TRANSITIONING TO FULL-FIELD DIGITAL MAMMOGRAPHY: THE IMPACT OF TECHNOLOGY CHANGE ON MAMMOGRAPHY VOLUMES IN NOVA SCOTIA

by

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DEDICATION

To all the neuroatypicals who do not think it is possible, and to my medical radiation technology colleagues who are the unsung healthcare providers to so, so many.

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ABSTRACT

Recently, mammography has transitioned from analog screen-film to digital imaging. Reduced digital acquisition and processing time has the potential to increase screening throughput. This has not been evaluated in a "real-world" context. This project evaluated the transition to digital mammography on screening mammography throughput volumes and the proportion of diagnostic mammograms performed in Nova Scotia, Canada. A multi-group interrupted time-series design was used to assess the effects of technology change at ten fixed sites of the Nova Scotia Breast Screening Program between 2006 and 2014. Four sites experienced a statistically significant increase in screening throughput volumes following the introduction of digital mammography while the remaining sites experienced no significant change. There was no change in the proportion of diagnostic mammograms. The heterogeneity of results between sites suggests that unmeasured site-specific factors (departmental factors or demand) limited the potential for improved throughput following the transition.

LIST OF ABBREVIATIONS AND SYMBOLS USED

BIS – NSBSP Database Breast Information System

CAR – Canadian Association of Radiologists

CCOHTA – Canadian Coordinating Office for Health Technology Assessment

DEA – Data Envelopment Analysis

FFDM – Full Field Digital Mammography (read: Digital)

FTE – Full Time Equivalent

HIS- Hospital Information System

ITS – Interrupted Time Series

IWK – IWK Health Centre

MRT – Medical Radiation Technologist

NSBSP – Nova Scotia Breast Screening Program

NSHA – Nova Scotia Health Authority

PACS- Picture Archive Communication System

RIS- Radiology Information System

SFM – Screen Film Mammography (read: Analog)

SOP – Standard Operating Procedures

USPSTF – United States Preventative Services Task Force

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CHAPTER 1. INTRODUCTION

Breast cancer is the third leading cancer cause of death in Canada and the second most prevalent cancer-causing death for Canadian women. In 2017, an estimated 26 300 new cases were diagnosed in women in Canada, resulting in an estimated 5 000 deaths.[1] In an effort to reduce morbidity and mortality rates from breast cancer among Canadian women, most provinces and territories have implemented breast screening programs to reduce cancer stage at diagnosis.[2]

The recognized gold standard for breast cancer screening is mammography. Mammography uses low dose x-rays to produce images of breast tissue for analysis, looking for abnormal findings characteristic of cancer.[3] Based on screening results, patients may be referred for diagnostic mammograms as well as other investigations. Screening mammography is directed at early detection of cancers in healthy, asymptomatic individuals, and is a focus of secondary disease prevention efforts in Canada.[4]

Technology changes in diagnostic imaging are common, and mammography equipment has undergone a transformational change from conventional film to digital imaging. While these new imaging technologies are often implemented with promises of increased productivity, time savings and improved workflow, the evaluation of new technology implementations in "real-world" settings is often absent. To date, much of the literature evaluating the transition to digital mammography from analog has focused on factors such as spatial resolution, sensitivity, specificity, and abnormal call rates.[5-8]

The transition to digital imaging in radiology has widely been reported to yield workflow improvements such as improved patient throughput and decreased imaging time.[9-14] It is expected that these same benefits also translate to improvements in mammography workflow and throughput. Two studies found the transition to digital mammography decreased acquisition time ranging from 18.1 – 37.3% for diagnostic mammography[15], and 35% for screening mammography.[16] These estimates measured potential improvement, and did not consider other resource and worksite factors that affect throughput.

In Nova Scotia, the Provincial Mammography Review issued a recommendation in 2005 to transition all mammography to full-field digital mammography (FFDM). This transition was phased across several years, using only one vendor, with sites transitioning at different time points. This provides a natural experiment for the investigation of the technology transition impact on mammography throughput volumes in a "real-world" setting.

A number of other factors may impact changes in throughput resulting from the transition to digital technology. First, there is some evidence of increased abnormal call rates with digital screening mammography, which could lead to proportionally more diagnostic mammograms.[5] An increase in the screen abnormal rate could increase the demand for follow-up diagnostic mammograms. The demand for follow-up diagnostic mammograms is relevant to this study and to screening throughput volumes because diagnostic mammograms have a greater clinical urgency, and thus given scheduling priority over screening mammograms. The potential gains in screening throughput may thus be offset by an increased demand for diagnostic mammograms. Abnormal screening

mammograms only account for a portion of diagnostic mammogram referrals, along with patients with a personal history of breast cancer, suspicious clinical findings, and patients presenting with symptoms of breast cancer.

In addition, the booking schedules are largely determined by each individual site, where the number of appointments, appointment type and appointment length could also affect screening throughput volumes. The realization of potential gains in throughput may require the modification of other resources and workflow at the department level such as scheduling systems, layout and design, and staffing (number of full time equivalents (FTEs), experience of the medical radiation technologist (MRT), etc.). Finally, the demand for screening mammograms may not exceed the availability of screening mammography appointments from the analog phase. In such a case, limited demand for screening mammograms would limit potential increases in throughput from the transition to digital mammography.

The objective of this study was to measure the impact of the transition from film to digital mammography imaging on both screening throughput volumes and the proportion of diagnostic mammograms performed in Nova Scotia. The setting is amenable to a multi-group interrupted time series (ITS) design, which is a comparatively strong quasi-experimental design allowing for the measurement of an intervention effect (digital mammography) across sites, with each site acting as a control for the others.[17-19]

There appears to be no evidence of any similar published work in other settings. Measuring the impact of the transition to FFDM on screening mammography throughput volumes and the proportion of diagnostic mammograms provides evidence of the effect of a fundamental technological change on mammography in Nova Scotia. Identifying

sites that have realized the potential benefit of this change in technology can provide valuable information to inform policy and program development within the fixed resources of the public health system.

CHAPTER 2. BACKGROUND

2.1 BURDEN OF BREAST CANCER

Breast cancer is the third leading cause of cancer death in Canada. It is the second most common cause of cancer death for Canadian women, with 1 in 8 expected to develop it over their lifetime. In 2017, it was estimated 25.5% (26 300 cases) of new cancer diagnoses were for breast cancer.[1] Nova Scotia had the highest estimated age-standardized incidence rate for breast cancer per 100,000 people in Canada in 2015 [20], with an estimated 730 new cases of breast cancer diagnosed in 2017.[1] Over the past 25 years, provinces and territories across Canada, supported by the federal government, have established breast screening programs to address this disease burden.

2.2 BREAST CANCER SCREENING

Cancer screening programs aim to decrease disease burden by reducing morbidity and mortality rates through early detection and treatment in otherwise healthy, asymptomatic women.[21] Currently, eleven of Canada's thirteen provinces and territories have implemented breast screening programs. The Canadian Task Force on Preventive Health Care recommends breast screening mammography every 2-3 years for average risk women aged 50-74.[4] The Nova Scotia Breast Screening Program (NSBSP) was established in 1991 and targets asymptomatic women aged 50-69, but women aged 40+ may self-refer via a centralized provincial booking system for screening.

2.3 MAMMOGRAPHY

Mammography is a radiographic technique which uses low dose x-rays to produce images of compressed breast tissue.[22] These images are then reviewed for abnormal findings that may be characteristic of cancer. Screening mammograms are performed on asymptomatic women with no personal history of breast cancer, and typically involves two views for each breast. They are repeated every 2-3 years to detect changes over time and to facilitate early detection of pathology.[23] Alternatively, diagnostic mammograms are performed to investigate an abnormal screen, symptoms or a clinical finding; the MRT may acquire different or additional views for diagnostic mammograms relative to screening mammograms.

Historically, all radiographic imaging techniques, including mammography, have used conventional analog methods (film) for image acquisition, analysis and display. This method of mammography acquisition is termed screen-film mammography (SFM).[14, 22] Conventional mammography imaging was labour intensive for the MRT performing the exam. The SFM technique required four separate views and involved changing film between each view. Then, after acquisition, a considerable amount of time was needed to individually develop and produce the images for viewing. This process involved developing and fixing the film in a darkroom, or, more recently, in an automated film processer. This process was subject to complications such as overexposure, underexposure, artifacts, fog, film jam, issues with developer or fixer fluid, and mechanical failure of the processor.[14]

Recently, the transition to digital acquisition and storage of images occurred across all fields of diagnostic imaging. Improvements associated with digital diagnostic

imaging included ease of acquisition, analysis and display.[11, 13] This transition precipitated the change from screen film mammography (SFM) to full field digital mammography (FFDM) across the country.[14, 22] With FFDM, the mammogram is created as x-rays interact with a digital detector that converts the information into an electrical signal. The most notable difference between FFDM and SFM is that the mammogram itself is digital; the images are acquired, processed, and stored electronically.[22] The entire film developing step in the imaging workflow for the MRT is eliminated and technologists no longer have to stop and change film between images. From a workflow perspective, digital images display immediately to the MRT who can proceed with additional views if necessary; whereas in the analog workflow, the patient is required to wait for potential additional or repeat images while the film images were processed. It is expected that the transition to digital mammography should reduce mammography imaging times, have faster turn-around between images and patients, yield faster processing time, and result in shorter patient visits. These workflow savings should free-up time to allow for additional mammography appointments evidenced by increased throughput volumes following the introduction of FFDM.

Screening mammograms are often performed in high volumes using standard views for each woman. These mammograms are often not read in real time, given that the woman is assumed to be healthy. In contrast, diagnostic mammograms require more time than screening mammograms, as the former is a function of the nature of the referral (abnormal screen, symptoms, or clinical findings) where additional images may be required. Decisions may be made in real time with diagnostic mammograms regarding

the number and types of views. A radiologist may be involved during the procedure and review the images during the appointment.

Since mammography machines are capable of both screening and diagnostic mammography, and diagnostic mammography takes priority over screening mammography given that the woman is no longer assumed to be healthy, an increase in demand for diagnostic mammograms following the introduction of digital mammography could in turn lead to a reduction in the availability of screening mammography appointments. Additionally, because of the elapsed time between a potential abnormal screening mammogram and subsequent follow-up diagnostic mammograms (two-week target time-frame in Nova Scotia), evidence of a feedback loop would not be immediate. There are several indications for diagnostic mammography including an abnormal screening mammogram, physician referrals for patients with a personal history of breast cancer, or suspicious or symptomatic clinical findings. Only a portion of the diagnostic mammograms performed are a direct result of an abnormal screening mammogram. The national target abnormal screen rates for first time screening mammograms is <10%, and <5% for subsequent screens.[24]

In Nova Scotia, the provincial breast screening program (NSBSP) supports centralized booking and clinical reporting of all mammography, while the health authorities are responsible for service delivery and associated resource management. Between 2007 and 2010, all non-mobile mammography units in Nova Scotia transitioned from SFM to FFDM. Anticipated benefits of the transition for breast screening in Nova Scotia were, increased workflow, productivity and throughput. At 8 of the 10 fixed sites included in the study, both screening and diagnostic mammograms were performed. The

NSBSP monitors demand for both screening and diagnostic mammography in real time, assigning higher priority to diagnostic mammograms in the appointment booking process.

The majority of the digital mammography literature has focused on clinical outcomes such as recall rates, detection rates, and abnormal rates. There is some evidence supporting the potential for increased workflow and decreased imaging time as an outcome of digital imaging in mammography. However, these estimates measure potential improvement, in small samples or controlled settings, and do not consider other resource and worksite factors that affect throughput. This study is the first to evaluate "real-world" screening mammography throughput volumes and the proportion of diagnostic mammograms performed following the introduction of digital mammography.

2.4 LITERATURE REVIEW

2.4.1 Transition from Analog to Digital Imaging

Historically, literature on the transition from conventional film imaging to digital imaging focused primarily on general radiography acquisition parameters and departmental factors. This included workflow efficiencies such as image acquisition times, room turnaround times, processing, throughput, and image quality. Although early literature in this area did not focus specifically on the impact of digital imaging on mammography as a specialty within radiography, the overarching principles of digital imaging apply. Herein, the lessons from the literature on the potential impact of digital imaging are pertinent to mammography. This literature review will focus on potential workflow efficiencies accruing from the introduction of digital radiography.

Initial studies on the impact of digital radiography focused on assessing workflow efficiencies, throughput times, turn-around times of images, imaging time and cost justification.[9-13] An early study by Colin [13] found the implementation of digital imaging improved working conditions and decreased procedure and waiting times for patients in France. Specifically, when assessing 292 cases, the patient procedure time was reduced by 6 minutes while their waiting time decreased by 18 minutes. A study by May, Deer, and Dackiewicz[9], out of the Cleveland Clinic, supported the findings of decreased procedure time. They compared 38 analog procedures to 140 digital procedures to determine the total time difference (total time patient is in department) and found that digital radiography required only a third of the time of film imaging. [9] Similarly, Wideman and Gallet's [12] study on analog to digital workflow improvement surveyed seven sites, finding a 43% reduction in the average patient time.

Wideman and Gallet's [12] study also evaluated the difference in room utilization with digital versus analog imaging. They discovered the average time a patient was in the digital room to be 5 minutes compared to 9 minutes with the analog room. Additionally, they found the digital room was in use only 38% of the time, compared to 66% for the analog room, when a fixed number of patients was compared. This provides a theoretical basis for the potential increase in patient throughput with the digital room. [12]

Although these studies indicated that workflow and efficiency improvements can be achieved through the implementation of digital imaging in digital radiography, followed by a theoretical increase in throughput volumes, they did not directly evaluate throughput as a parameter. Additionally, while Wideman and Gallet's [12] study provided little information on methods used for data collection, May, Deer, and Dackiewicz's[9]

method included direct on-site comparisons of the changes in technology during the transition period by assessing analog versus digital rooms simultaneously.[9, 12] A simple method for analyzing pre- and post-transition data collected on-site, this methodological approach did not account for potential changes in trend over time or variations in duration of the pre- and post- intervention.[11] While on-site data collection comparing analog and digital workflow is useful, it is not feasible once the transition to digital imaging has occurred and analog processes are no longer being performed.

Other studies focused on turnaround times between cases and throughput volumes rather than imaging time. A time-motion study was conducted by Pathi and Langlois [10], where an observer measured the start and end times for the digital and analog imaging rooms for five weeks. They evaluated the efficiency of digital radiography in emergency departments and found a 70% decrease in turnaround time for digital radiographs. Turn-around time is a unique measure as it represents the complete imaging cycle, from start to finish as there are several aspects involved in diagnostic imaging beyond the acquisition of the images themselves. [10]

Furthermore, in a study performed in San Francisco, researchers analyzed chest radiographs in two outpatient settings where throughput was measured from the time a patient entered the procedure room, until they left the room. This study directly measured throughput as a measure of productivity where productivity was calculated as the "number of patients moved through the room per hour". They found throughput increased by 30% with digital radiography, enabling medical radiation technologists (MRTs) to image 2.5 more patients per hour.[11]

These studies provided a broader assessment and included throughput in their analysis. However, they used simple on-site data collection that is not achievable once the transitions are complete (where the analog environment is not available for measurement), and pre-/post- methods do not have the ability to assess trends over time. While these studies provide valuable information on digital changes in radiography, there are nuances specific to mammography that they do not address.

Literature on the conversion to digital mammography has focused more specifically on comparing screen film mammography (SFM) to full-field digital mammography (FFDM). This literature has focused primarily on diagnostic performance and utility of digital mammography related to radiation dose, sensitivity, specificity, and spatial resolution regarding recall and cancer detection rates.[5-8, 14] Few studies detailing workflow improvements of the screening mammography due to the transition to digital mammography have been conducted.

A comprehensive descriptive screening mammography workflow study out of Germany, performed by Bick, Diekmann, and Fallenberg [25], looked at a variety of factors related to the digital transition. These included image acquisition, examination time, image processing, image quality, viewing and reporting, and storage compared to traditional film mammography. The key finding across all of these indicators was the potential for improvement of overall workflow with screening mammography in the digital environment.[25]

In 2002, the Canadian Coordination Office for Health Technology Assessment (CCOHTA) released a report on FFDM versus SFM that included technical, clinical and economic assessments. Their report concluded that overall, digital mammography was

expected to reduce time for the patient as well as for the MRT during acquisition.[14] There may also be cost savings relative to staffing with the introduction of digital mammography, as the new technology was expected to save on the number of full time equivalents (FTEs) required compared to analog.[14] This finding is an indirect indicator of the potential for decreased workload with digital mammography imaging.

As with general radiography, studies have also been performed comparing analog to digital imaging times for mammography. Berns et al.[16] study used recorded examination times for 100 digital, compared to 100 analog, mammography acquisitions. They found a 35% decrease in acquisition time (moment patient enters mammography room to when they depart post-processing) for digital screening mammography.[16] The Kuzmiak et al. [15] study that measured the improvement in mammography acquisition times between analog and digital recorded the actual imaging and processing times in the mammography department with a stop watch. They found a reduction in imaging time between 18.1 -37.3 % for digital diagnostic mammography[15], with an absolute time savings of between 2.36 - 4.86 minutes.[15] Both of these studies, directly measured the decrease in imaging time as a result of digital mammography, however they did not expressly measure the impact on throughput.

Since the literature demonstrates the potential for improvements in FFDM workflow, time savings, and productivity, it has helped rationalize the cost of the SFM to FFDM transition. However, most of this research does not assess "real-world" changes in throughput associated with the transition to digital imaging. The literature regarding the mammography transition has predominantly used on-site methods of data collection at a single site, followed by pre-/post- designs, measuring the difference in means with a

Student's t-test. While on-site data collection is a valuable measure of frontline improvements as a result of digital imaging, on-site data collection to assess differences in analog versus digital acquisition is no longer possible once sites have fully transitioned to digital.

Additionally, the aforementioned studies do not specifically measure whether the transition to digital mammography increased mammography throughput volumes. They used the improved imaging time as a proxy for potential increase in throughput. While measuring imaging time differences between analog and digital mammography provides valuable specific information about image acquisition, these small, and for the most part, single site studies did not address the potentially limiting real-world factors that may also affect throughput. These include department layout, availability of appointments, staffing and demand. These studies also did not evaluate the impact of digital mammography on the proportion of diagnostic mammograms performed. Overall, evaluating system level data across multiple sites using a tool that allows for the consideration and measurement of changes in output during the pre-and post-intervention phases and the subsequent impact over time would be preferred.[18] Limitations in these studies could be overcome by using methods such as interrupted time series designs to assess "real-world" changes in trends associated with the implementation of digital imaging.

2.4.2 Interrupted Time Series

Interrupted time series (ITS) is a quasi-experimental design which can be used for serially collected observational data. Using a multi-group ITS design adds rigour to the study as each group acts as the control group for the others. This is valuable when evaluating system level interventions by providing additional systematic control for

historical and secular trends. ITS methods can be used to demonstrate a change in level (or intercept) in the outcome of interest immediately following the introduction of the intervention in question, as well as a change in trend (or slope) that indicates an overall, continuous change in outcome over time, following the intervention. [17-19, 26-28] ITS results can be clearly communicated through graphs, comparing findings counterfactually to the pre-intervention values. ITS analysis requires data that is collected over regular intervals which makes aggregate data from well-maintained databases ideal. [17-19, 26-28]

Historically, ITS methods have been used in a variety of population health settings to measure the impact of interventions, such as public policies, on changes in population health outcomes. For instance, studies have been performed using an ITS approach to measure the effect of copayments on drug use in the presence of annual payment limits[29], the impact of public transportation strikes on use of a bicycle share program in London[30], as well as the influence of the recommendation of routine rotavirus vaccination on hospitalization rates in Germany.[26] The findings of these studies using ITS results were used to provide evidence of the effects of policy change and inform future practice.

ITS methods have also been used to evaluate factors in diagnostic imaging. One of the strengths of diagnostic imaging data for ITS analysis are the meticulous, robust medical health records maintained in hospital information systems (HIS), radiology information systems (RIS) and picture archive and communication systems (PACS). ITS studies in diagnostic imaging have included risk stratification to decrease unnecessary diagnostic imaging for acute appendicitis[31], impact of reimbursement policy change on

CT and MRI use for low back pain in Ontario[32], and evaluation of the effectiveness of access to MRI in emergency situations.[33]

ITS methods have also been used to analyze specific changes in mammography pertaining to policy and education interventions, and external media influences. These policy studies have focused on screening rates following a change in US Preventive Service Task Force (USPSTF) Guidelines[34] and The Affordable Care Act.[35]
Jiang, Hughes, and Duszak [34] used ITS methods to examine changes to screening mammography rates in the Medicare population before and after the release of the USPSTF screening mammography guidelines in 2009. Using a 5% sample from Medicare claims data between 2005 and 2012, they conducted an ITS model with segmented regression analysis where the primary outcome was the monthly screening mammography rate per 1000 beneficiaries. They found an immediate decrease in level of monthly screening mammograms per 1000 beneficiaries following the guideline change, and the change in slope was no longer increasing with statistical significance.[34] Nelson, Weerasinghe, and Grunkemeier's [35] ITS model of monthly mammography volumes from January 1, 2008 through to December 1, 2012 found the Affordable Care Act was associated with an increase in 232 mammograms per month.

Further studies used ITS methods to evaluate education, media and celebrity influences on mammography throughput volumes. Michielutte et al.[36] used an ITS design to evaluate the impact of a community screening education program on screening mammography volumes per month before and after the program activities. They examined the count of mammograms performed, as well as the percentage of mammograms that were age-eligible for the program. Their findings demonstrated that

the education program increased mammography screening rates in the study population.[36] Page et al. [37] used ITS methods to evaluate the effects of a media campaign that targeted Italian-speaking women in New South Wales, Australia on mammography screening participation. They determined that Italian language radio and newspaper advertisements did not increase mammography screening with statistical significance in the target population. These results are beneficial as they inform future initiatives and outreach.[37] A study by Huesch et al. [38], evaluated the change in weekly screening throughput mammography volumes at a hospital in the US following Angelina Jolies' public disclosure of her prophylactic double mastectomy for *BRCA1* gene marker status.

These studies demonstrated the use of ITS to measure interventions related to health policy, education, and media interventions on mammography throughput volumes.[34-38] These general ITS principles can be applied to evaluate the impact of the introduction of digital mammography on screening throughput volumes. In Nova Scotia, no known provincial studies have expressly measured digital technology change as an intervention in mammography, and the impact on both screening throughput volumes and the proportion of diagnostic mammograms performed.

2.5 LIMITATIONS OF LITERATURE

A review of the literature suggests that the introduction of digital imaging in radiology should lead to a decrease in imaging acquisition time, and the theoretical potential for increased throughput. This was found to translate into decreased imaging time for both screening and diagnostic mammography as well, although the number of studies in this area are limited.

Administrators and policy makers require reliable resources to inform decision making rationale as well as limitations of interventions. This information is not always readily available and can at times be of poor quality.[27] The majority of diagnostic imaging literature evaluating the impact of transitioning to a digital imaging department was often a simple before-and-after design, used to measure the impact or outcome of an intervention. These measures are limited because they do not address any underlying secular trend which may be contributing to the findings. A simple before-and-after design has the risk of falsely attributing changes to the intervention in question.[17-19, 27]

There are a few studies that use an ITS method to analyze other factors related to mammography, however these have focused on specific program rates such as detection and participation. The use of ITS methods to measure changes in mammography throughput volumes as a result of the transition to digital mammography is novel. This study will intersect the potential for increased mammography throughput volumes, the proportion of diagnostic mammograms performed and the use of ITS methods to evaluate the change in level (mean monthly mammograms) and trend (slope of the change over time) following the implementation of digital mammography. There is utility in demonstrating both the effect of digital mammography and the use of ITS methods to determine this for future research in diagnostic imaging.

2.6 NOVA SCOTIA CONTEXT

The implementation of a provincial standard for screening mammography makes the Nova Scotia program unique among organized breast screening programs in Canada. There are twelve fixed sites under the umbrella of the NSBSP, along with one mobile unit. These sites are located across the province in regional health facilities, with four sites located in an urban setting. There are no private mammography clinics in Nova Scotia. All sites are part of the Nova Scotia Health Authority (NSHA) and the IWK Health Centre (IWK), with university affiliation. Eight sites are combined screening and diagnostic mammography sites (where both are performed using shared equipment, with diagnostic mammograms taking clinical priority and additional time for imaging); and where diagnostic mammography management is influenced by the NSBSP.

In Nova Scotia, asymptomatic average risk women aged 40 and older are able to self-refer for screening via a central phone number to book a screening mammogram at any of the NSBSP's screening sites. A province-wide central booking system allows the program to fully manage available appointments slots that are largely determined by individual sites within the NSHA and IWK. The NSBSP information system (BIS), together with the provincial PACS, supports standardized patient management and reporting of breast imaging across the province in accordance with NSBSP and Canadian Association of Radiologists (CAR) accreditation standards and volumes. Both the radiologists and MRTs complete ongoing continuing medical education credits in mammography to maintain accreditation with CAR.[24, 39]

The province-wide transition from SFM to FFDM began in 2007. By the end of 2010, all fixed sites of the NSBSP were screening with FFDM.[39] The potential for improved throughput resulting from a more efficient workflow with FFDM relative to SFM is important for mammographic capacity in Nova Scotia, where the current screening participation rate for average risk women for the period 2015-2016 was 54.6%.[24] Improving efficiency and increasing throughput provides an opportunity to maximize output with fixed resources. Assuming unmet demand, identifying areas for increased throughput can support Nova Scotia in reaching the national target for screening participation.

2.6.1 Site Variation

The imaging protocol techniques, and equipment used to perform mammograms across Nova Scotia are standardized, but site-level resources do vary. These site-level resources include the staffing complement (FTEs) and imaging equipment (number of mammography machines). These differences could prove relevant to variation in volume of mammograms performed across the sites. By identifying sites with the greatest throughput volumes following the introduction of digital mammography, further information of best practices can be shared with other sites within the NSBSP and used to improve overall throughput capacity.

2.7 SUMMARY

Breast screening programs use mammography imaging to look for abnormal findings characteristic of cancer in asymptomatic women. Over the past 10 years, mammography imaging has transitioned from film to digital imaging. Previous research

of this technological change has focused on imaging acquisition parameters, and recall and detection rates, while the evaluation of throughput changes in "real-world" settings is absent. There are a number of other factors that may impact changes in throughput resulting from the transition to digital technology such as competing resources between screening and diagnostic mammography, appointment availability, demand for screening appointments, department layout and staffing resources.

The transition from analog mammography to digital mammography in Nova Scotia which was phased across several years, provides a natural experiment for the investigation of the technology transition impact in a "real-world" setting. Describing the variation in screening throughput volume changes across sites is essential to build robust indicators of program and departmental performance and thus ensuring sufficient and timely screening mammography appointments for the target population. However, an evaluation of waitlists and demand are beyond the scope of this study.

Since the target population for any screening program is asymptomatic individuals without underlying disease processes[21], the potential for improved screening capacity with digital imaging (FFDM) is particularly relevant to this study as the NSBSP strives to improve access to screening mammography and meet the national participation target of 70%.[24] By identifying sites with the greatest throughput volumes and determining the departmental factors associated with greater throughput, these sites can be used as a benchmark, and best practices can be shared with other sites within the NSBSP. These data can be used to inform policy and decision makers to improve process at sites with lower screening throughput.

CHAPTER 3. STUDY PURPOSE AND OBJECTIVES

3.1 PURPOSE OF STUDY

The purpose of this study is to estimate the effect of the introduction of digital mammography on screening throughput volumes and the proportion of diagnostic mammograms in Nova Scotia over the years 2006 to 2014. It was expected that the change to digital mammography would increase the screening throughput volumes, given the faster imaging times and reduced processing times when digital is compared to analog imaging. Additionally, if the introduction of digital mammography resulted in a greater screening test abnormal rate for screening mammograms, the proportion of diagnostic mammograms performed may also increase. While diagnostic mammograms are performed for a variety of reasons (abnormal screen, symptomatic women, clinical findings), an increase in the proportion of diagnostic mammograms performed in Nova Scotia might limit screening throughput volumes as a result of this feedback loop.

3.2 OBJECTIVES

The objectives of this thesis are:

Objective 1: To determine the change in screening mammography volumes in Nova Scotia following the introduction of digital mammography, and to explore potential variation in changes in throughput between sites.

Objective 2: To determine if the proportion of diagnostic mammograms performed in Nova Scotia changed following the introduction of digital mammography.

CHAPTER 4. MANUSCRIPT

Assessing changes in throughput of screening mammograms following the transition from film to digital technology in Nova Scotia using a multi-group, interrupted time-series design.

ABSTRACT

Background: Mammography is the gold standard for breast screening and has undergone a transformation from conventional film to digital mammography. Evidence suggests the transition to digital mammography can reduce imaging acquisition times by 18-37%, and thus has potential to increase throughput. Additionally, if the abnormal rates for digital screening mammograms are higher, this may increase the demand for diagnostic mammograms, potentially offsetting any potential gains in capacity for screening mammograms. In Nova Scotia, 10 mammography sites transitioned from analog to digital technology between 2007 and 2010. This provided a natural experiment to evaluate the effect of the transition on throughput volumes in a "real-world" setting.

Method: A multi-group interrupted time-series (ITS) design was used to assess the pre- and post- effects of the transition to digital mammography on screening throughput volumes for the screening sites. Changes in the proportion of diagnostic mammograms performed following the transition were also analyzed. Estimated effects were adjusted for seasonality and site-specific resources.

Results: Four sites in Nova Scotia experienced a statistically significant increase in screening throughput volumes following the introduction of digital mammography. However, there was marked heterogeneity across sites, where the remaining sites experienced no statistically significant change in screening throughput volumes following the intervention. A pooled analysis for all sites found that at the system level, overall the introduction of digital mammography did not statistically significantly change the screening throughput volumes, or the proportion of diagnostic mammograms performed in Nova Scotia.

Conclusion: After the transition to digital mammography, increases in throughput were observed in some sites but not others, suggesting that unmeasured site-specific factors may have limited the potential for improved throughput following the transition. Possible reasons for unrealized potential gains in throughput in some sites include departmental factors such as layout and staffing, booking schedule limitations (availability of appointments), and no additional unmet demand for appointments.

4.1 INTRODUCTION

Breast cancer is the third leading cancer cause of death in Canada and the second most prevalent cancer-causing death for Canadian women. In 2017, an estimated 26 300 new cases were diagnosed in women in Canada, and with an estimated 5 000 deaths.[1] With the significant prevalence of breast cancer in Canadian women, most provinces and territories have implemented breast screening programs in an effort to decrease morbidity and mortality rates.[2]

The gold standard for breast cancer screening is mammography. Mammography uses low dose x-rays to produce images of breast tissue for analysis, looking for abnormal findings characteristic of cancer.[3] Based on screening results, patients may be referred for further investigation (diagnostic mammography).

In radiology, the introduction of digital imaging technology is associated with decreased imaging times, improved throughput volumes, and improved image quality.[4-14] Although there is literature supporting the decrease in imaging times and improved image quality, limited studies have evaluated the impact of digital mammography on throughput volumes in "real-world" settings. Two studies evaluated the transition from analog to digital mammography imaging time workflow and found a reduction in imaging time of 18-37%, which indicated the potential for greater throughput volumes.[15,16]

Additionally, screening throughput volumes may be affected by the demands of diagnostic mammograms. Compared to film, digital mammography is associated with higher detection rates of abnormalities. An abnormal screening mammogram may trigger a follow-up diagnostic mammography appointment. Since diagnostic

mammograms are a priority exam, typically performed on the same mammography scanner as the screens and require additional time and resources above those needed for a screen, potential gains in screening throughput may, over time, be offset by associated increase in demand for diagnostic mammograms.

The Nova Scotia Breast Screening Program (NSBSP) supports breast imaging across the province by providing centralized appointment booking and clinical reporting functions. The NSBSP books all screening and diagnostic appointments in Nova Scotia for all 12 sites and the mobile unite via the central booking system. In Nova Scotia, the Provincial Mammography Review issued a recommendation in 2005 to transition all mammography to full-field digital mammography (FFDM).[17] This transition was phased across several years by way of one vendor, with sites transitioning at different time points between 2007 and 2010, providing a natural experiment for the investigation of the technology transition impact in a "real-world" setting.

4.1.1 Study Objectives

This study employed a multi-group, interrupted time series (ITS) design to evaluate the impact of the transition from film to digital technology on the throughput of screening mammograms across the fixed screening sites in Nova Scotia that qualified for inclusion. Specifically, our objectives were: (1) to determine the change in screening mammography volumes in Nova Scotia following the introduction of digital mammography, and to explore potential variation in changes in throughput between sites; and (2) to determine if the proportion of diagnostic mammograms performed in Nova Scotia changed following the introduction of digital mammography.

4.2 METHODS

4.2.1 Study Design

The NSBSP provides a natural experiment to evaluate the effects of the transition to digital mammography on screening mammography throughput volumes in Nova Scotia since the fixed sites made the transition at different calendar points between 2007 and 2010 (Figure 4.1), in different seasons, with different levels of site resources, but employing equipment from one vendor in a stable population.

A multi-group ITS design was used to assess the transition to digital mammography on screening throughput volumes, treating the fixed sites of the NSBSP as groups. A similar design was used to assess effects on the proportion of diagnostic mammograms performed in Nova Scotia.

4.2.2. Study Population

The study population was restricted to the 10 provincial fixed sites that transitioned from analog to digital mammography. Excluded were one site that transitioned from computed radiography, and the newest site which was established as only digital. Eight of the fixed sites perform both screening and diagnostic mammograms, one performs primarily screening mammograms, and one performs primarily diagnostic mammograms. To address the first objective evaluating screening throughput, the analysis was restricted to the nine sites that perform screening. For the second objective evaluating the change in the proportion of diagnostic mammograms, a pooled analysis for all participating sites of the NSBSP were included.

4.2.3 Data

The study data consisted of aggregate, monthly, site-specific counts of screening and diagnostic mammograms from the NSBSP Information System (BIS), which provides central booking and patient management functions for all breast imaging cases in Nova Scotia. The NSBSP also provided data on site-specific resources including MRT staffing, measured as full-time equivalents (FTEs), and number of mammography machines. For this study, all mammograms (screening and diagnostic) performed at the eligible fixed sites between January 2006 and December 2014 were included.

4.2.4 Outcomes and Measures

The primary outcome variable was volume of screening mammograms performed per site per month. The proportion of all mammograms that were diagnostic was a secondary outcome variable. The primary exposure of interest was the introduction of FFDM. The unit of analysis was 1080 site-months (108 months per site).

Time was measured as the number of months since the beginning of the study (January 2006- December 2014). Additionally, an indicator variable for time following the intervention was included starting [with 1] in the observation period immediately following the intervention and runs sequentially until the last observation[18,19] A preliminary analysis of season indicated that there were seasonal trends in the data, with December historically having fewer screening mammograms per month, and May having more mammograms per month. Based on monthly patterns, the decision was made to collapse the monthly data into four seasons. Season was measured using a factor variable (Winter = 0, Spring = 1, Summer = 2, Fall = 3).

Throughput may depend upon human and machine resources at each site. To account for resources, two variables were included in the analysis, one for the number of machines, and the other as the number of full-time equivalent staff per machine (Table 4.1). The number of screening mammograms performed per month, per FTE per machine was evaluated for each site that performed screening mammograms.

The proportion of diagnostic mammograms per month, per FTE per machine was evaluated using pooled data from all sites included in the study, as the NSBSP may influence diagnostic mammography appointments, and there may be interaction amongst sites as a result.

4.2.5 Ethical Considerations

Ethics approval was granted by the IWK Health Centre Research Ethics Board.

4.2.6 Statistical Analysis

ITS is a strong quasi-experimental design for measuring an intervention or policy change when a randomized control trial is not possible, and serially collected observational data are available.[19-23] ITS allows for the measurement of change in slope and intercept following an intervention (digital mammography). It can clearly communicate results, graphically, when compared counterfactually to a projection of pre-intervention values or other series serving as controls. An intervention is said to have an effect when the post-intervention observations have a change in level or slope compared to the pre-intervention observations, and when compared to other series that experience the interventions at different time points.[19-23]

For the analysis, pooled and site-specific models were run. This study followed the established ITS analysis convention using the following segmented regression equation.[20-22,24]

Model 1:

A pooled model of the following form was estimated:

$$\hat{Y}_t = \beta_0 + \beta_1\, time_t + \beta_2\, intervention_t + \beta_3\, time_t{*}intervention_t + \beta_4\, FTEM_t + \beta_5 machine_t + \beta_6 season_t\, e_t$$

Where $\hat{Y}_t$ is the primary outcome (screening mammography throughput volumes) in month; subscript $_t$ represents period t; $time_t$ indicates the number of months from the start of the series, beginning January 2006 as month 1, through to December, 2014 as month 108; $intervention_t$ is a binary variable taking the values 0 in the pre-intervention segment and 1 in the post-intervention segment; $time_t{*}intervention_t$ is an interaction term with 0 in the pre-intervention segment, starting with 1 in the observation period immediately following the intervention and runs sequentially until the last observation.[19,25] The coefficient β_0 estimates the baseline monthly screening mammography rate at the beginning of the study (SFM); β_1 estimates the baseline trend screening mammogram throughput of SFM (pre-intervention segment); β_2 estimates the change in level in the post-intervention segment (FFDM), β_3 estimates the change in trend (slope) in the post-intervention segment (FFDM); and e_t represents the random error term.

Additional terms were included to adjust for seasonality and departmental resources (FTEs per Machine) where β_4 is the change in level adjusted due to site resources; $FTEM_t$ – measured as the number of FTEs per Machine in period t; β_5 is

coefficient for site resource adjustment (number of Mammography Machines); $Machine_t$ – variable for the number of machines in period t; β_6 is the coefficient for season and $Season_t$ is a factor variable measured with an indicator variable for season (0=Winter, 1 = Spring, 2 = Summer, 3= Fall).

In the pooled model, control was achieved by comparison to other sites which were pre- or post-transition, and the model estimated the average effect on throughput across sites. In the site-specific model, shown below in Model 2, each site was compared to a reference site, Site 1, and we estimated differences in the change in level and slope between sites. Site 1 was used as the reference site because it had 1 FTE and 1 machine for both the analog and digital phases of the study. Sites also provided their own baseline control, through a counterfactual comparison with the extrapolated pre-transition trend. This allowed for a comparison of screening throughput volumes over the entirety of the transition by site.

Model 2:

The site specific model had the following form:

$$\hat{Y}_{it} = \beta_0 + \beta_1 time_{it} + \beta_2 tech_{it} + \beta_3 time_t * intervention_{it} + \beta_4 FTEM_{it} + \beta_5 Machine_{it} + \beta_6 Season_{it} + \beta_7 Site_{it} + \beta_8 (Site_i * time_t \text{ interaction}) + \beta_9 (Site_i * tech \text{ interaction}_{it}) + \beta_{10} (Site_i * time_t * intervention_{i(t-t0)}) + e_{it}$$

Here, $\hat{Y}it$ is the primary outcome for site i, at time t; β_0 is the baseline monthly screening mammography level at the beginning of the study (SFM) for the reference site; β_1 estimates the baseline trend screening mammogram throughput of SFM (pre-intervention segment) for the reference site; $time_{it}$ - measured as the number of months from the beginning of the study at site i; β_2 estimates the change in level in the post-

intervention segment (FFDM) for the reference site; $tech_{it}$ – indicator variable with 0 for analog, and 1 for digital for site i in period t; β_3 estimates the change in trend (slope) in the post-intervention segment (FFDM) for the reference site; $time_t$*$intervention_t$ - measured as the number of months since intervention (0 for analog); β_4 is the change in level adjusted due to site resources; $FTEM_{it}$ – measured as the number of FTEs per machine in site i at month t; β_5 is coefficient for site resource adjustment (number of Mammography Machines); $Machine_{it}$ –variable for the number of machines at site i in period t; *Season* - measured with an indicator variable for season (0=Winter, 1 = Spring, 2 = Summer, 3= Fall); β_7 estimates the baseline difference between sites; $Site_i$ represents the sites; β_8 estimates the baseline level of each site compared to reference site ; $Site_i$*$time_{it}$ *interaction* - measured as the number of months from the beginning of the study for each site; β_9 is the interaction between site and technology that estimates the change is level by site compared to reference site; $Site_i$*$tech\ interaction_{it}$ - indicator with 0 for analog, and 1 for digital for each site; β_{10} is the interaction between site and intervention that estimates the change in slope of sites compared to reference site; $Site_i$ * $time_t$*$intervention_{it}$ interaction is measured as the number of months since intervention (0 for analog) for each site; and e_{it} estimates the error. The primary purpose of this model was to estimate whether the effect of the intervention on level and slope differed between sites, and this the focus of inference was on the overall significance of interaction terms (assessed using a Wald test).

The models were estimated using a feasible generalized least squares (xtgls command in Stata) linear model, which accounts for the presence of autocorrelation and heteroskedasticity in the error term. Given the a priori assumption of autocorrelation

within sites and heteroskedasticity across sites, a heteroskedastic, but uncorrelated error structure across panels (Sites), as well as a first order autocorrelation, AR1, within panels was used.[26]

An additional pooled ITS model was run with the same criteria listed in Model 1 by changing $\hat{Y}t$ (where Y was changed to represent the proportion of diagnostic mammograms performed) to explore the proportion of diagnostic mammograms performed in Nova Scotia.

Using the fully adjusted models above, estimated regression lines for of the statistically significant changes were created and plotted against observed data for each site. The figures generated in Stata are scatter-plots of the real-world data, with predicted regression lines for both the counterfactual, and digital trend. These predicted values were then used to describe the estimated change in screening throughput volumes at sites with statistically significant results.

4.3 RESULTS

4.3.1 Characteristics of Data

The study data consisted of a total of 567,860 mammograms from 10 fixed sites, of which 362,763 were screening mammograms. There were 22 MRT FTEs across all sites during the analog phase working on 15 machines. This changed to 24.6 FTEs working on 13 machines following the transition to digital mammography. The unadjusted mean number of monthly mammograms are shown for both analog and digital phases in Table 4.1, as well as the mean number of monthly mammograms per machine per FTE. Most sites had an increase in the overall mean number of monthly

mammograms per machine per FTE following the introduction of digital mammography, with the exception of three sites (Table 4.1).

The unadjusted mean monthly number of mammograms increased by 33.9% over the study period, and the mean monthly number of mammograms pre-intervention was 435.3 (95% CI 398.6,472.0) compared to 582.8 (95% CI 560.6, 605.0) in the post-intervention phase. The overall mean monthly number of mammograms per machine per FTE increased by 17% from 192.9 (95% CI 182.7, 203.1) to 225.7 (95% CI 218.3,233.0).

4.3.2 Interrupted Time Series Findings

These results of the ITS pooled models (overall effect across all eligible sites, adjusted for seasonality, site resources and autocorrelation) show that screening mammography throughput volumes and the proportion of diagnostic mammograms performed in Nova Scotia did not statistically significantly change following the introduction of digital mammography (Table 4.2 and Table 4.3). The findings from the site interaction model (site-specific effect across for eligible sites, adjusted for seasonality, site resources and autocorrelation, compared to the reference site, Site 1, showed heterogeneity across sites, with the volume of screening mammograms increasing with statistical significance at four sites (Table 4.2). Unadjusted models and results can be found in Appendix B and C.

4.3.2.1 Screening Mammography Findings:

In the pooled model for screening mammography throughput volumes, the coefficients in Table 4.2 (left-hand column) represent the overall mean screening throughput volumes per site, adjusted for seasonality and site factors. The site

interaction model coefficients are the mean values per site, compared to the reference site, Site 1, and are also adjusted for seasonality and site factors (Table 4.2, right-hand column). For the site interaction model, the magnitude of the heterogeneity is illustrated in Table 4.2 of the regression model (adjusted for seasonality, site resources, and autocorrelation) where four sites had a statistically significant change in screening throughput volumes following the intervention that increased by 69.4 (95% CI 4.8, 134.0) to of 453.6 (95% CI 321.2, 586.0) in mean screening monthly mammogram volumes compared to reference site, Site 1 (Table 4.2). The five remaining sites that perform screening mammograms saw no statistically significant change in screening throughput volumes compared to the reference site, Site1.

The site-specific effects of the transition to digital mammography in Nova Scotia on screening throughput volumes are displayed in Figures 4.2-4.5. These clearly show the change in throughput volumes following the introduction of digital mammography. Only the graphs for the sites with a statistically significant change are included. Here, the hash-marked lines represent the counterfactual analog slope, or the predicted slope had the intervention not occurred. The solid line represents the actual slope pre-and-post introduction of digital mammography, fully adjusted for seasonality and site factors.

According to the fully adjusted regression for the predicted counterfactual and digital trends for the four sites with statistically significant results, the mean monthly screening mammography volumes increased ranging from 35% for Site 6 up to 230% for Site 3 (Table 4.4, Figures 4.2 – 4.5). When re-evaluated at 24 months following the introduction of digital mammography, the increase in intercept compared to analog ranged from 39% for Site 6 to 183% for Site 3. (Table 4.4, Figures 4.2 – 4.5).

4.3.2.2 Diagnostic Mammography Findings:

Similarly, for the pooled model examining the proportion of diagnostic mammograms following the introduction of FFDM, the coefficients in Table 4.3 represent the overall mean proportion of diagnostic values, adjusted for seasonality and site factors. This finding indicates that immediately following the introduction of digital mammography, the number proportion of diagnostic mammograms did not change statistically significantly.

4.4 DISCUSSION

4.4.1 Summary of Results

This appears to be the first study to evaluate the "real-world" impact of the transition to digital mammography on both screening throughput volumes and the proportion of diagnostic mammograms. Four sites experienced a statistically significant increase in mean monthly screening mammography volumes, however no statistically significant change was found following the intervention in a pooled model across all eligible sites. There was also statistically significant heterogeneity found between sites.

4.4.2 Screening Findings

Previous studies, in controlled environments, found decreased imaging times for screening and diagnostic mammograms in the digital environment, compared to film, in the range of 18-37%.[4,5] In our "real-world" evaluation of the transition to digital mammography, statistically significant increases in screening throughput volumes, consistent in magnitude to the literature, were observed in only four of nine sites. The

other sites experienced small and not statistically significant, positive changes in intercept and slope.

4.4.3 Potential Factors Limiting Improvements in Throughput

There were five sites in Nova Scotia that experienced no statistically significant change in screening throughput volumes following the introduction of digital mammography. Although every effort was made to include other inputs in the ITS model that may contribute to changes in screening throughput volumes, these variables do not capture all factors that may affect a sites ability to actualize an increase in screening throughput volumes in the "real-world".

A number of other factors may impact changes in throughput resulting from the transition to digital technology. There is some evidence of potentially increased abnormal call rates with digital screening mammography in the literature[6]. The interconnectedness of screening and diagnostic mammography was originally hypothesized to potentially limit gains in screening throughput as time for screens may be offset by an increased demand for diagnostic mammograms. However, this was not the case in our findings.

In addition, the booking schedules are largely determined by each individual site, where the number of appointments, appointment type and appointment length could limit screening throughput volumes. Also, the realization of potential gains in throughput may require the modification of other resources and workflow at the department level, such as layout and design, and staffing (number of FTEs, experience of MRT, etc.). Finally, screening throughput volumes could also be impacted by the

demand for access to screening mammograms where throughput need not increase unless there is sufficient demand for the resource.

4.4.3.1 Feedback and Diagnostic Proportion Findings

The pooled analysis indicated that there was no statistically significant change in the proportion of diagnostic mammograms following the transition to digital mammography in Nova Scotia. Abnormal screening mammograms are only one of a number of indications for diagnostic mammography. Thus only a large increase in demand for diagnostic mammograms from abnormal screens would change the proportion of diagnostic mammograms performed in Nova Scotia. Additionally, it was discovered that the NSBSP actively manage diagnostic mammograms appointments and may influence where and when diagnostic mammograms are performed.

Other factors may affect screening throughout volumes. The booking system is centrally operated by the NSBSP; however, the booking templates are largely generated by the individual sites and provided to the NSBSP to use accordingly. The number, length and type of appointments (screening, diagnostic, core biopsy etc) are primarily decided by the sites. The booking templates control the number of appointments, and ultimately the volume of screening and diagnostic mammograms performed; however, within the booking system, a diagnostic mammography appointment may be flipped to a screening appointment, and vice versa according to real-time fluctuations in demand and need. If the booking templates were not adjusted as a result of decreased acquisition times required for digital imaging, there may be no change in throughput.

4.4.3.2 Site Resources

In mammography, like the rest of diagnostic imaging, the technology is only part of the imaging experience, for MRTs and for patients. Workflow and staffing complement related to departmental resources do not necessarily affect throughput in a linear manner. There are a variety of departmental factors in the literature that may have also limited screening mammography throughput volume changes, including site layout and medical radiation technologist (MRTs) experience (pace, age, adaptability, computer literacy etc).

4.4.3.3 Demand and Preference

Waitlists and demand are key concepts in the world of diagnostic imaging, and those principles apply to mammography as well. While a measure of the demand and wait time for screening mammograms in Nova Scotia are beyond the scope of this study, these factors may affect the volume of screening throughput appointments. In some areas, demand may have been met prior to the introduction of FFDM, and additional appointments may not have been required.

4.4.4 Strengths and Limitations

At the time of this study, all FFDM mammography machines in Nova Scotia were purchased from a single vendor. This level of equipment standardization eliminates inter-vendor variation in imaging platforms and technique, when comparing factors affecting throughput across sites. The images performed in a screening mammogram are standard, though there are a variety of factors (mobility, body composition, breast size) that could potentially affect the number of images. Additionally, all mammography data

came from a single source, ensuring standardized data collection. This study used a complete population, rather than a sample, so no sampling error is present.

While there are no defined number of observations in the pre-and post-intervention phases required for ITS analysis, a minimum of 8 or 9 data points in each of the phases has been recommended. [18,20,21,24] Ultimately, ITS designs improve before-and-after studies with the inclusion of multiple, serially collected data points over time that can detect whether the change was in fact due to the intervention beyond an existing underlying trend.[18-25] A strength of this study was the length of the pre/post phases where the minimum pre-intervention phase was 18 months, and the shortest post-intervention phase was 55 months. The breadth of the data collection across the fixed sites, the inter-site comparison, as well as the per-site comparison to the whole program served as the control for global shifts in trend and are a strength of this study.

The ITS design and associated regression model is powerful in measuring changes following an intervention, particularly in the case of a multi-group design. In this case, these limitations were considered a priori and adjusted for in the multi-group design. This allowed the use of other sites as controls, as well as test for heterogeneity across the sites themselves. The strength of the ITS design is that the coefficients, while "real-world" throughput data, allowed for adjustment for seasonality, autocorrelation, FTEs, number of machines, and shown relative to a reference site.

Assumptions were made at the beginning of this project that present methodological limitations. One of these assumptions was that the sites operate independently of each other. However, the NSBSP manages wait-times in real-time, by making minor adjustments to the schedules to balance demand both within and between

sites by adjusting patient volumes. This practice violates a key assumption in the model. Although the site-specific analysis provides additional information beyond the pooled analysis, the interpretation of site-level results does not account for systemic interactions between sites participating in a larger program.

A further limitation was the assumption that women have both their screening mammogram and diagnostic mammogram done at the same site. Although women are automatically booked into a diagnostic site which is the same as the screening site, women may contact the NSBSP to change the location of the diagnostic appointment. Site 3 provided a great example of the interaction between screening volumes and diagnostic proportions, as well as the potential influence and interaction between the other sites (Figure 4.3 and 4.8).

Measuring the proportion of diagnostic mammograms allowed for the evaluation of diagnostic mammograms relative to all mammograms performed. Since Site 3 did not perform any diagnostic mammograms for 18 months following the introduction of digital mammography, it is reasonable to expect that the volume of diagnostic mammograms at the neighbouring primarily diagnostic mammography site would have increased. Additionally, the results from Site 3 provide evidence of a complex system, where each site is not independent, but rather functions as part of a regional network. This reiterates the limitation of pre/post testing, even with ITS methods. However, a casual perusal of the graphs for Site 3 (Figure 4.3 and 4.8), shows there are additional factors beyond digital mammography contributing to the results.

An analysis of site level resources beyond staffing levels and equipment were beyond the scope of this study. Additional site factors may have influenced screening

throughput volumes beyond that of digital mammography. The inability to measure and account for these factors is a limitation. The fixed mammography sites are not only part of a larger system with the NSBSP, but they are also part of diagnostic imaging departments, and may be subject to a variety of influences such as demand for MRTs to work in other areas or departmental policies, independent of mammography which may confound the analysis.

4.5 IMPLICATIONS FOR FURTHER RESEARCH

In Nova Scotia, further investigation into site-level factors at the four sites that experienced the statistically significant increase in screening throughput volumes may provide information on how to achieve comparable improvements across other sites. Further study addressing the alternative hypothesis (additional site-level factors, demand) may provide valuable insight into factors that may impede or improve screening throughput volumes, in addition to digital mammography. A value stream mapping study or data envelopment analysis (DEA) may highlight factors that increase screening throughput volumes, following the introduction of digital mammography. In future research, a site-level analysis might address variation in workflow across sites. By identifying sites with the greatest throughput volumes and determining the departmental factors associated with greater throughput, these sites can be used as a benchmark, and best practices can be shared with other sites within the NSBSP.

Beyond this study, there is tremendous potential for the use of ITS methods in further research in diagnostic imaging. While ITS methods have traditionally been used to evaluate population health policy changes, this project applied these tools to

measuring a change in technology. The benefit of ITS over simple pre-post intervention analyses is that ITS measures both a change in outcome of interest (e.g., mean number of procedures) and trends over time, while adjusting for autocorrelation and seasonality. In diagnostic imaging, changes in technologies and procedures are common and ITS methods could prove a useful and beneficial tool for evaluating these changes, both immediately following the intervention, and with the trend over time.

4.6 CONCLUSION

The findings reported in this study suggest that the transition to digital mammography in Nova Scotia yielded mixed results by site. Though the pooled results were not statistically significant, four sites saw substantial increases in screening mammography throughput volumes with the introduction of digital mammography. Likewise, the proportion of diagnostic mammograms performed did not change with the introduction of digital mammography in the pooled analysis. Further investigation of the sites that experienced the statistically significant increase in screening throughput volumes may provide insights into how to actualize these results across all sites, thus increasing the capacity for additional screening appointments and improving access to screening mammograms to women across Nova Scotia.

TABLE 4.1: Summary of transition factors and resources by site

Site	Date of Transition	ANALOG						DIGITAL					
		FTE	Machines	Mean Monthly Mammograms			Mammograms per Machine per FTE	FTE	Machines	Mean Monthly Mammograms			Mammograms per Machine per FTE
				Screening	Diagnostic	Overall				Screening	Diagnostic	Overall	
1	03/ 2010	1	1	153.8	82.8	236.6	236.6	1	1	160.6	97.6	258.2	258.2
2	03/2010	1.7	1	217.8	134.3	352.1	207.1	1.7	1	320.2	132.6	452.8	266.4
3	05/ 2010	1	1	216.6	97.5	314.1	314.1	2	1	618.4	114.8	733.2	366.6
4	05/2008	4.3	2	1541.6	.	1541.6	179.3	4.3	1	1216.7	.	1222.9	284.4
5	05/ 2008	4	4	.	783.8	783.8	49.0	5	4	.	759.2	759.2	38.0
6	05 2008	2	1	309.3	217.5	526.9	263.4	2	1	405.9	211.0	617.0	308.5
7	03/ 2010	1	1	179.9	82.8	262.7	262.7	1.6	1	252.6	95.9	348.4	217.8
9	05/2008	2	1	0.8	238.6	239.4	119.7	2	1	87.4	274.1	361.5	180.7
10	03/2010	3	1	152.3	101.7	254.0	84.7	3	1	357.6	131.1	488.6	162.9
11	07/ 2007	2	2	252.3	83.6	335.9	84.0	2	1	304.2	130.4	434.6	217.3
Overall Monthly Means				272.1	163.2	435.3	192.9			375.5	206.6	582.8	225.7

Note – Site 4 performs screening mammograms only. Site 5 performs diagnostic mammograms only.

TABLE 4.2: ITS regression parameters measuring the change in screening mammography throughput volumes following transition from analog to digital mammography

	Screening Mammograms								
	Adjusted* Model Pooled Sites					Adjusted* Model + Site Interaction			
	Coefficient	95% CI				Coefficient	95% CI		
Analog Intercept	275.93	(	222.19	,	329.67)	143.97	(54.66	,	233.28)
Analog Slope	-0.38	(	-1.86	,	1.10)	-0.04	(-0.94	,	0.85)
Change in Intercept	41.24	(	-3.11	,	85.59)	6.36	(-30.47	,	43.19)
Change in Slope	1.03	(	-0.91	,	2.98)	0.18	(-1.04	,	1.39)
Analog Intercept by Site (compared to Site 1)						**P<0.0001**			
2						39.41	(-34.64	,	113.46)
3						25.25	(-58.09	,	108.58)
4						1512.14	(1237.86	,	1786.42)
6						189.36	(85.11	,	293.61)
7						51.43	(-0.50	,	103.36)
9						-156.18	(-271.67	,	-40.68)
10						-30.08	(-210.02	,	149.87)
11						133.96	(-46.65	,	314.58)
Analog Slope by Site (compared to Site1)						**P= 0.1204**			
2						0.93	(-0.52	,	2.39)
3						1.93	(-0.73	,	4.58)
4						-7.73	(-16.51	,	1.05)
6						-2.57	(-5.75	,	0.62)
7						-0.75	(-2.34	,	0.83)
9						0.24	(-3.99	,	4.46)
10						0.97	(-1.06	,	2.99)
11						-0.97	(-7.49	,	5.54)
Change in INTERCEPT by Site (compared to Site 1)						**P<0.0001**			
2						30.00	(-29.91	,	89.90)
3						453.58	(321.21	,	585.96)
4						16.71	(-182.55	,	215.98)
6						115.85	(44.62	,	187.08)
7						69.37	(4.76	,	133.97)
9						84.86	(-5.39	,	175.11)
10						191.09	(107.83	,	274.34)
11						15.60	(-100.76	,	131.96)
Change in SLOPE by Site (compared to Site 1)						**P<0.0079**			
2						0.57	(-1.41	,	2.55)
3						-6.54	(-10.29	,	-2.80)
4						1.30	(-7.80	,	10.39)
6						2.97	(-0.41	,	6.36)
7						1.14	(-0.81	,	3.08)
9						-0.57	(-5.01	,	3.87)
10						-1.40	(-4.15	,	1.35)
11						1.12	(-5.48	,	7.71)
FTEs per Machine	132.10	(	94.83	,	169.36)	-0.34	(-86.05	,	85.38)
Machines	293.57	(	163.93	,	423.22)	-29.71	(-184.57	,	125.16)
Season (vs Winter)						**P<0.001**			
Spring	-2.18	(	-16.90	,	12.55)	4.35	(-6.74	,	15.44)
Summer	23.60	(	6.67	,	40.53)	24.01	(12.36	,	35.67)
Fall	14.71	(	-0.01	,	29.43)	18.43	(7.37	,	29.48)

Wald test of linear hypothesis after estimation
***Summary of model estimated using FGLS with AR1 autocorrelation, a**djusted for Site Resources (FTEs per Machine, Machines) and Seasonality.
Pooled model is for all sites except Site 5

TABLE 4.3: ITS regression parameters measuring the change in proportion of diagnostic mammography following transition from analog to digital mammography – pooled model

	Proportion of Diagnostic Mammograms				
	Adjusted Model*, Pooled Sites				
	Coef.		95% CI		
Analog Intercept	0.2565	(	0.2085	, 0.3044	)
Analog Slope	0.0011	(	-0.0003	, 0.0024	)
Change in Intercept	-0.0138	(	-0.0404	, 0.0127	)
Change in Slope	-0.0008	(	-0.0025	, 0.0009	)
FTEs per Machine	-0.0473	(	-0.0721	, -0.0225	)
Machines	0.2239	(	0.2100	, 0.2378	)
Season (vs Winter)					
Spring	-0.0020	(	-0.0104	, 0.0064	)
Summer	0.0006	(	-0.0091	, 0.0103	)
Fall	-0.0006	(	-0.0090	, 0.0078	)

***Summary of model estimated using FGLS with AR1 autocorrelation,** adjusted for Site Resources (FTEs per Machine, Machines) and Seasonality.

Table 4.4: Predicted mean screening volume by site per month for sites with statistically significant change following the transition from analog to digital mammography

Regression Prediction	Site 3	Site 6	Site 7	Site 10
Analog	223.8	290.1	156.8	174.1
digital at implementation	735.8	392.2	245.2	375.7
digital 24 months after implementation	635.2	404.2	252.6	365.1
% Change at intervention	230%	35%	56.3%	115%
% Change at 24 months post -intervention	183%	39%	61%	110%

Note: Prediction of model estimated using FGLS with AR1 autocorrelation, Adjusted for Site Resources (FTEs per Machine) and Seasonality

FIGURE 4.1:Timeline of transition to digital mammography

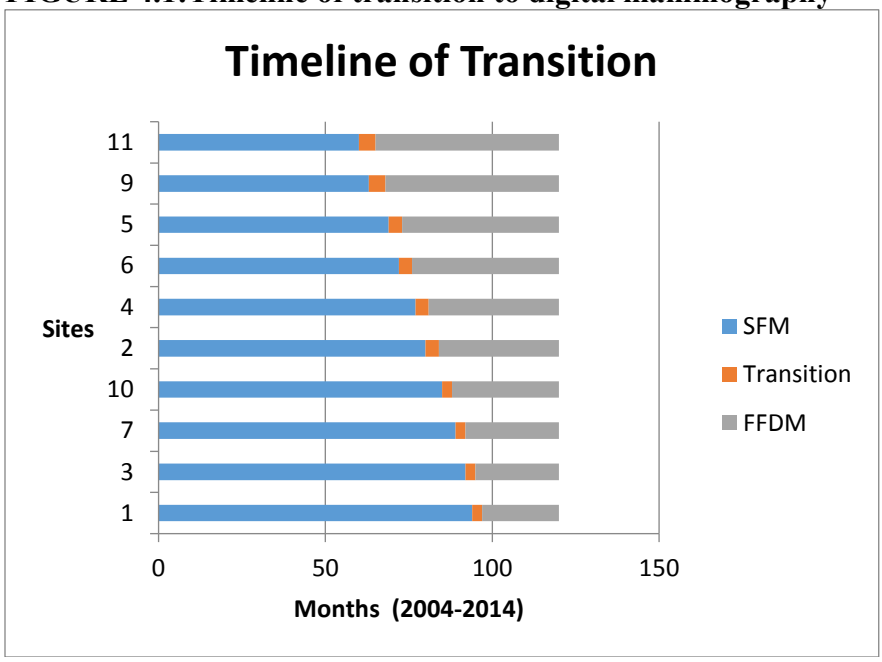
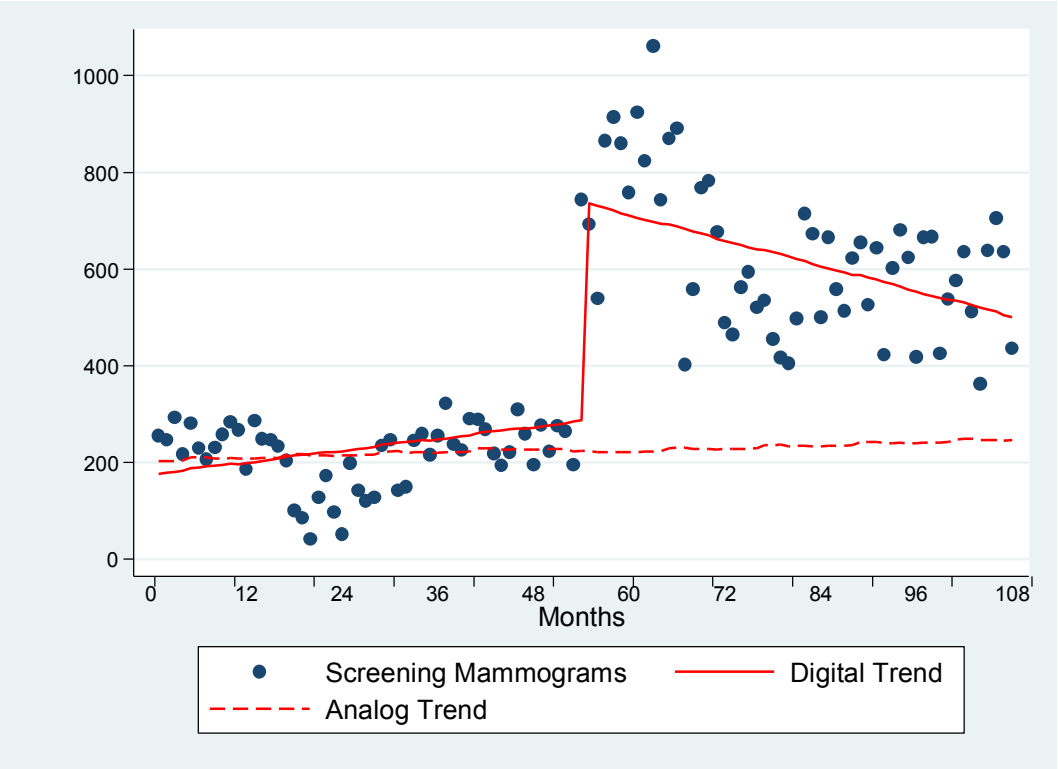


FIGURE 4.2: Observed screening mammograms by site and month

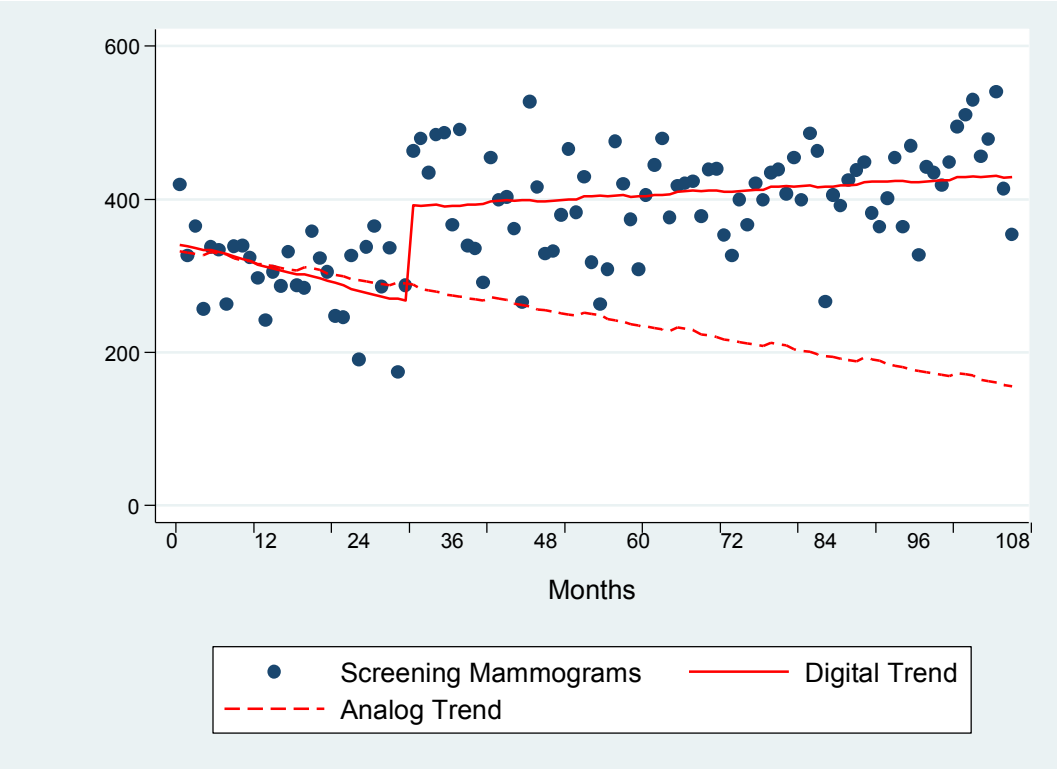
Note: Time adjusted so that zero represents the transition time

FIGURE 4.3: Observed and predicted screening mammograms by month – Site 3



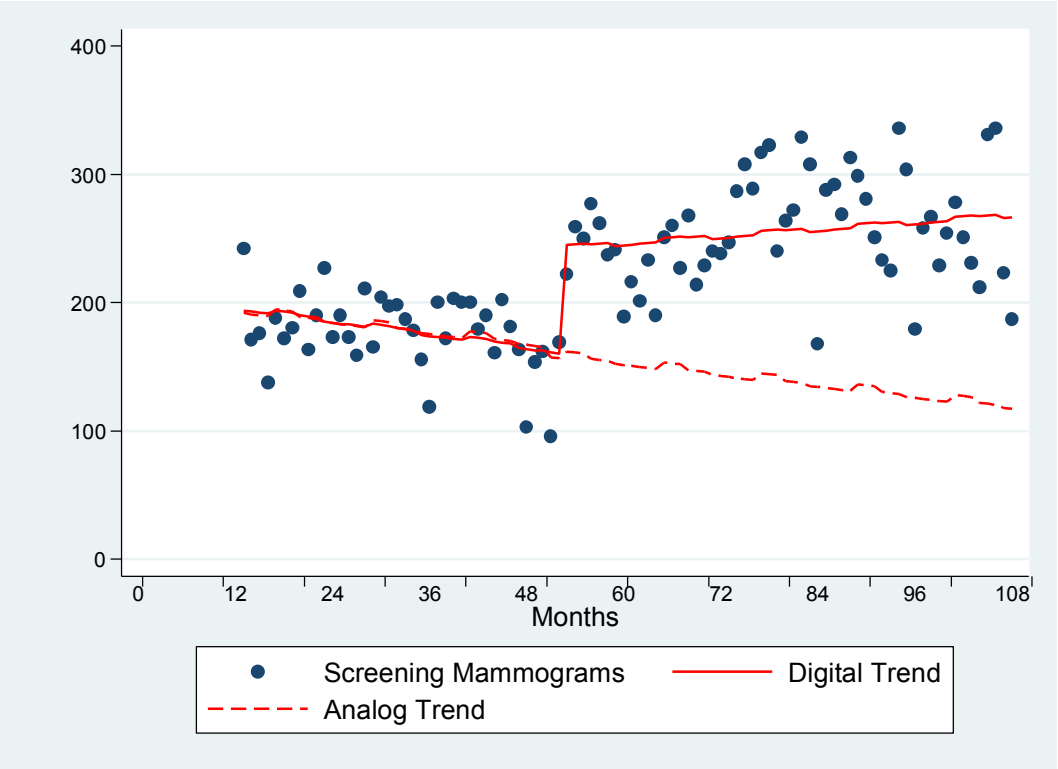
Note: Regression line adjusted for season and resources (FTEs and Machines)

FIGURE 4.4: Observed and predicted screening mammograms by month – Site 6



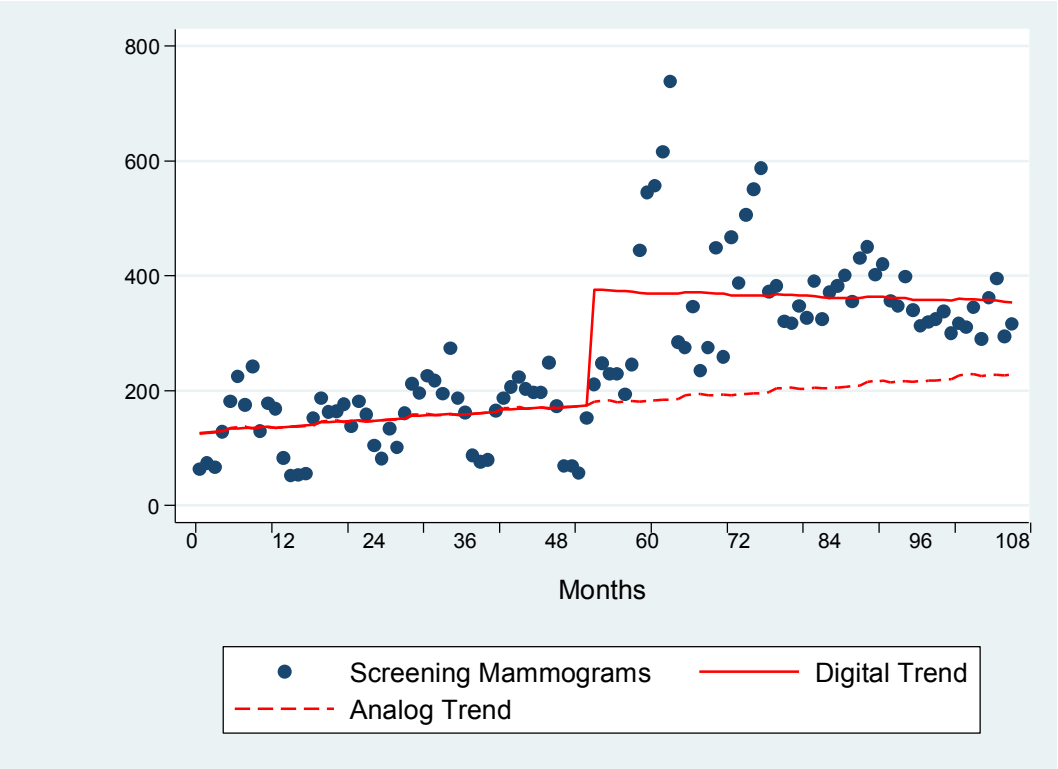
Note: Regression line adjusted for season and resources (FTEs and Machines)

FIGURE 4.5: Observed and predicted screening mammograms by month – Site 7



Note: Regression line adjusted for season and resources (FTEs and Machines)

FIGURE 4.6: Observed and predicted screening mammograms by month – Site 10



Note: Regression line adjusted for season and resources (FTEs and Machines)

FIGURE 4.7: Observed proportion of diagnostic mammograms per month by site-combined screening/diagnostic sites only

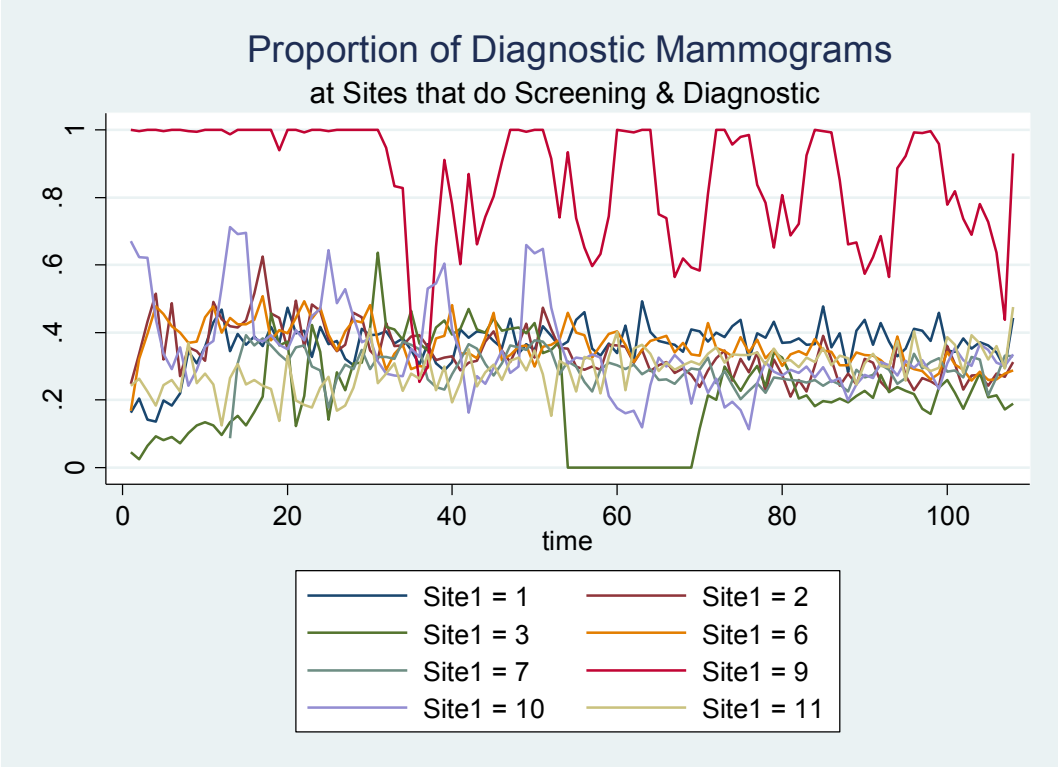
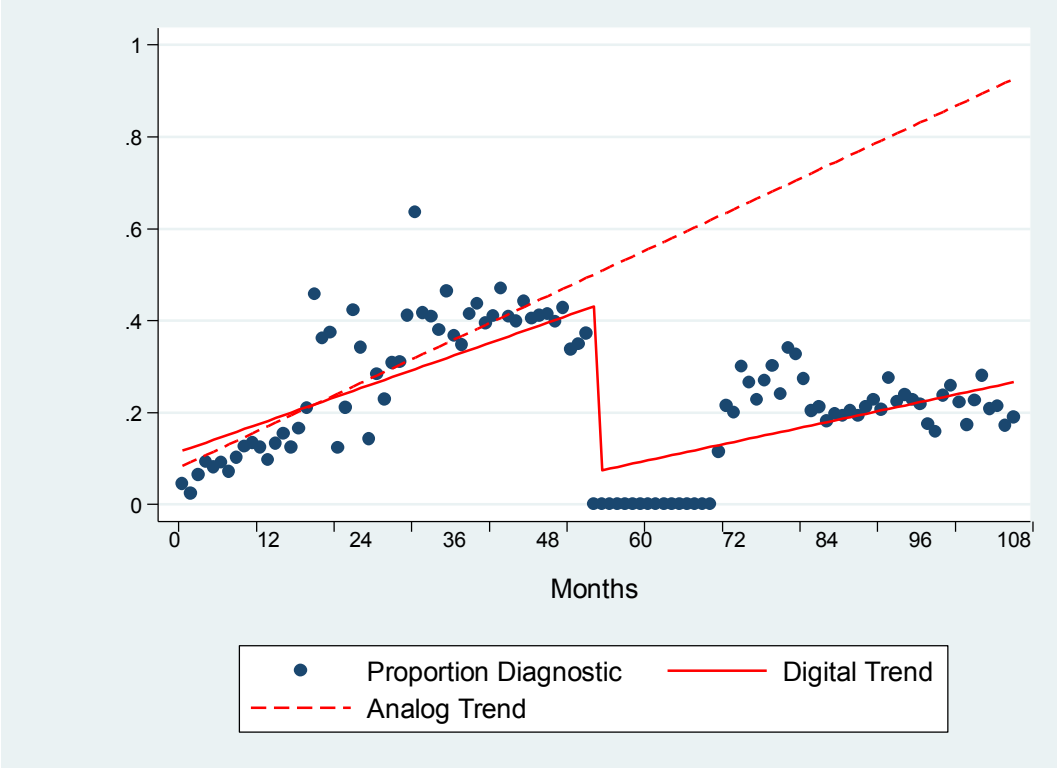


FIGURE 4.8: Observed and unadjusted predicted proportion of diagnostic mammograms by month – Site 3



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CHAPTER 5. DISCUSSION

5.1 REVIEW OF RESULTS

In this study, the effect of a fundamental change in imaging technology was measured. At the program level, the data on mammograms were complete and easily structured for analysis, making ITS an ideal method for measuring the impact of the intervention (digital technology) on throughput volumes. Variation in mammography throughput volumes between sites were suspected prior to this study, but not formally measured.

This study revealed a statistically significant increase in throughput volumes immediately following the introduction of digital mammography of 35-230%, at four sites of the NSBSP. The remaining sites had increases in screening throughout volumes that while not statistically significant, may still have clinical significance. For most sites there was a small, yet non-statistically significant positive change in slope. This was predictable as, in a stable system, changes in slope over time are not expected. Further investigation of the four sites that did show a statistically significant increase in throughput may provide insights for the remaining sites to increase capacity for screening mammograms across Nova Scotia. The effect of digital mammography on the proportion of diagnostic mammograms was non-statistically significant in the pooled model.

Caution should be used when interpreting an immediate change in level of proportion of diagnostic mammograms performed following the introduction of digital mammography, as this is not indicative of a feedback mechanism resulting from positive screening mammograms in the digital mammography environment. A feedback

relationship would have involved a delay between the intervention and an increase in subsequent diagnostic mammograms. While the screening test abnormal rate may be a function of the technology (and there are some indications it can be higher for digital than analog), this effect would take some time to translate into an increased demand for follow-up diagnostic mammography. For instance, if the number of positive screening mammograms increased with digital mammography, the demand for subsequent diagnostic mammograms would also increase, thereby potentially decreasing the volume of screening appointments available within this fixed resource. Diagnostic mammograms are performed for several clinical indications in addition to an abnormal screening mammogram. It is unlikely that a small increase in demand for diagnostic mammograms from abnormal screens would change the proportion of diagnostic mammograms performed in Nova Scotia. The relationship between diagnostic and screening mammograms is relevant to this project because both screening and diagnostic mammograms use the same resources; however, diagnostic mammograms take clinical priority and require more time. In addition, there is a relationship between screening and diagnostic tests, where a positive screening mammogram begets an appointment for a follow-up diagnostic mammogram. The NSBSP closely monitors the time between abnormal screens and follow-up diagnostic mammograms, and can influence when, where and how many diagnostic mammogram appointments are being allotted, in conjunction with the sites. This system level interaction was beyond measure in this study, and was the rationale for measuring the proportion of diagnostic mammograms with a pooled analysis.

Additionally, while accounted for in the model, there were resource changes that occurred during the transition to digital mammography. A description of changes across the sites can be found in Table 4.1, including the date of transition to digital and changes in FTE and machines during the course of the study. The staffing complement remained the same for seven sites and increased at three others. Two sites reduced the number of mammography machines in their compliment with the introduction of digital mammography.

While the fully adjusted site-specific model accounted for variations in resources by site, two of the sites that experienced a statistically significant increase in level following the introduction of digital mammography, also experienced increases in FTEs during that time. In the current study, it is not possible to determine whether the digital throughput increased in part because of staffing, or if staffing increased in part because of expected increases in throughput. It is important to note that the model used in this study was not intended to be a parsimonious model, but rather inclusive of factors that may contribute to or influence the output variable (screening throughput volumes) in addition to the intervention (digital mammography).

The sites with the greatest changes in throughput volumes following the introduction of digital mammography were not always the sites with the most resources. The greatest change in level of screening with digital mammography was found for site 3 which had a resource complement of 2 FTEs and 1 mammography machine; Site 6 and 9 also have 2 FTEs and one machine, and Site 7 had 1.7 FTEs with one machine (Table 4.1).

5.2 STRENGTHS AND LIMITATIONS

While ITS is an effective tool at measuring changes in outcomes following an intervention, both immediately with a change in level, and over time with a change in slope, there are limitations to consider when conducting an ITS analysis. Common limitations of ITS include autocorrelation, insufficient number of observations for pre- and post-interventions, and seasonality were adjusted for in the models.

In a natural experiment such as this, there were undoubtedly external factors that contributed to or potentially confound the results. While every effort was taken to control for potential confounders such as resource allocation (staffing and machine), season and a factor to account for screening and digital mammograms sharing said resources, the potential for unknown influences exists. The relationship between structural factors and throughput volumes, including the central booking schedules (number of appointment slots available, length of appointment slot), departmental design (location of mammography scanner relative to waiting area, change room or technologist work area), and other site specific factors identify issues may result in unmeasured site variation. An internal study limitation was the assumption that the reported changes in FTE and Machine factors pre-and post-intervention, coincided with the transition to digital. However, the exact dates of any change in resource are unknown.

At the outset of this study, it was thought that a simple comparison of the analog booking templates to the digital would provide an indication of whether scheduling adjustments had been made as a result of the potential increase in capacity and decreased imaging time for digital mammography. Unfortunately, the historic booking templates from the analog era were unavailable. There were two limitations due to variations in the

booking templates across and within sites. First, there are several sites that alternate between what is known as a one-tech or two-tech schedule, where the number of appointment slots in the booking template provided to the central booking department alternates depending on staffing levels (Appendix A). For instance, sites may alter their booking schedules based on staff vacation, holidays, or planned downtimes. While it is known that these vary, it was assumed that this variation is consistent year to year. Second, the inability to control for measured changes in the number of appointment slots allotted in the booking templates to the NSBSP pre-and post-intervention is a considerable gap. If the booking templates did not change with the introduction of digital mammography to include additional appointment slots to account for expected decreased acquisition time, then it is unlikely that changes throughput would be found. The limitation in booking template appointments may lead researchers to falsely interpret no change in throughput volumes with no effect from the technology change, rather than due to limitations beyond the technology itself.

CHAPTER 6. CONCLUSION

Breast cancer is a significant public health concern as it is the second leading cancer cause of death for Canadian women and mammography is the gold standard for screening. As mammography along with the rest of diagnostic imaging converts from conventional film to diagnostic imaging, improvements in workflow, productivity and throughput should be evaluated.

The transition to digital mammography took place between 2007 and 2010 across all fixed mammography sites in Nova Scotia. This study evaluated the impact of this technology transition on screening throughput volumes and the proportion of diagnostic mammograms performed across Nova Scotia.

Overall, at the system level, there was no statistically significant effect on screening throughput volumes or the proportion of diagnostic mammograms performed following the introduction of digital mammography in Nova Scotia after adjusting for seasonality, autocorrelation, FTEs and number of machines. However, the results varied greatly across sites. Though the pooled results were not statistically significant, the site results showed that four sites experienced substantial increases in screening mammography throughput volumes with the introduction of digital mammography that were statistically significant.

A simple pre-/post-test of the screening throughput volumes in Nova Scotia indicated that the volumes of mammography imaging (both screening and diagnostic) increased after the introduction of digital mammography; however, results from such an analysis can be misleading. An environmental scan revealed that there was an increase in

staffing resources of 4.6 FTEs across the province in mammography, and that two sites decreased the number of mammography machines with the introduction of digital mammography. Our ITS analysis adjusted for these site factors, as well as seasonality and autocorrelation, which adds rigor to the findings beyond that of a simple pre/post study that does not account for changes in resources, or trends over time.

Significant capital was used to purchase new digital equipment to replace conventional analog mammography rooms, with the reasonable expectation of certain gains such as improved record keeping, sharing of files, streamlined reporting, and increased imaging capacity. The variation in effect of the introduction of digital mammography in Nova Scotia was expected as the governance and administration of breast screening in Nova Scotia is complex.

A number of other factors may affect throughput beyond the transition to digital technology. These potential factors include variations in booking schedules (the number of appointments, appointment type and appointment length could affect screening throughput volumes), departmental resources and workflow such as layout and design, and staffing (e.g., number of FTEs, experience of MRT), and no demand for additional screening mammogram appointments.

In the context of the NSBSP the results of this study, both the pooled and site-specific findings, add value and knowledge for breast imaging in Nova Scotia. Seeing no statistically significant effect at the pooled level for both screening throughput volumes and the proportion of diagnostic mammograms performed is as relevant and interesting as the statistically significant changes seen at a selection of sites. There is as much, if not more to be learned from the sites that experienced no statistically significant effect, as

there is from the sites that did. In a system of fixed resources, understanding limitations and restrictions are as valuable as having champion sites that exceed predicted expectations.

Further investigation of the sites that experienced the statistically significant increase in screening throughput volumes may provide insights into how to actualize these findings across all sites. Additionally, understanding why other sites may not have seen a change may add valuable information about limitations preventing the increase in throughput volumes. Both are essential components for increasing the capacity for additional screening appointments to improve access to screening mammograms for women across Nova Scotia.

6.1 IMPLICATIONS FOR FUTURE RESEARCH

The breast screening program in Nova Scotia is currently accessed via self-referral. With a participation rate of 54.6% in 2015-2016 of the target population, relative to national breast screening target participation of 70%, finding opportunities to increase participation are of value to the NSBSP. This potential for additional capacity is relevant to the NSBSP as they pilot a program to begin formally inviting eligible women to participate in breast screening in Nova Scotia. Understanding the factors that made some sites more productive could yield valuable information, and unrealized capacity in a system of fixed resources. A value stream mapping workflow study of a selection of sites would provide invaluable site level measures and data on departmental factors influencing throughput. A site level investigation may highlight areas and considerations to improve or manage site specific resources to increase screening throughput at the

remaining sites of the NSBSP. It may also be beneficial to do a similar study at a selection of sites that had no statistically significant increase in screening throughput volumes following the introduction of digital mammography to understand site level limitations. This type of research would provide first-hand, on the ground-level measures, compared to the program level investigation used in the current study. Finding the potential for additional capacity in a fixed-resource system is an important factor for policy and decision makers.

Secondly, there is tremendous potential for the broader use of ITS methods in further research in diagnostic imaging. While ITS methods have traditionally been used to evaluate population health policy changes, this project applied these tools to measuring a change in technology. With the advent of electronic health records, and the storage of digital images and relevant information in systems such as PACS (Picture Archiving and Communication System), systematic health data is maintained amidst the ever-changing world of diagnostic imaging. In diagnostic imaging, changes in technologies and procedures are common and ITS methods could prove a useful and beneficial tool for evaluating these changes, both immediately following the intervention, and with the trend over time. The methods also produce highly interpretable graphics, which can convey results to a variety of audiences, and provide useable evidence and context for policy and decision makers.

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39. Personal communication with Trena Metcalfe, Program Manager, NSBSP

APPENDIX A

Site 3 Booking Template

Quality Control Wed from 11:30-12:15

2 Tech Schedule			1 Tech Schedule		
Time	Screening	Diagnostic	Time	Screening	Diagnostic
8:00	1		8:00	1	
8:15	2		8:15	1	
8:30	2		8:30	1	
8:45	2		8:45	2	
9:00	2		9:00	1	
9:15	2		9:15	1	
09:30	1		09:30	break	
09:45	2		09:45	1	
10:00	2		10:00	1	
10:15	2		10:15	1	
10:30	2		10:30	1	
10:45	2		10:45	2	
11:00	2		11:00	1	
11:15	2		11:15	1	
11:30	1		11:30	lunch	
11:45	1		11:45	lunch	
12:00	2		12:00	lunch	
12:15	1		12:15	1	
12:30	1		12:30	1	
12:45	2		12:45	1	
13:00		1	13:00		1
13:15		1	13:15		1
13:30		1	13:30		1
13:45	1	1	13:45		1
14:00		1	14:00		break
14:15		1	14:15		break
14:30		1	14:30		1
14:45	1	1	14:45		1
15:00		1	15:00		1
15:15		1	15:15		1
15:30		1	15:30		
1545		1	1545		
16:00			16:00		

If no diagnostic booked transfer to 2 screens except for break times and 3:45
If 12:15-12:45 screens are not booked can be transferred to dx -1 each 15 mins
Book down Wed from 12:00-12:45 for QC if 1 tech schedule

APPENDIX B

TABLE 4.5: ITS models for screening throughput by sites- unadjusted and season-resource adjusted

		For All Sites*					
	EFFECTS	**Unadjusted Model**			**Seasonally and Resource Adjusted Model**		
		Coef	(95% CI)		Coef	(95% CI)	
	Analog Level	154.20	(126.19 ,	182.22)	143.97	(54.66 ,	233.28)
	Analog Trend	-0.10	(-1.01 ,	0.82)	-0.04	(-0.94 ,	0.85)
	Change in level	11.29	(-26.30 ,	48.87)	6.36	(-30.47 ,	43.19)
	Change in Trend	0.16	(-1.09 ,	1.40)	0.18	(-1.04 ,	1.39)
Site (vs Site 1)							
2	Analog Level	40.99	(-5.43 ,	87.40)	39.41	(-34.64 ,	113.46)
	Analog Trend	0.93	(-0.59 ,	2.45)	0.93	(-0.52 ,	2.39)
	Change in level	29.93	(-32.34 ,	92.21)	30.00	(-29.91 ,	89.90)
	Change in Trend	0.58	(-1.48 ,	2.64)	0.57	(-1.41 ,	2.55)
3	Analog Level	23.26	(-62.14 ,	108.66)	25.25	(-58.09 ,	108.58)
	Analog Trend	2.04	(-0.66 ,	4.74)	1.93	(-0.73 ,	4.58)
	Change in level	447.83	(331.28 ,	564.39)	453.58	(321.21 ,	585.96)
	Change in Trend	-6.56	(-10.40 ,	-2.72)	-6.54	(-10.29 ,	-2.80)
4	Analog Level	1488.97	(1330.48 ,	1647.47)	1512.14	(1237.86 ,	1786.42)
	Analog Trend	-7.32	(-16.08 ,	1.43)	-7.73	(-16.51 ,	1.05)
	Change in level	30.82	(-146.85 ,	208.49)	16.71	(-182.55 ,	215.98)
	Change in Trend	0.95	(-8.16 ,	10.05)	1.30	(-7.80 ,	10.39)
6	Analog Level	189.74	(126.99 ,	252.50)	189.36	(85.11 ,	293.61)
	Analog Trend	-2.47	(-5.74 ,	0.80)	-2.57	(-5.75 ,	0.62)
	Change in level	111.19	(38.26 ,	184.13)	115.85	(44.62 ,	187.08)
	Change in Trend	2.94	(-0.54 ,	6.42)	2.97	(-0.41 ,	6.36)
7	Analog Level	52.46	(1.02 ,	103.91)	51.43	(-0.50 ,	103.36)
	Analog Trend	-0.78	(-2.32 ,	0.77)	-0.75	(-2.34 ,	0.83)
	Change in level	70.75	(17.99 ,	123.51)	69.37	(4.76 ,	133.97)
	Change in Trend	1.16	(-0.77 ,	3.10)	1.14	(-0.81 ,	3.08)

	For All Sites*					
	EFFECTS	**Unadjusted Model**			**Seasonally and Resource Adjusted Model**	
		Coef	(95% CI)		Coef	(95% CI)
9	Analog Level	-156.38	(-236.82 , -75.94)		-156.18	(-271.67 , -40.68)
	Analog Trend	0.38	(-3.93 , 4.69)		0.24	(-3.99 , 4.46)
	Change in level	79.12	(-12.84 , 171.09)		84.86	(-5.39 , 175.11)
	Change in Trend	-0.64	(-5.18 , 3.89)		-0.57	(-5.01 , 3.87)
10	Analog Level	-26.33	(-88.56 , 35.89)		-30.08	(-210.02 , 149.87)
	Analog Trend	0.98	(-1.05 , 3.01)		0.97	(-1.06 , 2.99)
	Change in level	190.22	(106.74 , 273.71)		191.09	(107.83 , 274.34)
	Change in Trend	-1.40	(-4.16 , 1.36)		-1.40	(-4.15 , 1.35)
11	Analog Level	105.38	(29.24 , 181.53)		133.96	(-46.65 , 314.58)
	Analog Trend	0.03	(-6.16 , 6.22)		-0.97	(-7.49 , 5.54)
	Change in level	20.92	(-63.94 , 105.79)		15.60	(-100.76 , 131.96)
	Change in Trend	0.20	(-6.10 , 6.50)		1.12	(-5.48 , 7.71)
Seasonality (vs Winter)						
	Spring				4.35	(-6.74 , 15.44)
	Summer		N/A		24.01	(12.36 , 35.67)
	Fall				18.43	(7.37 , 29.48)
Resources						
	FTEs per Machine		N/A		2.01	(-82.46 , 86.49)
	Machines				-20.60	(-172.05 , 130.85)

*Except Site 5 (diagnostic only)

APPENDIX C

	Pooled Data (All Sites*)																							
	Unadjusted Model					Adjusted for seasonality					Adjusted for FTEs per Machine					Adjusted For All Resources (FTEs per Machine and Machines)					Fully Adjusted Model (Seasonality and All Resources)				
Type of Effect	Coef.		(95% CI)			Coef.		(95% CI)			Coef.		(95% CI)			Coef.		(95% CI)			Coef.		(95% CI)		
Baseline level	243.25	(	164.51	,	321.98)	237.67	(	158.56	,	316.78)	282.85	(	223.42	,	342.27)	284.11	(	230.79	,	337.44)	275.93	(	222.19	,	329.67)
Underlying slope	-0.97	(	-3.11	,	1.17)	-0.83	(	-2.99	,	1.32)	-1.01	(	-2.61	,	0.59)	-0.51	(	-2.00	,	0.97)	-0.38	(	-1.86	,	1.10)
Change in level	48.64	(	2.75	,	94.54)	31.98	(	-14.72	,	78.68)	51.37	(	7.72	,	95.01)	54.11	(	10.45	,	97.78)	41.24	(	-3.11	,	85.59)
Change in slope	1.95	(	-0.92	,	4.81)	2.03	(	-0.84	,	4.90)	1.61	(	-0.52	,	3.74)	0.98	(	-0.97	,	2.94)	1.03	(	-0.91	,	2.98)
Seasonality (vs Winter)																									
Spring	N/A					4.52	(	-6.46	,	15.50)	N/A					N/A					-2.18	(	-16.90	,	12.55)
Summer						24.23	(	12.68	,	35.79)											23.60	(	6.67	,	40.53)
Fall						18.58	(	7.61	,	29.55)											14.71	(	-0.01	,	29.43)
Resources																									
FTEs per Machine	N/A					N/A					85.12	(	45.07	,	125.17)	130.34	(	93.13	,	167.55)	132.10	(	94.83	,	169.36)
Machine											N/A					288.14	(	157.58	,	418.70)	293.57	(	163.93	,	423.22)