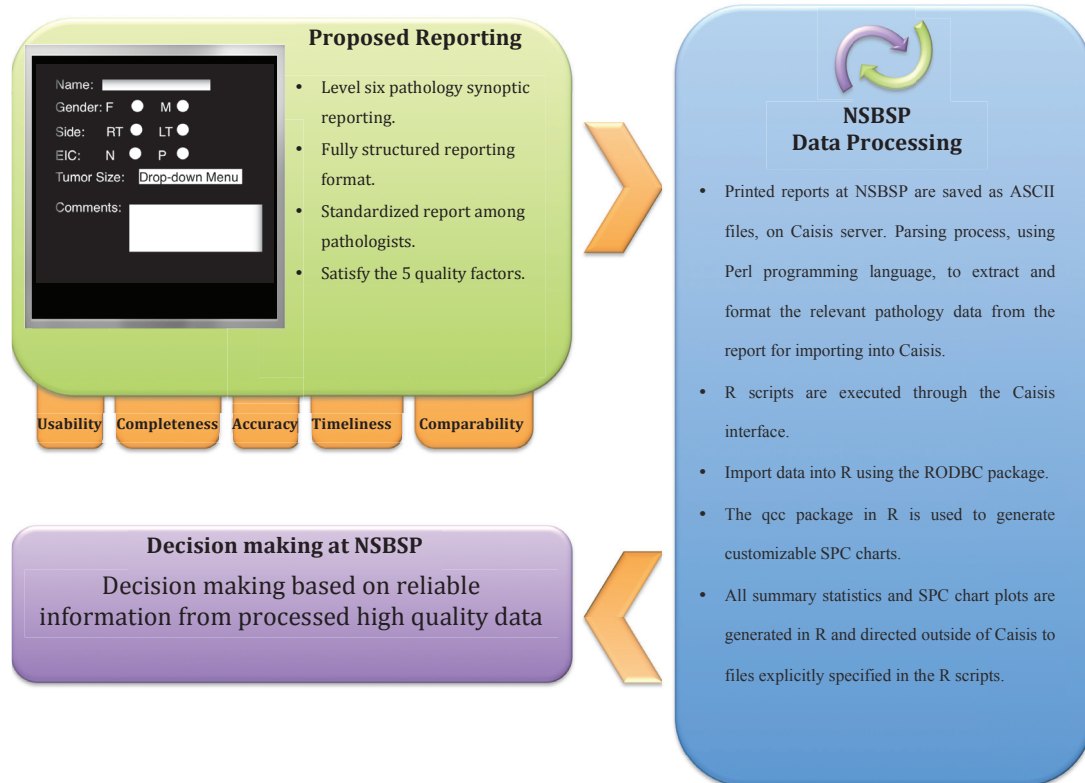

Proposed Reporting

- Level six pathology synoptic reporting.
- Fully structured reporting format.
- Standardized report among pathologists.
- Satisfy the 5 quality factors.

Usability   Completeness   Accuracy   Timeliness   Comparability

NSBSP Data Processing

- Printed reports at NSBSP are saved as ASCII files, on Caisis server. Parsing process, using Perl programming language, to extract and format the relevant pathology data from the report for importing into Caisis.
- R scripts are executed through the Caisis interface.
- Import data into R using the RODBC package.
- The qcc package in R is used to generate customizable SPC charts.
- All summary statistics and SPC chart plots are generated in R and directed outside of Caisis to files explicitly specified in the R scripts.

Decision making at NSBSP

Decision making based on reliable information from processed high quality data

Figure 4: Proposed Data Processing And SPC Generation Framework

4.5 Control Charts Interpretation and Feasibility Evaluation

Accurate and successful control chart interpretation can be achieved if the charts are built appropriately (16). Two considerations were taken to build the proper control chart:

a. Control chart type, based on data type and users' needs.

b. Control chart sensitivity by defining the proper UCL and LCL based on national targets or user defined context-specific limits.

Multiple control charts for each key performance indicator were generated and interpreted based on the SPC plan (see Chapter 3); (for codes used to generate charts see Appendix 4). The main criterion for the interpretation was to identify a correspondence between the pre-identified control tests/patterns (see Chapter 3) and any detected developing trends on the charts. To confirm the ability of the control charts to detect emerging trends that represent special causes, decision makers were asked to confirm the plausibility of identified trends. A list of pre-defined special causes (see chapter 3), were used to assist decision makers to identify the causes that influence trends development.

As mentioned before key performance indicators at national and local levels were selected, defined and required data were extracted to be used for SPC charts generation. However, only local indicators were used to build the charts and other indicators were dropped due to sparse data availability by quarter. Narrowing the window by using a month or a week at the time interval was not feasible due to the insufficient data for stable process to be evaluated.
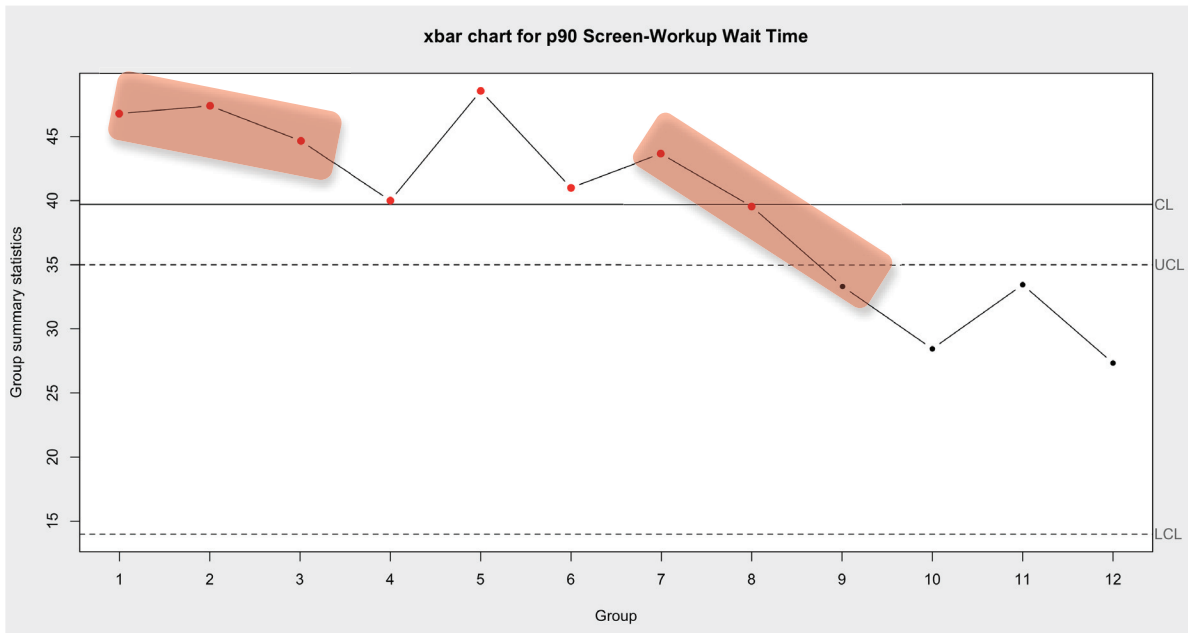
4.5.1 Screen-Workup Wait Time

Figure 5: Screen-Workup Wait Time Xbar Control Chart

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
39.705	35	14	8	xbar	14

Table 5: Screen-Workup Wait Time xbar Control Chart Criteria

The xbar control chart for Screen-Workup wait time that was developed based on decision makers' needs showed (see Table 5) (see Figure 5):

a. Eight samples, from the third quarter of 2009 to second quarter of 2011, beyond the UCL =35 days.

b. Two developing trends, three samples form a continuous pattern on one side of the centerline.

Observations of NSBSP Users and Decision makers: Screen-Workup wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national

target which the program strives to meet. An investigation was undertaken that lead to identification of two special causes of variation in wait times: wait times between screening to report by radiologists is highly dependent on radiologists availability and availability of diagnostic appointments required for the diagnostic workup appointments. Both causes matched the pre-identified special causes (see Chapter 3).
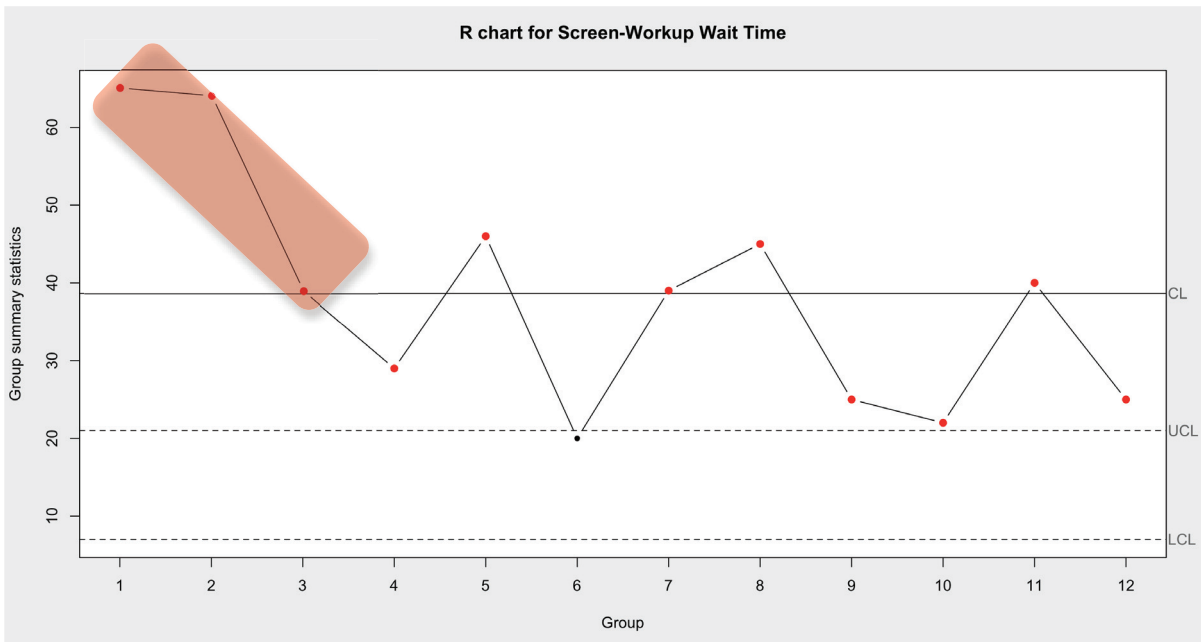

Figure 6: Screen-Workup Wait Time R Control Chart

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
38.642	21	7	11	R	13

Table 6: Screen-Workup Wait Time R Control Chart Criteria

The R control chart for Screen-Workup wait time that was developed based on decision makers' needs showed (see Table 6) (see Figure 6):

a. Eleven samples, from the third quarter of 2009 to third quarter of 2010 and from the first quarter of 2011 to third quarter of 2012, beyond the UCL =21 days.

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b. One developing trend, three samples form a continuous pattern on one side of the centerline.

Observations of NSBSP Users and Decision makers: Screen-Workup wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national target. The R chart is a valuable decision tool because it shows the variation among districts. Each group sample on the chart represents the range between the highest and lowest wait time between districts. The special causes of variation are the demand on the screening services, the availability of screening appointments and radiologists availability. All causes matched the pre-identified special causes (see Chapter 3).

4.5.2 Image-Core Wait Time
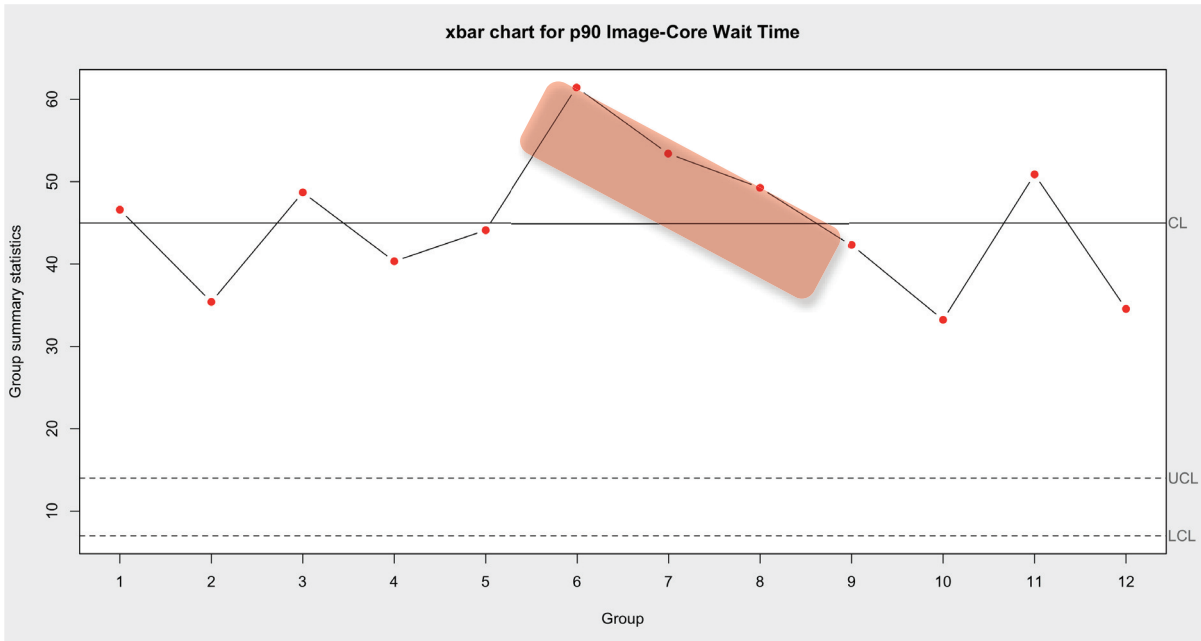
Figure 7: Image-Core Wait Time xbar Control Char

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
44.99	14	7	12	xbar	13

Table 7: Image-Core Wait Time xbar Control Chart Criteria

The xbar control chart for Image-Core wait time that was developed based on decision makers' needs showed (see Table 7) (see Figure 7):

a. Twelve samples, from the third quarter of 2009 to second quarter of 2012, beyond the UCL =14 days.

b. One developing trend, three samples form a continuous pattern on one side of the centerline.

Observations of NSBSP Users and Decision makers: Image-Core wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national target.

The chart confirms what NSBSP knows to be a concern. The wait time from image to core is too long provincially. Core biopsy wait times have a direct relationship to radiologists' availability. This differs for different districts. Radiologists' experience is also a factor as less experienced radiologists tend to recommend more core biopsy thus increasing volume.
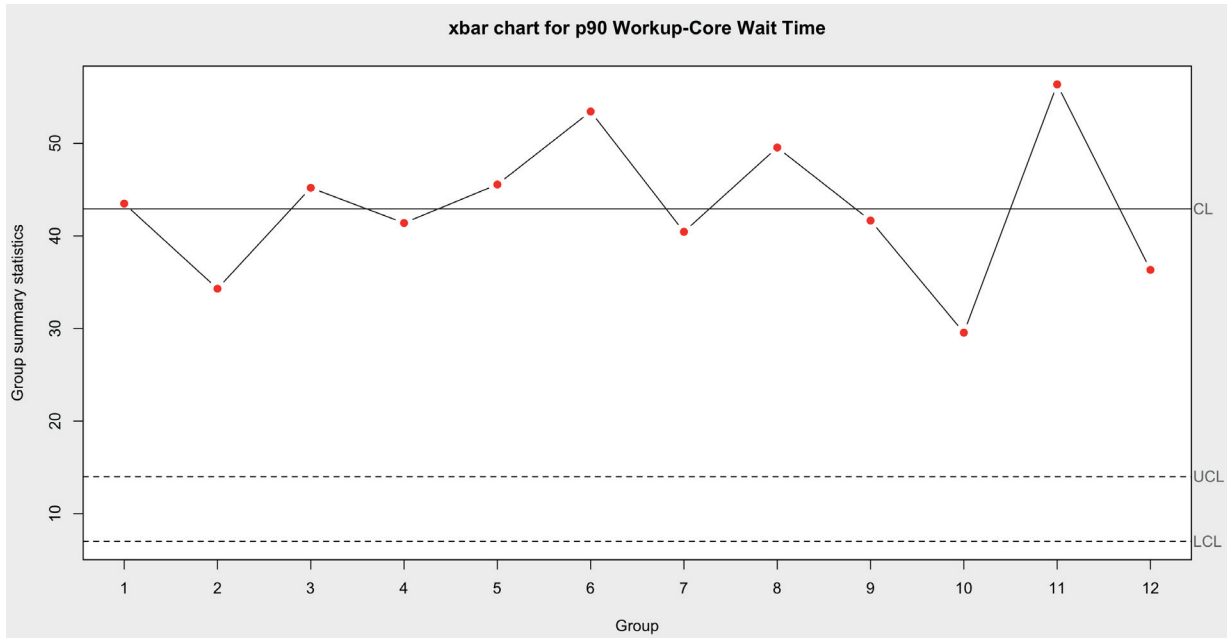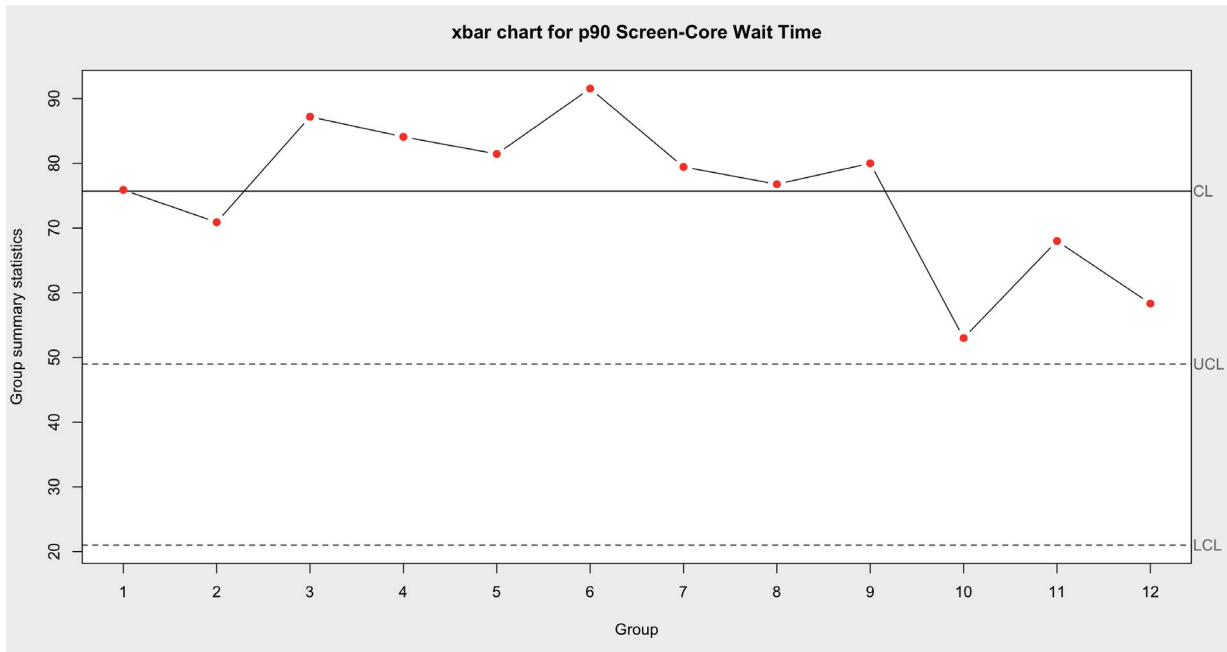
4.5.3 Workup-Core Wait Time

Figure 8: Workup-Core Wait Time xbar Control Chart

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
42.918	14	7	12	xbar	12

Table 8: Workup-Core Wait Time xbar Control Chart Criteria

The xbar control chart for Workup-Core wait time that was developed based on decision makers' needs showed (see Table 8) (see Figure 8):

a. Twelve samples, from the third quarter of 2009 to second quarter of 2012, beyond the UCL = 14 days.

Observations of NSBSP Users and Decision makers: Workup-Core wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national target. The chart confirms what NSBSP knows to be a concern. The wait time from diagnostic workup to core biopsy is too long provincially. Core biopsy wait times have a direct relationship to radiologists' availability. This differs for different districts.

4.5.4 Screen-Core Wait Time

Figure 9: Screen-Core Wait Time xbar Control Chart

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
75.696	49	21	12	xbar	12

Table 9: Screen-Core Wait Time xbar Control Chart Criteria

The xbar control chart for Screen-Core wait time that was developed based on decision makers' needs showed (see Table 9) (see Figure 9):

a. Twelve samples, from the third quarter of 2009 to second quarter of 2012, beyond the UCL = 49 days.

Observations of NSBSP Users and Decision makers: Screen-Core wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national target. The wait time for screen to core has been on the increase. As a result of reporting this to the districts there has been some improvement. The wait time is very dependent

on the radiologists' availability, but where there have been improvements in screen to diagnostic workup this has a positive effect on screen to core biopsy.
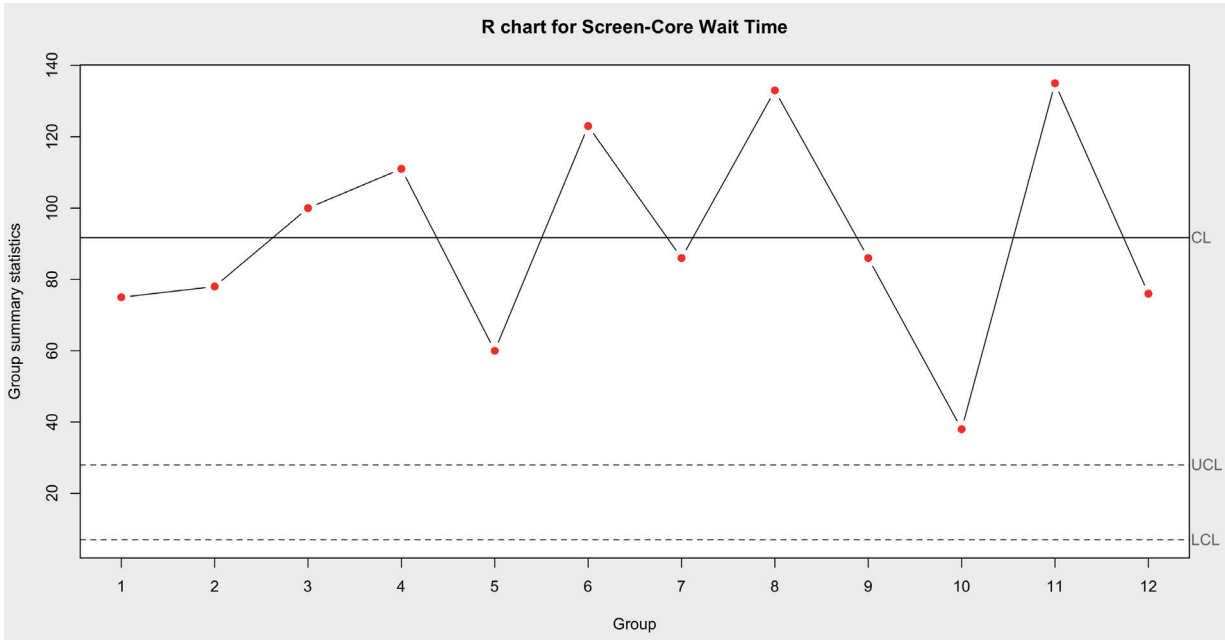

Figure 10: Screen-Core Wait Time R Control Chart

Centerline	UCL	LCL	Samples beyond limits	Type	Detected trends
75.696	28	7	12	R	12

Table 10: Screen-Core Wait Time R Control Chart Criteria

The R control chart for Screen-Core wait time that was developed based on decision makers' needs showed (see Table 10) (see Figure 10):

a. Twelve samples, from the third quarter of 2009 to second quarter of 2012, beyond the UCL = 28 days.

Observations of NSBSP Users and Decision makers: Screen-Core wait times in the period from the third quarter of 2009 to second quarter of 2011 were beyond the national

target. The availability of radiologists at some districts was identified as special cause. In some districts the radiologist who orders the core biopsy most likely is the one who performs it. The R chart shows the variation among the districts; some districts have more radiologists compared to other districts. Consequently, radiologists can order the core biopsy and other available radiologists can perform it. This cause matched the pre-identified special cause (see Chapter 3).

4.6 Value of SPC Charts To NSBSP

Based on these retrospective analyses, it is clear that SPC charts are a feasible surveillance tool that are sensitive enough to detect changes in performance and facilitate the identification of the special causes associated with the observed change. In addition, the charts showed the ability to document and present the performance of processes in an easy way that facilitate interpretation. Consequently, investigations and performance comparison across time or sites can be achieved effectively. All results were confirmed by decision makers at NSBSP. The SPC plan facilitated the usage and understanding of the charts. The plan was provided to users at NSBSP for future usage and adaptation.

Chapter 5 Conclusion

This chapter will discuss research findings in the context of existing literature, then explore the strengths and limitations of SPC, supplemented with feedback from decision makers and clinicians at NSBSP. It closes with conclusion reached and recommendations for future work.

5.1 Findings

The lack of adoption of standardized reporting templates at QEII pathology labs lead to a significant diversity among pathology reports. This diversity has a direct impact on reporting quality and data extracted from reports. In addition, the current reporting method that is equivalent to level three, based on CAP synoptic reporting levels, does not satisfy the usability factor which requires data to be collected in discrete form (2). This reinforce the existing knowledge, as the literature indicates that lack of adoption standardized reporting methods affect report's completeness, accuracy, usability, timeliness and comparability (2,3,32).

SPC charts can be used to monitor processes within breast screening frameworks but with minor limitations that will be discussed later in this chapter. This confirms the findings in current literature that demonstrated the usability of SPC in other medical frameworks such as transfusion diseases (57), hospice care of cancer patients (19) and employee health in relation to work environment (20).

5.2 Strengths and limitations

The research's main objective was to demonstrate the feasibility of SPC as a decision tool in the breast-screening context at the NSBSP. As a secondary objective, the research aimed to identify a suitable reporting method to improve the performance of SPC decision tool. Three factors were considered in evaluating the research objectives: utilization of OSS, the five reporting quality factors, and interoperability among involved components. The strengths and limitations of the proposed solution are explored as follows:

5.2.1 Strengths:

a. **Integration among systems and ease of use**

To have a reliable solution it was essential to select systems that integrate with each other without additional financial resources. This challenge was overcome by selecting R software as the language used to perform statistical analysis and as a graphical environment for plotting graphs. The ability to use R as a plug-in with Caisis makes it easy for non-programmers and clinicians with no expertise with statistical software packages to generate the SPC charts.

b. **SPC charts are able to detect developing trends**

Through using the pre-identified list of special causes that might affect process and SPC tests, clinicians and decision makers were able to confirm the ability of the charts to monitor and detect developing trends in the breast screening framework.

c. SPC charts can be used to develop local indicators

Analyzing charts that represent the historical performance will offer NSBSP the opportunity to develop local indicators limits and performance warning threshold.

d. Using CAP checklist reporting templates to avoid diversity among pathology reports

The research showed that pathologists at QEII are aware of CAP checklist. Consensus among the pathologists will facilitate the adoption of CAP templates as a synoptic reporting method to avoid diversity among reports.

5.2.2 Limitations:

a. Resources

The scarce financial resources at NSBSP were a major factor in shaping the research. Decision makers at the NSBSP are eager to improve performance at all levels, without incurring new costs. Resources issues were overcome through the identification of OSS solutions and through the availability of a scholarship from King Saud University Saudi Arabia to cover the cost of human resources for the development of a solution.

b. Data definition and extraction

It was challenging to consider concordance between the selected indicators that represent local needs and indicators at the national level. NSBSP has its local needs that can be defined through local key performance indicators. Due to the flexibility of SPC, the usage of local performance indicators is possible. This

challenge was expected due to the lack of adoption of a reporting method that facilitates complete and usable data collection.

c. **Agreement among multidisciplinary stakeholders**

It was challenging to bring everybody to the same table. The diversity in backgrounds, needs and approach had a direct impact on the overall productivity. Research supervisors were concerned about the academic approach behind the solution as well as academic deadlines. Clinicians are result driven and wanted to have a functioning tool to monitor and evaluate clinical performance. Decision makers at NSBSP were concerned about the limitation of available resources and the accuracy of the decision tool. Furthermore, scheduling and organizing meetings with all stakeholders for collaborative research were tedious due to the limitation of availability slots that suits every member. Fortunately, all members had shared values and showed genuine interest in the research. They were aware of the importance of having a surveillance tool to monitor and evaluate processes across the screening sites in Nova Scotia.

d. **SPC and events based on sparse data**

SPC charts showed a limitation in generating charts for national indicators that were selected and defined in the research. Due to the sparse data and events at NS that represent national indicators, it was impractical to generate SPC charts to monitor this subset of indicators. SPC charts use successive windows, years or quarters, as a time interval to compare events. Consequently, due to the

insufficient data for stable process to be evaluated, it was not feasible to narrow the time interval window to overcome the sparse events issue.

5.3 Summary and Recommendations

By upgrading the current reporting method from level three to level six (according to the synoptic reporting levels by CAP) the five quality standards of reporting will be achievable: accuracy, timeliness, completeness, comparability and usability. The survey showed that clinicians are familiar with synoptic reporting but they need consensus to overcome the diversity issue. Implementing a standard synoptic reporting template such as the CAP checklist at QEII and NSBSP laboratories will overcome diversity among pathology reports. Consequently, building a surveillance tool that uses reliable data to monitor trends in key performance indicators will be achievable. Using SPC plan and charts as a surveillance tool to monitor clinical process at NSBSP showed a high level of feasibility in detecting developing trends and isolating causes behind the changes in performance. Decision makers were able to confirm the utility of this tool. To transfer the research to a practical solution at NSBSP and to perform further research, it is recommended to:

a. Implement and use CAP charts at NSBSP as a surveillance tool to monitor key performance indicators.

b. Ensure that all employees have access to SPC charts to monitor their performance and compare it with other sites across Nova Scotia.

c. Use R as the main environment for statistical computing and graphics to generate

SPC charts within Caisis environment.

d. Focus on and consider OSS solutions in future systems update to overcome financial and systems integration barriers.

e. Perform further research to identify a surveillance tool that can be used to monitor processes based on sparse events within narrow timeframe window.

f. Develop local indicators' upper and lower limits based on observations from SPC charts.[1]

g. Improve and upgrade the SPC plan that was provided through this research. This can be achieved by refining the current plan and expand it by developing an action plan based on information provided by the charts.

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[1] The recommendation reinforce the current literature that addresses local indicators development (57)

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Appendix 1
Synoptic reporting survey

1. **Had you ever heard of the term Synoptic Reporting?**

   ○ Yes
   ○ No

2. **Had you ever attended/participated in Synoptic Reporting CME?**

   ○ Yes
   ○ No

3. **In the medical school did you receive any significant instruction on the subject of Synoptic Reporting, if any?**

   ○ Yes
   ○ No

4. **Do you expect any resistance by clinicians if Synoptic Reporting will be introduced at your organization?**

   ○ Yes
   ○ No

5. **What do you know about the College of American Pathologist (CAP) Breast Cancer pathology-reporting checklist?**

   ○ Yes
   ○ No

Finish

CAP Reporting Elements

Patients with DCIS Breast (without invasive carcinoma or microinvasion).

1. **The following are reporting elements by CAP that represent the minimum required reporting elements for patients with DCIS Breast (without invasive carcinoma or microinvasion).**

   Please rate each element according to how useful you feel the element is for patient care.

	Not useful	Not very useful	Neutral	Useful	Very Useful
Specimen (partial breast, total breast ...etc)	○	○	○	○	○
Procedure (with/without wire-guided, total mastectomy...etc)	○	○	○	○	○
Lymph Node Sampling	○	○	○	○	○
Specimen Integrity	○	○	○	○	○
Specimen Size	○	○	○	○	○
Specimen Laterality	○	○	○	○	○
Tumor Site	○	○	○	○	○
Size of DCIS	○	○	○	○	○
Histologic Type	○	○	○	○	○
Architectural Patterns	○	○	○	○	○
Nuclear Grade	○	○	○	○	○
Necrosis	○	○	○	○	○
Margins Assessment	○	○	○	○	○
Treatment Effect	○	○	○	○	○
Lymph Nodes (extranodal extension, method of evaluation of Sentinel Lymph Nodes)	○	○	○	○	○
Pathologic Staging	○	○	○	○	○
Ancillary Studies	○	○	○	○	○
Microclacifications	○	○	○	○	○
Clinical History	○	○	○	○	○

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CAP Reporting Elements

Patients with DCIS Breast (without invasive carcinoma or microinvasion).

2. **Please indicate the elements below that you <u>currently</u> report.**

	Yes	No
Specimen (partial breast, total breast ...etc)	○	○
Procedure (with/without wire-guided, total mastectomy...etc)	○	○
Lymph Node Sampling	○	○
Specimen Integrity	○	○
Specimen Size	○	○
Specimen Laterality	○	○
Tumor Site	○	○
Size of DCIS	○	○
Histologic Type	○	○
Architectural Patterns	○	○
Nuclear Grade	○	○
Necrosis	○	○
Margins Assessment	○	○
Treatment Effect	○	○
Lymph Nodes (extranodal extension, method of evaluation of Sentinel Lymph Nodes)	○	○
Pathologic Staging	○	○
Ancillary Studies	○	○
Microclacifications	○	○
Clinical History	○	○

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CAP Reporting Elements

Patients with Invasive Carcinoma of the Breast and DCIS with Microinvasion.

5. The following are reporting elements by CAP that represent the minimum required reporting elements for patients with Invasive Carcinoma of the Breast and DCIS with Microinvasion.

Please rate each element according to how useful you feel the element is for patient care.

	Not useful	Not very useful	Neutral	Useful	Very Useful
Specimen (partial breast, total breast...etc)	○	○	○	○	○
Procedure (with/without wire-guided, total mastectomy...etc)	○	○	○	○	○
Lymph Node Sampling	○	○	○	○	○
Specimen Integrity	○	○	○	○	○
Specimen Size	○	○	○	○	○
Specimen Laterality	○	○	○	○	○
Tumor Site (Invasive Carcinoma)	○	○	○	○	○
Tumor Size (Size of Largest Invasive Carcinoma)	○	○	○	○	○
Tumor Focality	○	○	○	○	○
Microscopic and Macroscopic Extent of Tumor	○	○	○	○	○
DCIS	○	○	○	○	○
Size of DCIS	○	○	○	○	○
Architectural Patterns	○	○	○	○	○
Nuclear Grade	○	○	○	○	○
Necrosis	○	○	○	○	○
Lobular Carcinoma In Situ	○	○	○	○	○
Histological Type of Invasive Carcinoma	○	○	○	○	○
Histological Grade: Nottingham Histologic Score	○	○	○	○	○
Nuclear Pleomorphisim	○	○	○	○	○
Mitotic Count	○	○	○	○	○
Overall Grade	○	○	○	○	○
Margins Assessment	○	○	○	○	○
Treatment Effect: Response to Presurgical Therapy	○	○		○	○
Lymph Vascular Invasion	○	○	○	○	○
Lymph Nodes (extranodal extension, method of evaluation of Sentinel Lymph Nodes)	○	○	○	○	○
Pathologic Staging	○	○	○	○	○
Ancillary Studies	○	○	○	○	○
Microclacifications	○	○	○	○	○
Clinical History	○	○	○	○	○

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CAP Reporting Elements

Patients with Invasive Carcinoma of the Breast and DCIS with Microinvasion.

6. Please indicate the elements below that you <u>currently</u> report.

	Yes	No
Specimen (partial breast, total breast...etc)	○	○
Procedure (with/without wire-guided, total mastectomy...etc)	○	○
Lymph Node Sampling	○	○
Specimen Integrity	○	○
Specimen Size	○	○
Specimen Laterality	○	○
Tumor Site (Invasive Carcinoma)	○	○
Tumor Size (Size of Largest Invasive Carcinoma)	○	○
Tumor Focality	○	○
Microscopic and Macroscopic Extent of Tumor	○	○
DCIS	○	○
Size of DCIS	○	○
Architectural Patterns	○	○
Nuclear Grade	○	○
Necrosis	○	○
Lobular Carcinoma In Situ	○	○
Histological Type of Invasive Carcinoma	○	○
Histological Grade: Nottingham Histologic Score	○	○
Nuclear Pleomorphisim	○	○
Mitotic Count	○	○
Overall Grade	○	○
Margins Assessment	○	○
Treatment Effect: Response to Presurgical Therapy	○	○
Lymph Vascular Invasion	○	○
Lymph Nodes (extranodal extension, method of evaluation of Sentinel Lymph Nodes)	○	○
Pathologic Staging	○	○
Ancillary Studies	○	○
Microclacifications	○	○
Clinical History	○	○

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Appendix 2
Pathology report Sample A

Surgical Pathology Final Report

Temporary Copy   Page 1 of 4

Case

Collected:

Ordered by:

Diagnosis

BREAST (RIGHT), COMPLETION MASTECTOMY: MULTICENTRIC INVASIVE DUCTAL
CARCINOMA, NO SPECIAL TYPE, GRADE 2-3 (1.1 CM, 0.7 CM AND 0.4 CM MICROSCOPIC
MEASUREMENTS) WITH DUCTAL CARCINOMA IN SITU, INTERMEDIATE TO HIGH GRADE,
COMEDO AND NON-COMEDO PATTERNS AND FOCAL LYMPHATIC-VASCULAR INVASION
-MARGINS OF EXCISION APPEAR NEGATIVE FOR MALIGNANCY
-TUMOR #1: ER POSITIVE, PR NEGATIVE, NEGATIVE FOR HER-2/NEU PROTEIN
OVEREXPRESSION
-ER, PR AND HER-2/NEU IHC ARE PENDING FOR TUMORS #2 AND #3
-REMOTE SURGICAL SCAR, OUTER MIDLINE
-PLEASE SEE REPORT.

Pathologist
(Electronic Signature)
Verified: 2012/07/30

Comment

Three foci of invasive ductal carcinoma and DCIS are identified in this mastectomy in the outer
midline, upper midline, and lower inner quadrant regions. A remote surgical scar is identified in the
outer midline; however, multiple sections of the scar do not contain tumor. Grossly, the invasive tumor
identified in the outer midline was found 1.5 cm from the surgical scar. It appears that the multifocal
disease most likely represents new primary tumors as malignancy is not seen in association with the
previous surgical site.

Specimen Received

A   Right breast

Clinical History

Hospital Identifier: K00629775
Recurrent right breast cancer.

Gross Description

The specimen is received in one container numbered 19078. The container is labeled with the
patient's name "HT" and this corresponds with the name on the requisition "HT". The anatomic site of
the specimen is documented on the container "right breast, suture lateral".

A. The specimen is in mastectomy including ellipse of skin and nipple. A suture marks the lateral
margin, as per the requisition. The specimen is labeled as a right breast, as per the requisition. The
ellipse of skin is 18.5 cm from medial to lateral x 9.5 cm from superior to inferior and appears
unremarkable. The nipple is 1.3 cm diameter and appears unremarkable. The remaining breast
tissue is 22.5 cm from medial to lateral x 16 cm from superior to inferior x 7.5 cm from anterior to
deep. The specimen weighs 590 g.
The specimen was placed in formalin in the OR at 1030 hrs., 2012/06/21. The specimen was
received in the laboratory at 1056 hrs., 2012/06/21. The specimen was inked, sliced and placed in
formalin in the inflammatory at 1114 hrs., 2012/06/21.

On cut section, there is a scar-like area with fat necrosis, in the outer midline, 2.0 x 1.2 x 1.5 cm, and it is 2.5 cm from the deep margin, 2 cm from the anterior margin, 3.5 cm from the inferior margin, 4 cm from the superior margin, 4.5 cm from the lateral margin and is 3 cm from the nipple.

Also identified on cut section, is a grey-yellow, firm, ill-defined mass, 1.6 cm from superior to inferior x 1.2 cm from anterior to deep x 0.7 cm from medial to lateral. This mass is 2.7 cm from the skin surface, 4.0 cm from the deep margin, 3.5 cm from the inferior margin, 8.5 cm from the superior margin, 2.0 cm inferior to the nipple in the inferior midline. This mass is 1.5 cm from the query scar-like area described above. No needle core biopsy tract is identified.

Also identified on cut section, in the superior midline, is an ill-defined, grey-yellow, firm mass, 0.6 cm from anterior to deep x 0.5 cm from superior to inferior x 0.5 cm from medial to lateral. This mass is 3.0 cm from the deep margin, 4.0 cm from the skin surface, 4.3 cm from the superior margin, 9.5 cm from the inferior margin and is 2.0 cm superior to the nipple. This mass is 4.5 cm from the mass in the inferior midline, and is 3 cm from the scar-like area described above. No needle core biopsy tract is identified.

A third, yellow-grey, firm mass is identified in the inner lower quadrant, 1.5 cm from superior to inferior x 0.7 cm from anterior to deep x 0.6 cm from medial to lateral. This mass is 1.9 cm from the skin surface, 4.0 cm from the deep margin, 4.5 cm from the inferior margin, 6.5 cm from the superior margin, 6.0 cm from the medial margin and is 3.5 cm from the nipple. A possible core tract is identified within the mass.

The remaining breast tissue is unremarkable.

Representative sections are submitted as follows:

A1-A2 - continuous section of the scar-like area in the outer midline including deep margin

A3-A4 - continuous section of the scar-like area including deep margin

A5 - the remainder of the scar-like area

A6-A8 - the first described mass in toto from the inferior midline (no margins)

A9 - deep margin below first described mass

A10 - inferior margin adjacent first described mass

A11 - section of tissue between first and second described masses

A12-A13 - second described mass in toto (no margins)

A14 - deep margin low second described mass

A15 - superior margin adjacent second described mass

A16-A18 - the third described mass in toto (no margins), with A18 including skin

A19 - deep margin below third described mass

A20 - inferior margin adjacent third described mass

A21 - inner lower quadrant, 1 cm from third described mass and (3 cm from inferior margin, 5 cm from deep margin)

A22 - inner upper quadrant including deep margin

A23 - outer upper quadrant including anterior margin

A24 - outer lower quadrant including deep margin

A25 - nipple

A26 - one possible lymph node, 0.4 cm in greatest dimension

Case reviewed with Dr. C. Wang.

2012/06/22 10:44

AMC:AMC

Microscopic Description

Surgical Pathology Final Report
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Case:
Collected: Patient:
Ordered by: ID:
                                                  Location:

Procedure: Completion mastectomy

Axillary Surgery: No

Side: Right

Tumor Locations(s): Outer midline (tumor #1), upper midline (tumor #2), and lower inner quadrant (tumor #3)

Histologic Type(s): Invasive ductal carcinoma, no special type

Distribution of Tumor: Multicentric: 3 invasive foci are identified

Tumor Size: Tumor #1: 1.1 cm microscopic measurement; Tumor #2. 0.7 cm microscopic measurement; Tumor #3: 0.4 cm microscopic measurement

Nottingham Grade:	Tumor #1	Tumor #2	Tumor #3
Tubule Formation Score:	3/3	3/3	3/3
Nuclear Grade:	3/3	3/3	3/3
Mitotic Score:	2/3	1/3	2/3
Total:	8/9	7/9	8/9
Grade:	3	2	3

Lymphatic/Vascular Invasion: Identified focally in association with tumors #1 and 3

In Situ Component: Ductal carcinoma in situ, mainly intermediate to high grade, solid, cribriform, micropapillary and comedo patterns. DCIS is associated with 2 invasive foci (outer midline and LIQ) and is present in the lower inner quadrant in association with the core biopsy tract

FIC Status: Negative

Calcification: Associated with DCIS and benign ducts.

Resection Margins Involvement:
    Invasive carcinoma. Negative, blocks taken of closest margins to the 3 invasive foci and DCIS are negative for malignancy.
    DCIS: Negative

Lymph Nodes:
    Resected: 0

Nipple and Skin Involvement: There is no direct skin invasion, dermal lymphatic invasion or mammary Paget's disease. DCIS, low grade, involves the central actiferous ducts.

Chest Wall Involvement:
    Skeletal Muscle: Tissue is not present.

Abnormalities in non-neoplastic breast tissue: A remote surgical scar is present in the outer midline. A core biopsy tract is associated with DCIS in the lower inner quadrant. The background breast tissue appears atrophic.

Hormone Receptors:
        Ordered: Block A6 (tumor #1)
        Result: ER strongly positive (100% of cells), PR negative
Comment: There is appropriate staining of benign internal control epithelium and external controls.
ER and PR IHC for tumors #2 and 3 is pending and results will follow in an addendum report.

HER2/neu IHC: Tumor #1 shows weak complete membranous staining of less than 10% of cells with
4B5 and DAKO A0485 antibodies (negative for HER 2/neu protein overexpression).
Comment: External controls have stained appropriately. HER-2/neu IHC for tumors #2 and 3 is
pending and results will follow in an addendum report.

pTN Stage: mpT1c

Correlation with previous relevant pathology report: SP-12-14428, SP-99-21212, SP-99-7402.

Pink Rose Information Package: Previously sent.

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Discussion

Immunohistochemical staining for hormone receptors has been applied on representative blocks of the smaller foci of invasive ductal carcinoma (tumors #2 and #3; blocks A12 and A21). Both invasive carcinomas are strongly positive for ER IHC (100% of cells) and both are strongly positive for PR IHC (90-100% of cells). There is appropriate staining of internal control epithelium and external controls.

These invasive foci are negative for Her2/neu protein overexpression with 4B5 and DAKO A0485 antibodies. External controls have stained appropriately.

Diagnosis

BREAST (RIGHT), COMPLETION MASTECTOMY: MULTICENTRIC INVASIVE DUCTAL CARCINOMA, NO SPECIAL TYPE, GRADE 2-3 (1.1 CM, 0.7 CM AND 0.4 CM MICROSCOPIC MEASUREMENTS) WITH DUCTAL CARCINOMA IN SITU, INTERMEDIATE TO HIGH GRADE, COMEDO AND NON-COMEDO PATTERNS AND FOCAL LYMPHATIC-VASCULAR INVASION
- MARGINS OF EXCISION APPEAR NEGATIVE FOR MALIGNANCY
- TUMOR #1: ER POSITIVE, PR NEGATIVE, NEGATIVE FOR Her2/NEU PROTEIN OVEREXPRESSION
- TUMORS #2 AND #3: ER POSITIVE, PR POSITIVE, NEGATIVE FOR HER-2/NEU PROTEIN OVEREXPRESSION
- REMOTE SURGICAL SCAR, OUTER MIDLINE
- PLEASE SEE REPORT.

Pathologist
(Electronic Signature)
Verified: 2012/08/01

Appendix 3
Pathology report Sample B

Diagnosis

A) BREAST TISSUE (LEFT), WIRE LOCALIZATION EXCISION:
1. MULTIFOCAL INVASIVE DUCTAL CARCINOMA - NOS
TUMOR #1
- SIZE = 2.1 CM (MICROSCOPIC MEASUREMENT) - A1.
- GRADE 3
- LYMPHOVASCULAR INVASION IDENTIFIED (EXTENSIVE).
- CALCIFICATIONS PRESENT
- MARGINS
  - DEEP = 1.7 CM
  - ANTERIOR = 0.25 CM - A4; 0.18 CM - A6
  - SUPERIOR = 2.2 CM
  - INFERIOR = 0.7 CM - A9
  - MEDIAL = 2.0 CM
  - LATERAL = 3.3 CM
- ER - NEGATIVE; PR - POSITIVE (WEAK ~ 50%).
- EQUIVOCAL FOR HER-2/NEU PROTEIN OVEREXPRESSION.
- CARBON CORE TRACT WITH BIOPSY RELATED CHANGES.
TUMOR #2
- SIZE = 1.1 CM (MICROSCOPIC MEASUREMENT) - A13.
- GRADE 3
- LYMPHOVASCULAR INVASION IDENTIFIED (EXTENSIVE).
- CALCIFICATIONS NOT PRESENT
- MARGINS
  - DEEP = 0.2 CM - A14; 0.3 CM - A13
  - ANTERIOR = 1.3 CM
  - SUPERIOR = 2.2 CM
  - INFERIOR = 0.4 CM - A13
  - MEDIAL = 0.4 CM
- TUMOR IN LYMPHATIC CHANNEL 0.18 CM FROM DEEP MARGIN - A14
- ER - NEGATIVE; PR - POSITIVE (WEAK ~ 50%).
- EQUIVOCAL FOR HER-2/NEU PROTEIN OVEREXPRESSION.
- CARBON CORE TRACT NOT PRESENT.

2. HIGH GRADE DUCTAL CARCINOMA IN SITU (SOLID AND COMEDO PATTERNS) PRESENT IN
ASSOCIATION WITH TUMOR #1 AND TUMOR #2 - SEE COMMENT
- CALCIFICATIONS PRESENT IN TUMOR #1
- NECROSIS PRESENT (COMEDO PATTERN)
- MARGINS
  - DEEP - 0.3 CM - A13
  - ANTERIOR = 0.2 CM - A4
  - INFERIOR = 0.4 CM - A13; 0.5 CM - A9

3. NON-NEOPLASTIC BREAST TISSUE WITH NO PATHOLOGICAL DIAGNOSIS.

B) LEFT AXILLARY SENTINEL LYMPH NODES:
- ONE OF TWO LYMPH NODES POSITIVE FOR METASTASIS (1/2).
- SIZE = 0.4 CM
- NEGATIVE FOR EXTRANODAL EXTENSION.

Pathologist
(Electronic Signature)
Verified: 2012/06/30

Comment

It is difficult to assess the extent of the in situ carcinoma. The H&E configuration suggests an extensive in situ component, and there is some staining with heavy chain myosin at the periphery of some rounded nests of cells. However, the p63 is mostly negative, and these areas could represent a combination of invasive tumor, in situ carcinoma, and involvement of lymphatic channels. Although an extensive in situ component was suspected on the H&E evaluation, the EIC status is actually best regarded as negative in view of the negative p63 staining and extensive lymphatic involvement.

Specimen Received

A   Left breast segment
B   Left axillary sentinel nodes

Clinical History

Core invasive breast cancer.

Gross Description

The case is received in two containers. All the containers are numbered 18146 and have been designated A and B in the laboratory. The patient's name on each container is "MH" and this corresponds with the name on the accompanying requisitions "MH".

A. The specimen container is labelled "left breast segment". The specimen was placed in formalin in the OR at 1245 hrs. on 2012/06/13. The specimen was received in the laboratory at 1332 hrs. on 2012/06/13 where it was inked, sliced and placed in formalin in the laboratory at 1347 hrs. on 2012/06/13. The specimen is a portion of breast tissue received in a Dubbin container including four straight pins, and one localization wire denoting areas of radiological interest. A photocopy of an x-ray accompanies the specimen. A long suture marks the lateral margin, a short suture marks the superior margin, and a double suture marks the deep margin, as per the requisition. This orientates the specimen is a portion of left breast. The superior margin is inked green, the inferior margin is inked red, the deep margin is inked black and the remaining margins are inked blue. The specimen weighs 82 g. There is a thin strip of skin present on the surface, 4.0 cm from medial to lateral x 1.5 cm from superior to inferior. The skin is unremarkable. No nipple is present. The remaining breast tissue is 9 cm from medial to lateral x 8 cm from superior to inferior x 3 cm from anterior to deep. On cut section, below the pinned area, there is a well delineated, grey, firm mass with lobulated borders, 1.9 cm from superior to inferior x 1.2 cm from anterior to deep x 1.3 cm from medial to lateral. The mass is 0.3 cm from the anterior margin, 1.7 cm from the deep margin, 2.2 cm from the inferior margin, 2.2 cm from the superior margin, 2.3 cm from the lateral margin and 2.0 cm from the medial margin. A needle core biopsy tract is identified within the mass.

Representative sections are submitted as follows:
A1-A2 - continuous section the greatest dimension of the mass microscopic measurement, including

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Case
Collected:
Ordered by:
                                                        Patient
                                                        D:
                                                        Location

needle core biopsy tract, anterior and deep margins
A3 - section of the mass including anterior margin
A4-A5 next continuous section of the mass including anterior and deep margins
A6 A7 - continuous section of the mass including anterior and deep margins
A8 - superior margin adjacent to mass
A9 - inferior margin adjacent to mass
A10 - radial section of the medial margin
A11 - radial section of the lateral margin
A12 - section including skin

On further sectioning, a second mass is identified, at the medial end of the specimen, 0.7 x 0.6 x 0.5 cm, and it is 0.5 cm from the medial margin. The mass is fairly well-circumscribed, grey and firm. The mass is 0.4 cm from the deep margin, 1.3 cm from the anterior margin and 0.5 cm from the inferior margin. No needle core biopsy tract is identified in this mass are surrounding tissue. This mass is located outside the pinned area.

Further representative sections are submitted as follows:
A13 - the mass in toto including anterior, inferior and deep margins
A14 - shave of the medial margin directly behind the section taken in A13

B. The specimen container is labelled "left axillary sentinel nodes". The specimen is two grey nodules of soft tissue, consistent with lymph nodes, 0.7 x 0.5 x 0.5 cm and 1.8 x 1.3 x 1.0 cm. In toto as follows:
B1 - one lymph node bisected
B2-B4 - one lymph node trisected

Case reviewed with Dr. H. Sapp.

2012/06/14 09:56

AMC:AMC

Microscopic Description
Procedure: Wire localization excision (Specimen "A")

Axillary Surgery: Sentinel lymph node sampling (Specimen 'B')

Side: Left

Tumor Locations(s): Not designated

Histologic Type(s): Invasive ductal carcinoma - NOS

Distribution of Tumor: Multifocal

Tumor Size:
TUMOR #1
SIZE INVASIVE = 2.1 CM
TUMOR #2

SIZE INVASIVE = 1.1 CM

Nottingham Grade: TUMOR #1 AND TUMOR #2
  Tubule Formation Score: 3/3
  Nuclear Grade: 3/3
  Mitotic Score: 3/3
  Total: 9/9
  Grade: 3

Lymphatic/Vascular Invasion: Present (extensive)

In Situ Component: High grade ductal carcinoma in situ (solid and comedo patterns)

EIC Status: Negative (see comment)

Calcification: Calcifications are present in the invasive and in situ components in Tumor #1 and are absent in the invasive and in situ components in Tumor #2.

Resection Margins Involvement:
Invasive carcinoma:
TUMOR #1
  - DEEP = 1.7 CM
  - ANTERIOR = 0.25 CM - A4; 0.18 CM - A6
  - SUPERIOR = 2.2 CM
  - INFERIOR = 0.7 CM - A9
  - MEDIAL = 2.0 CM
  - LATERAL = 3.3 CM

TUMOR #2
  - DEEP = 0.2 CM - A14; 0.3 CM - A13
  - ANTERIOR = 1.3 CM
  - SUPERIOR = 2.2 CM
  - INFERIOR = 0.4 CM - A13
  - MEDIAL = 0.4 CM

DCIS:
  - DEEP = 0.3 CM - A13
  - ANTERIOR = 0.2 CM - A4
  - INFERIOR = 0.4 CM - A13; 0.5 CM - A9

Lymph Nodes:
  Involved: 1
  Resected: 2
  Size of nodal metastasis: 0.4 cm
  Extranodal extension: Not identified.

Nipple and Skin Involvement: Nipple not present. Skin not involved.

Chest Wall Involvement: Skeletal Muscle: Tissue not present

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Abnormalities in non-neoplastic breast tissue: None identified.

Hormone Receptors and HER2/neu IHC:
TUMOR #1
ER - Negative (no nuclear expression in tumor cells)
PR - Positive (weak nuclear expression in ~ 50% of tumor cells)
HER2/neu - Equivocal (weak to moderate complete membrane staining in >10% of tumor cells with
the DAKO and 4B5 antibodies). The material will be further evaluated by in situ hybridization and the
results will be reported in an addendum.

TUMOR #2
ER - Negative (no nuclear expression in tumor cells)
PR - Positive (weak nuclear expression in ~ 50% of tumor cells)
HER2/neu - Equivocal (weak to moderate incomplete and complete membrane staining in ~10% of
tumor cells with the DAKO and 4B5 antibodies). The material will not be evaluated by in situ
hybridization since the staining in TUMOR #1 is more convincing.

pTN Stage:
TUMOR #1 pT2
TUMOR #2 pT1c

Correlation with previous relevant pathology report: SP11-36555

Pink Rose Information Package: Previously sent

Appendix 4
R codes

Code correction to violating.runs function in qcc package
from R-help newsgroup.

https://stat.ethz.ch/pipermail/r-help/2005-November/083680.html

Leif Kirschenbaum leif at reflectivity.com
Wed Nov 30 19:37:41 CET 2005

- Previous message: [R] strange plots with type = "h" option
- Next message: [R] strange plots with type = "h" option
- **Messages sorted by:** [date] [thread] [subject] [author]

```
violating.runs<-function (object, run.length =
qcc.options("run.length"))
{
    center <- object$center
    statistics <- c(object$statistics, object$new.statistics)
    cl <- object$limits
    violators <- numeric()

  for(i in 1:2){
   diffs <- statistics - center
   if(i==2) {
    diffs <- c(0,diff(statistics))
     ## need to decrement run.length since we're looking at
differences between points
     run.length<-run.length-1
   }
   diffs[diffs > 0] <- 1
   diffs[diffs < 0] <- -1
   runs <- rle(diffs)
   index.lengths <- (1:length(runs$lengths))[runs$lengths >=
run.length]
   index.stats <- 1:length(statistics)
   vruns <- rep(runs$lengths >= run.length, runs$lengths)
   vruns.above <- (vruns & (diffs > 0))
   vruns.below <- (vruns & (diffs < 0))
   rvruns.above <- rle(vruns.above)
   rvruns.below <- rle(vruns.below)
   vbeg.above <-
```

```
cumsum(rvruns.above$lengths)[rvruns.above$values]-
(rvruns.above$lengths - run.length)[rvruns.above$values]
    vend.above <-
cumsum(rvruns.above$lengths)[rvruns.above$values]
    vbeg.below <-
cumsum(rvruns.below$lengths)[rvruns.below$values]-
(rvruns.below$lengths - run.length)[rvruns.below$values]
    vend.below <-
cumsum(rvruns.below$lengths)[rvruns.below$values]
    if (length(vbeg.above)) {
        for (i in 1:length(vbeg.above)) violators <- c(violators,
vbeg.above[i]:vend.above[i])
    }
    if (length(vbeg.below)) {
        for (i in 1:length(vbeg.below)) violators <- c(violators,
vbeg.below[i]:vend.below[i])
    }
  } ## ENDOF for i in 1:2
    return(violators)
}


R version 2.15.1 (2012-06-22) -- "Roasted Marshmallows"
Copyright (C) 2012 The R Foundation for Statistical Computing
ISBN 3-900051-07-0
Platform: i386-apple-darwin9.8.0/i386 (32-bit)

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  Natural language support but running in an English locale

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'citation()' on how to cite R or R packages in publications.

Type 'demo()' for some demos, 'help()' for on-line help, or
'help.start()' for an HTML browser interface to help.
Type 'q()' to quit R.

[R.app GUI 1.52 (6188) i386-apple-darwin9.8.0]

[History restored from /Users/DarkLord/.Rapp.history]
```

```
> waitq <- read.csv("/Users/DarkLord/Desktop/thesis R
code/wait_q-k.csv",header=TRUE)
> waitq


> library(qcc)
```
```
> ##
> ## Correct some typos in violating.runs from qcc package
> ## Added test for run.length of points monotonically increasing
or decreasing
> ## The simplest way is to re-run the code but with "diffs"
> ## representing the sign of the difference from one point to
the next
> ##
> violating.runs<-function (object, run.length =
qcc.options("run.length"))
+ {
+     center <- object$center
+     statistics <- c(object$statistics, object$new.statistics)
+     cl <- object$limits
+     violators <- numeric()
+
+   for(i in 1:2){
+     diffs <- statistics - center
+     if(i==2) {
+       diffs <- c(0,diff(statistics))
+    ## need to decrement run.length since we're looking at
differences between points
+       run.length<-run.length-1
+     }
+     diffs[diffs > 0] <- 1
+     diffs[diffs < 0] <- -1
+     runs <- rle(diffs)
+     index.lengths <- (1:length(runs$lengths))[runs$lengths >=
run.length]
+     index.stats <- 1:length(statistics)
+     vruns <- rep(runs$lengths >= run.length, runs$lengths)
+     vruns.above <- (vruns & (diffs > 0))
+     vruns.below <- (vruns & (diffs < 0))
```

```
+       rvruns.above <- rle(vruns.above)
+       rvruns.below <- rle(vruns.below)
+       vbeg.above <-
cumsum(rvruns.above$lengths)[rvruns.above$values]-
(rvruns.above$lengths - run.length)[rvruns.above$values]
+       vend.above <-
cumsum(rvruns.above$lengths)[rvruns.above$values]
+       vbeg.below <-
cumsum(rvruns.below$lengths)[rvruns.below$values]-
(rvruns.below$lengths - run.length)[rvruns.below$values]
+       vend.below <-
cumsum(rvruns.below$lengths)[rvruns.below$values]
+     if (length(vbeg.above)) {
+         for (i in 1:length(vbeg.above)) violators <-
c(violators, vbeg.above[i]:vend.above[i])
+     }
+     if (length(vbeg.below)) {
+         for (i in 1:length(vbeg.below)) violators <-
c(violators, vbeg.below[i]:vend.below[i])
+     }
+   } ## ENDOF for i in 1:2
+     return(violators)
+ }
>
>
> # qccoptionsOld <- qcc.options()
> # qcc.options(run.length="4")
> # qcc(districtsp90k, type="xbar", nsigmas=2)
> # qcc.options(qccoptionsOld)
>
>
> # WAIT TIMES ANALYSIS USING SPC
>
> waitQ$yearQuarter <- rep(0,dim(waitQ)[1])
>
>
> waitQ[waitQ$year==2009 & waitQ$q==3,]$yearQuarter <- 1
> waitQ[waitQ$year==2009 & waitQ$q==4,]$yearQuarter <- 2
> waitQ[waitQ$year==2010 & waitQ$q==1,]$yearQuarter <- 3
> waitQ[waitQ$year==2010 & waitQ$q==2,]$yearQuarter <- 4
> waitQ[waitQ$year==2010 & waitQ$q==3,]$yearQuarter <- 5
> waitQ[waitQ$year==2010 & waitQ$q==4,]$yearQuarter <- 6
> waitQ[waitQ$year==2011 & waitQ$q==1,]$yearQuarter <- 7
> waitQ[waitQ$year==2011 & waitQ$q==2,]$yearQuarter <- 8
```

```
> waitQ[waitQ$year==2011 & waitQ$q==3,]$yearQuarter <- 9
> waitQ[waitQ$year==2011 & waitQ$q==4,]$yearQuarter <- 10
> waitQ[waitQ$year==2012 & waitQ$q==1,]$yearQuarter <- 11
> waitQ[waitQ$year==2012 & waitQ$q==2,]$yearQuarter <- 12
>
> waitQ$p90k ²
  [1] 63 49 34 38 48 29 21 86 55 45 44 46 36 54 68 39 17 81 49 40
60 44 59 37 62 28 23 55 32 47 43 23 40 29 50 45 23 47 48 52 48 40
 [43] 42 NA 75 42 29 55 51 55 34 44 33 NA 48 35 34 43 45 53 49 32
35 NA 45 41 34 48 38 71 46 20 24 NA 64 30 30 40 37 65 33 28 34 NA
 [85] 39 33 21 34 32 46 22 22 30 NA 33 21 28 28 29 43 31 36 27 NA
33 25 20 33 36 60 22 18 22 NA 27 25 19 34 36 43
> p90kByYearAndQuarter <-qcc.groups(waitQ$p90k,waitQ$yearQuarter)
>
> p90kByYearAndQuarter
   [,1] [,2] [,3] [,4] [,5] [,6] [,7] [,8] [,9] [,10]
1    63   49   34   38   48   29   21   86   55    45
2    44   46   36   54   68   39   17   81   49    40
3    60   44   59   37   62   28   23   55   32    47
4    43   23   40   29   50   45   23   47   48    52
5    48   40   42   NA   75   42   29   55   51    55
6    34   44   33   NA   48   35   34   43   45    53
7    49   32   35   NA   45   41   34   48   38    71
8    46   20   24   NA   64   30   30   40   37    65
9    33   28   34   NA   39   33   21   34   32    46
10   22   22   30   NA   33   21   28   28   29    43
11   31   36   27   NA   33   25   20   33   36    60
12   22   18   22   NA   27   25   19   34   36    43
> indq <- read.csv("/Users/DarkLord/Desktop/thesis R code/ind_q-
k.csv",header=TRUE)
>
> indQ <- indq[indq$district < 10, ]
> indQ$yearQuarter <- rep(0,dim(indQ)[1])
> indQ[indQ$year==2009 & indQ$q==3,]$yearQuarter <- 1
> indQ[indQ$year==2009 & indQ$q==4,]$yearQuarter <- 2
> indQ[indQ$year==2010 & indQ$q==1,]$yearQuarter <- 3
> indQ[indQ$year==2010 & indQ$q==2,]$yearQuarter <- 4
> indQ[indQ$year==2010 & indQ$q==3,]$yearQuarter <- 5
> indQ[indQ$year==2010 & indQ$q==4,]$yearQuarter <- 6
> indQ[indQ$year==2011 & indQ$q==1,]$yearQuarter <- 7
```

---

[2] "p90" refers 90th percentile, "k" refers to screen-workup wait time: Time in days between date of the screen to date of the workup. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter-yearly

```
> indQ[indQ$year==2011 & indQ$q==2,]$yearQuarter <- 8
> indQ[indQ$year==2011 & indQ$q==3,]$yearQuarter <- 9
> indQ[indQ$year==2011 & indQ$q==4,]$yearQuarter <- 10
> indQ[indQ$year==2012 & indQ$q==1,]$yearQuarter <- 11
> indQ[indQ$year==2012 & indQ$q==2,]$yearQuarter <- 12

> qcc(abnrateByYearAndQuarter,type="p")
Error in qcc(abnrateByYearAndQuarter, type = "p") :
  sample 'sizes' must be given for a p Chart
>
> p90kByYearAndQuarter <-
qcc.groups(waitQ$p90k,waitQ$yearQuarter) ³
> qcc(p90kByYearAndQuarter,type="xbar",limits=c(14,35))
List of 11
 $ call      : language qcc(data = p90kByYearAndQuarter, type =
"xbar", limits = c(14, 35))
 $ type      : chr "xbar"
 $ data.name : chr "p90kByYearAndQuarter"
 $ data      : int [1:12, 1:10] 63 44 60 43 48 34 49 46 33 22 ...
  ..- attr(*, "dimnames")=List of 2
 $ statistics: Named num [1:12] 46.8 47.4 44.7 40 48.6 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes     : Named int [1:12] 10 10 10 10 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center    : num 39.7
 $ std.dev   : num 12.7
 $ nsigmas   : num 3
 $ limits    : num [1, 1:2] 14 35
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
>
> qcc(p90kByYearAndQuarter,type="R",limits=c(7,21))
List of 11
 $ call      : language qcc(data = p90kByYearAndQuarter, type =
"R", limits = c(7, 21))
 $ type      : chr "R"
 $ data.name : chr "p90kByYearAndQuarter"
 $ data      : int [1:12, 1:10] 63 44 60 43 48 34 49 46 33 22 ...
  ..- attr(*, "dimnames")=List of 2
```

---

[3] "k" refers to screen-workup wait time: Time in days between date of the screen to date of the workup. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter-yearly

```
 $ statistics: Named int [1:12] 65 64 39 29 46 20 39 45 25 22 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes      : Named int [1:12] 10 10 10 10 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center     : num 38.6
 $ std.dev    : num 12.7
 $ nsigmas    : num 3
 $ limits     : num [1, 1:2] 7 21
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
> p90iByYearAndQuarter <-
qcc.groups(waitQ$p90i,waitQ$yearQuarter) 4
> qcc(p90iByYearAndQuarter,type="xbar",limits=c(7,14))
List of 11
 $ call       : language qcc(data = p90iByYearAndQuarter, type =
"xbar", limits = c(7, 14))
 $ type       : chr "xbar"
 $ data.name  : chr "p90iByYearAndQuarter"
 $ data       : int [1:12, 1:10] 28 34 54 48 87 64 128 125 28 38
...
  ..- attr(*, "dimnames")=List of 2
 $ statistics: Named num [1:12] 46.6 35.4 48.7 40.3 44.1 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes      : Named int [1:12] 10 10 10 9 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center     : num 45
 $ std.dev    : num 25
 $ nsigmas    : num 3
 $ limits     : num [1, 1:2] 7 14
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
>
> p90wByYearAndQuarter <-
qcc.groups(waitQ$p90w,waitQ$yearQuarter) 5
```

---

[4] "i" refers to image-core wait time: Time from date of most recent investigative image in diagnostic radiology to date of first surgery. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter-yearly.

[5] "w" refers to workup-core wait time: Time from date of workup to date of first core biopsy. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter-yearly.

```
> qcc(p90wByYearAndQuarter,type="xbar",limits=c(7,14))
List of 11
 $ call      : language qcc(data = p90wByYearAndQuarter, type =
"xbar", limits = c(7, 14))
 $ type      : chr "xbar"
 $ data.name : chr "p90wByYearAndQuarter"
 $ data      : int [1:12, 1:10] 24 34 54 48 87 28 32 125 28 38
...
  ..- attr(*, "dimnames")=List of 2
 $ statistics: Named num [1:12] 43.5 34.3 45.2 41.4 45.6 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes     : Named int [1:12] 10 10 10 10 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center    : num 42.9
 $ std.dev   : num 23.7
 $ nsigmas   : num 3
 $ limits    : num [1, 1:2] 7 14
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
>
> p90sByYearAndQuarter <-
qcc.groups(waitQ$p90s,waitQ$yearQuarter) 6
> qcc(p90sByYearAndQuarter,type="xbar",limits=c(21,49))
List of 11
 $ call      : language qcc(data = p90sByYearAndQuarter, type =
"xbar", limits = c(21, 49))
 $ type      : chr "xbar"
 $ data.name : chr "p90sByYearAndQuarter"
 $ data      : int [1:12, 1:10] 50 50 114 107 108 64 128 160 51
51 ...
  ..- attr(*, "dimnames")=List of 2
 $ statistics: Named num [1:12] 75.9 70.9 87.2 84.1 81.4 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes     : Named int [1:12] 10 10 10 10 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center    : num 75.7
 $ std.dev   : num 30.5
```

---

6 "s" refers to screen-core wait time: Time from date of first screen to date of first core biopsy. Analyses are done on 90th percentile of the distribution of the wait time for a given site for a given quarter-yearly.

```
 $ nsigmas   : num 3
 $ limits    : num [1, 1:2] 21 49
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
> p90sByYearAndQuarter <-
qcc.groups(waitQ$p90s,waitQ$yearQuarter)
> qcc(p90sByYearAndQuarter,type="R",limits=c(7,28))
List of 11
 $ call       : language qcc(data = p90sByYearAndQuarter, type =
"R", limits = c(7, 28))
 $ type       : chr "R"
 $ data.name : chr "p90sByYearAndQuarter"
 $ data       : int [1:12, 1:10] 50 50 114 107 108 64 128 160 51
51 ...
  ..- attr(*, "dimnames")=List of 2
 $ statistics: Named int [1:12] 75 78 100 111 60 123 86 133 86 38
...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ sizes      : Named int [1:12] 10 10 10 10 9 9 9 9 9 9 ...
  ..- attr(*, "names")= chr [1:12] "1" "2" "3" "4" ...
 $ center     : num 91.7
 $ std.dev    : num 30.5
 $ nsigmas    : num 3
 $ limits     : num [1, 1:2] 7 28
  ..- attr(*, "dimnames")=List of 2
 $ violations:List of 2
 - attr(*, "class")= chr "qcc"
```

Kappa

```
> qn1agree <- read.csv("/Users/DarkLord/Desktop/thesis R
code/kappaQn1.csv",header=TRUE)
> qn2agree <- read.csv("/Users/DarkLord/Desktop/thesis R
code/kappaQn2.csv",header=TRUE)
> qn3agree <- read.csv("/Users/DarkLord/Desktop/thesis R
code/kappaQn3.csv",header=TRUE)
> qn4agree <- read.csv("/Users/DarkLord/Desktop/thesis R
code/kappaQn4.csv",header=TRUE)
> qn5agree <- read.csv("/Users/DarkLord/Desktop/thesis R
code/kappaQn5.csv",header=TRUE)
>
> library(irr)
```

```
Loading required package: lpSolve
> kappam.fleiss(qn1agree,detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 4
    Raters = 4
     Kappa = 0.238

         z = 1.17
   p-value = 0.243

   Kappa      z p.value
n 0.238 1.166   0.243
y 0.238 1.166   0.243
> kappam.fleiss(qn2agree,detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 19
    Raters = 4
     Kappa = -0.0917

         z = -1.13
   p-value = 0.259

   Kappa       z p.value
2 -0.013 -0.142   0.887
3 -0.013 -0.142   0.887
4 -0.152 -1.618   0.106
5 -0.056 -0.593   0.553
> kappam.fleiss(qn3agree,detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 19
    Raters = 4
     Kappa = -0.0275

         z = -0.294
   p-value = 0.769

   Kappa       z p.value
n -0.028 -0.294   0.769
y -0.028 -0.294   0.769
> kappam.fleiss(qn4agree,detail=TRUE)
 Fleiss' Kappa for m Raters
```

```
  Subjects = 29
    Raters = 4
     Kappa = -0.0426

         z = -0.693
   p-value = 0.489


    Kappa      z p.value
3 -0.045 -0.594   0.552
4 -0.053 -0.705   0.481
5 -0.034 -0.447   0.655
> kappam.fleiss(qn5agree,detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 4
    Raters = 4
     Kappa = 0.238

         z = 1.17
   p-value = 0.243


    Kappa      z p.value
n 0.238 1.166   0.243
y 0.238 1.166   0.243
>
> kappam.fleiss(qn1agree[,-c(2,3)],detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 4
    Raters = 2
     Kappa = 0.467

         z = 0.933
   p-value = 0.351


    Kappa      z p.value
n 0.467 0.933   0.351
y 0.467 0.933   0.351
> kappam.fleiss(qn2agree[,-c(2,3)],detail=TRUE)
 Fleiss' Kappa for m Raters

  Subjects = 19
    Raters = 2
```

```
       Kappa = -0.141

           z = -0.728
   p-value = 0.467


     Kappa       z p.value
2 -0.027 -0.118   0.906
3 -0.027 -0.118   0.906
4 -0.357 -1.557   0.120
5  0.026  0.112   0.911
> kappam.fleiss(qn3agree[,-c(2,3)],detail=TRUE)
 Fleiss' Kappa for m Raters

 Subjects = 19
   Raters = 2
    Kappa = 0.309

        z = 1.35
  p-value = 0.178


   Kappa       z p.value
n 0.309 1.347   0.178
y 0.309 1.347   0.178
> kappam.fleiss(qn4agree[,-c(2,3)],detail=TRUE)
 Fleiss' Kappa for m Raters

 Subjects = 29
   Raters = 2
    Kappa = 0.00396

        z = 0.027
  p-value = 0.978


     Kappa       z p.value
3 -0.094 -0.508   0.611
4 -0.051 -0.273   0.785
5  0.085  0.456   0.649
> kappam.fleiss(qn5agree[,-c(2,3)],detail=TRUE)
 Fleiss' Kappa for m Raters

 Subjects = 4
   Raters = 2
    Kappa = 0.467
```

```
        z = 0.933
  p-value = 0.351

   Kappa     z p.value
n 0.467 0.933   0.351
y 0.467 0.933   0.351
```