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Leveraging the clinical microsystem to offset the limitations of breast cancer screening in the united states

Frida Velcani
Vassar College

Leveraging the clinical microsystem to offset the limitations of breast cancer screening in the United States

Frida Velcani
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Advisors

Janet Gray

Nancy Pokrywka

Dedicated to the memory of my grandmother,

Leni Goga

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Thank you to my friends and family for your overwhelming compassion and generosity. Every day, you inspire me to become a better version of myself.

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Table of Contents

INTRODUCTION

The magnitude of breast cancer in the United States and the human costs it regularly claims is disconcerting. Breast cancer is the second leading cause of death from cancer in American women.[1] My personal relationship with this subject matter is limited to first-hand observation. By virtue of my grandmother, Leni, who battled what began as a diagnosis of breast cancer turned to a decade long fight with metastatic cancer, I gained a sense of what it meant to be a caregiver. Leni displayed the true grit of an Albanian woman who was in reality, ill-equipped to take on the American healthcare system. In a medical landscape where healthcare providers have a stronghold on decision-making, it was clear that her autonomy would be compromised by a cultural barrier to communication. Her dominant language was Albanian, and she understood only a handful of words in English. Under these circumstances, her interactions with health professionals and support staff were mediated by my mother's translations which she often communicated piecemeal back to my grandma. In recognizing Leni's culturally-ingrained phobia of cancer, my mother was also careful to omit any language that hinted at her terminal diagnosis.

Leni spoke about the employees who engaged with her during chemotherapy sessions or visits to her oncologist with great enthusiasm. Their interactions were not traditional in the linguistic sense; she opted to receive and relay emotions through touch. Employees met her smile by gently resting their hand on her back, reassuring her that she was in competent care. Their spirit traveled back to her one-bedroom apartment which she adorned with the flushed pink roses given to her by the office clerk. Following each medical visit to Saint Vincent's Center for Cancer Care, patients are given a rose to commend their resilience during their separately long and arduous journeys. The symbolic significance of the rose may be interpreted in one of two ways depending on one's individual worldview. An optimistic outlook would reckon that each rose represent a mile successfully and valiantly completed by a patient training for their cancer treatment marathon. A less agreeable outlook would consider the rose a mark of an ephemeral existence. The fleeting nature of existence manifests over time as the petals become discolored and the rose hangs limply on its stem. With each medical visit, patients' bodies bear the brunt of cytotoxic drugs and other therapies. Although a patient may be well-informed of the end-goals of their treatment, they may not necessarily be prepared to experience the initial force of depreciating health caused by their intensive treatment.

I found myself wallowing in a pool of angst, not only frightened by my lack of control over the situation but my incapacity to identify with my grandma's internal turmoil. I was unsettled by the level of faith she vested in her providers. Rarely did she pause to consider the risks associated with getting treatment or the chances that it would not fully rid her body of the cancer. She dove in – head-first. Yes, my grandma had always been a woman of strong-will. But in this period of her life, she seemed to blindly express agreement with anyone who was responsible for her well-being. Cognizant of my own experiential limitations, this tension inspired me to embark on a scholarly journey to understand my grandmother's unique experiences as an immigrant woman navigating her personal health and wellness. Amidst a convoluted healthcare system and a shortage of social change, I attempt to reclaim control over our collective understanding of the provision of breast health services. Since screening is currently the gateway to the detection and subsequent treatment of breast cancer, it will be the primary focus of this thesis and the basis for creating best practices guidelines to meet women's unique health needs.

Breast cancer screening is a standard of care in the United States; it is widely believed to help asymptomatic women achieve earlier diagnosis and improve their likelihood of survival. In the interest of being consistent with the majority of literature published on this topic, "woman" is used to refer to individuals assigned biologically female at birth. This is not to negate the existence of breast cancer among men and genderqueer/non-binary/transgender individuals. In this thesis, I strive to characterize the diverse experiences of women who get breast cancer screening or are eligible for screening. A large proportion of women attend imaging centers to get annual or biennial screening. These are the hubs where patients come into contact with service and support staff who may shape the trajectory of their mammography experience. Lest we forget, these experiences are embedded in and inextricably tied to the broader use of medical technology and the organization of healthcare in the United States. Hence, focusing on screening as an isolated process will ultimately prove futile given its intersections with broader systemic behaviors and structural forces in the healthcare industry.

To cultivate a holistic understanding of the ecology in which the delivery of breast cancer screening services take place, the following chapters are organized around the concept of the clinical microsystem. The microsystem typifies a small unit of the larger healthcare organization. In this thesis, the clinical microsystem of a breast imaging center will be used as a conceptual model to illustrate the domains of screening. At a breast imaging center, clinicians and staff are working interdependently for a shared purpose to screen, educate and support women. Studies have shown that the care and outcomes delivered by our healthcare systems hinge on productive exchanges in the workplace between all incoming and outgoing actors. This includes interactions between healthcare professionals, support staff, patients as well as the technology operated in the clinic. Out of this web of relationships emerges a larger trend in patient outcomes.

In order to build a biological and historical framework, I begin by examining the ways that science and the field of radiology have been foundational parts of breast cancer screening. Chapter 1 delineates the biological, behavioral and underlying social factors that are associated with an increased risk of acquiring breast cancer. Understanding the pathogenesis and epidemiology of the disease will become the basis for developing any sort of targeted solution involving the microsystem, as discussed in later chapters. Additionally, Chapter 1 provides insight into the institutional underpinnings of radiology and how doctors have had to sacrifice "visibility" for productivity in managing high imaging volumes.

Screening examinations help women achieve early diagnosis. Mammography, a non-invasive imaging tool that utilizes low-dose x-ray, has been considered the gold standard for the early detection of breast cancer.[2] Although the mammography is rarely condemned in public, its shortcomings are well noted in research literature. High rates of false positive tests have contributed to the relatively high recall rates that exist in the U.S. The sensitivity of mammography also fares poorly among women with dense breasts.[3,4] Overdiagnosis of women with ductal carcinoma in situ (DCIS) has been an additional hotly contested topic.

The perceptions, attitudes and knowledge of patients undergoing screening mammography are documented in Chapter 3. A woman's decision to initially get a mammogram and subsequently adhere to screening is contingent on a variety of factors including her expectations and prior experiences getting a mammogram as well as her deeply-rooted personal values. A synthesis of relevant research on women's experiences of mammography yielded several prominent themes. Many women felt fearful during their visit which was heightened by the long waiting period to receive their screening results. The pain and discomfort experienced during a visit were also determining factors in follow-up compliance. Upholding a patient's autonomy in the decision-making process is equally as important, and calls for efforts to fully inform patients of the effects of ionizing radiation and breast density legislation.

The characteristics of high-performing microsystems are outlined in Chapter 4. Often times, current care may fall short of achieving an ideal version of care due to gaps in knowledge, poor clinical decision-making, unsafe transitions of care or ineffective teamwork.[5] Researchers have postulated how these breaches in performance may be "attributed to the way our clinical teams are organized and how they function and relate in the context of the larger healthcare organization."[5] This chapter discusses how clinical units can be leveraged to optimize the quality and safety of how we deliver breast cancer screening. According to literature, high performing microsystems demonstrate the following eight qualities: integration of information, alignment of role and training, measurement, interdependence of the care team, supportiveness of the larger system, connection to the community, constancy of purpose, and investment in improvement.[6] The clinical microsystem assessment tool will be used as an apparatus to engage breast cancer imaging teams in the process of clinical redesign.

The final chapter pushes a new agenda among healthcare professionals referred to as the personalized risk-based approach. This approach delivers differential services to women based on an assessment of their risks and affirming dialogue between them and their provider (technician, radiologist or primary care physician). In finding a delicate balance between achieving welfare gains for underserved female populations as well as profit seeking aims, a personalized risk-based approach can surmount many of the outstanding issues with screening. It combines various practices and imaging techniques that purportedly maximize specificity and sensitivity while minimizing cost and radiation exposure.[7]

CHAPTER 1: BACKGROUND

Pathogenesis and Epidemiology

Breast tissue may develop abnormalities which are sometimes deemed cancerous. Breast cancer forms in the breast tissue, particularly in the ducts (tubes that pass milk from the lobules to the nipple) and lobules (glands that make milk). A lump in the breast may indicate a growth of normal cells, cancer cells, or atypical cells which is the intermediate between them. Cancer cells divide uncontrollably and can spread into nearby tissues. If cells stay within the milk ducts or lobules it is considered non-invasive, also termed *in situ* masses. Many *in situ* masses will resolve on their own and/or not progress to invasive cancers. If the cancer has spread beyond the membranes of the mammary gland (ducts and lobules), into surrounding tissue, then it is called invasive. It may migrate beyond the breast by passing through the blood or lymph system. This condition is referred to as metastatic breast cancer.[1]

Cancer cells are differentiated from normal cells by their appearance in distinct *grades.* Grade 1 would indicate a low grade; cancer cells look mildly different from normal cells and are slow-growing. Grade 2 suggests cells that look different from normal cells; they grow slightly faster than normal cells. Grade 3 refers to cells that look very different from normal cells; they grow very fast.[1]

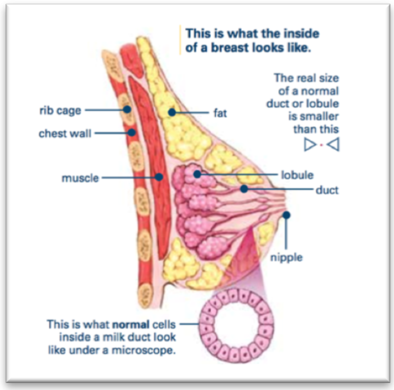

Figure 1. Anatomy of the female breast (Breastcancer.org 2016).

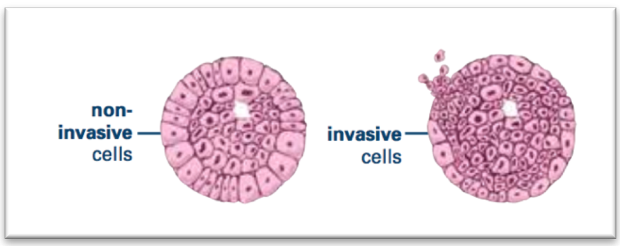

Figure 2. Visual comparison of a non-invasive cell and invasive cell (Breastcancer.org 2016).

Breast cancer is the second leading cause of death from cancer in American women, trailing lung cancer. About one woman in eight women (~12.4%) will be diagnosed with the invasive form of the disease over the course of her lifetime. In 2018, "an estimated 266,120 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S., along with 63,960 new cases of non-invasive (in situ) breast cancer."[1] In 2018, 2,550 new cases of invasive breast cancer are expected to be diagnosed in men.[1] Although this may occur in both women and men, a man's lifetime risk of breast cancer is lower at 1 in 1,000. Breast cancer incidence rates in the U.S. have been decreasing since 2000, concluding a two-decade period of rapid growth in breast cancer cases. The declining use of hormone replacement therapy (HRT) is hypothesized to have contributed to these decreasing rates.[8]

African-American women demonstrate higher rates of mortality from metastatic breast cancer than women of other race/ethnicities in the United States. The occurrence of breast cancer is more common in non-Hispanic Black women (NHB) under 45 years of age, relative to non-Hispanic White women (NHW). For Asian, Hispanic, and Native-American women, the life-time risk of developing and dying from breast cancer is lower. Between 1975 to 2013, the 5-year cause-specific survival of NHW women for metastatic breast cancer was (19-37%) higher as compared to other racial ethnic groups, especially NHB (16-26%). Some of the variables that account for the racial disparity between NHB and NHW, adjusting for age, include socioeconomic factors followed by tumor characteristics and finally metastatic pattern. African-American women are subsequently more likely to be diagnosed with advanced breast cancer characterized by high-grade tumors.[9]

A woman's risk increases with the following factors: age, a personal or family history of the disease, a known *BRCA1* or *BRCA2* gene mutation, beginning menstruation at an early age, older age at birth of first child or never having given birth, breast tissue that is dense, use of hormones such as estrogen and progesterone, obesity, and consumption of alcoholic beverages. A woman is also at high risk if they've identified a first-degree relative with a *BRCA1* or *BRCA2* gene mutation. She similarly qualifies as high-risk if a risk assessment tool measures her lifetime risk of breast cancer at about 20 to 25 percent or greater. Other risk factors include having radiation therapy to the chest when they were between the ages of 10 and 30 years, a genetic disease such as Li-Fraumeni syndrome, Cowden syndrome, or hereditary diffuse gastric cancer, or having a first-degree relative with one of these diseases.[10]

Breast Imaging Center: Service and Support Staff

Breast imaging centers support the philosophy of using opportunistic screening as a vital prevention strategy for women who are at average or high risk for breast cancer. Service and support staff at a breast imaging center typically include front desk receptionists, technicians, and breast radiologists. The front desk clerk is the first point of contact for patients visiting the medical office as well as the gatekeeper facilitating the patient's entry and continuous care. Patients are then handed off to the radiologic technologist or radiologic technician under whose custody they are for the bulk of the appointment. The technician's main responsibility is to operate the mammography machine to produce digital images. They position the patient's breast on the mammography unit and compress it with a clear plastic paddle in order to visualize the breast effectively. Certainly, the intimate nature of this interaction necessitates that technicians assume a comforting presence, helping to alleviate any anxiety felt by the patient. The examination process takes about 30 minutes and concludes after the radiologist deems the images suitable.

The breast radiologist analyzes the mammography images upon which they may report the results to the patient's primary care or referring physician. The referring provider may discuss the results of the mammogram, otherwise, most screening facilities will directly contact the patients to notify them of their results. Sometimes the radiologist will be entrusted with the task of specifically discussing an abnormal mammogram with the patient and her family.[11] Over the years, radiologists have established good rapport with other providers. Dubbed the 'voice of reason' among their colleagues, radiologists have the upper hand when it comes to decisions like whether or not to request follow-up exams or long-term monitoring upon discovery of an abnormality in the images.[10]

Administrative and clerical staff play a pivotal role in ensuring women have access to high quality services. A detailed description of their job expectations in the UK is available online through the National Health Service (NHS) Breast Screening Programme. Given the thoroughness of this data, I will be using UK performance standards for administrative and clerical staff to achieve a baseline understanding of their roles in the U.S. The operations within a breast screening office can easily become destabilized without up-to-date, reliable computer systems and more importantly, motivated and skillful employees. Staff are primarily responsible for ensuring timely and accurate exchange of information between the screening office (SO) and health authority (HA). In the UK, health authorities are local level officials and serve as a direct link between the Department of Health and the NHS. Staff also facilitate communication between the general practitioner (GP), primary health care team (PHCT), and the SO. They ensure that GPs and PHCTs are effectively promoting breast screening among their patients. Correspondence with patients is also maintained via written letters, telephone and face-to-face communication. Women eligible for screening are sent invitations on a regular basis and are communicated their results following their visit. They are also provided accurate and up-to-date literature informing them about the screening process.[12]

Radiologists: Evolution Through Time

When radiologists entered the scene in the late 1800s after the discovery of the x-ray, they came from wide-ranging professional backgrounds. Unlike modern day health experts, these radiologists were not necessarily board-certified MDs. Yet, relative to their present-day counterparts, their responsibilities were significantly more comprehensive. Radiologists performed the patient's imaging examination in addition to interpreting the acquired image. The radiologist would then communicate the findings directly to their patient and give them the option to keep the images. Decades later, a bureaucratic operation to legitimize the field of radiology changed workflow and patient-provider relations. Images were no longer a free souvenir nor a commodity to be purchased, they became the property of the medical office. Medical offices emphasized that patients were not being charged for their images, but rather for the one-on-one consultations they had with the radiologist. On the suggestion of the American Roentgen Ray Society in 1916, radiologists began exclusively consulting referring physicians with image results. As a final attempt to "enhance professional prestige," radiologists specialized in the lucrative craft of interpreting images while technicians were hired to fill in the remaining gaps.[13]

An adversarial healthcare system with hospitals and radiologists struggling to act in their own self-interest resulted in the contemporary manifestation of the 'Invisible Radiologist.' Rather than investing in private practice resources, circa 1930s, radiologists were galvanized to join hospitals that enjoyed a vast expanse of up-to-date equipment. Yet after being haphazardly placed in various hospital departments, they received minimal recognition for their work. As the lone radiologist in a section of surgery or cardiology, the radiologist was not only overshadowed but also under the jurisdiction of other providers in that department. Radiologists were further displaced from a position of visibility as hospitals prohibited them from billing for imaging services. The 1960s, however, brought a wave of technologic innovation and more formal radiologic training. Radiologists transformed into more marketable entities, eventually contributing to their own commoditization. In 1965, the Medicare bill finally gave radiologists the legitimacy to bill patients for their medical services. Despite increasing demand for radiologic procedures, radiologists continued to abide by traditional customs of not communicating with patients. Academic departments also failed to facilitate training programs to push forward a new standard of patient interaction. To this day, radiologists' offices are relegated to the background, isolated from the clinic and the patients that they serve.[13]

Although radiologists specializing in breast imaging have made significant progress in constructing a path towards visibility, they still pale in comparison to most long-term providers. Radiologists almost exclusively step out from behind the curtain when having to disclose an abnormal finding to a patient. As a result, their presence has tragically become a forewarning of illness.[14] A survey conducted between 2006 – 2007 shows that 77% of providers often or always communicated the abnormal results of diagnostic mammographic examinations to their patients. Yet, less than 47.3% communicated the normal results of diagnostic examinations.[13] The upside is that radiologists have presumably by this point mastered the art of responding to sorrow and anxiety.[14] The gloomy backdrop of their limited interactions with patients, however, may have also unintendedly weakened their bond with patients. Pathologists are similarly positioned at the bottom of the medical hierarchy in terms of patient contact. Automation has made their work more technologically intensive and as a result, commodified the fruit of their labor. Unlike pathology tests, the imaging services offered by radiologists are not solely differentiated by price. Radiologists have the opportunity to market themselves as indispensable members of the healthcare team, drawing on their expertise to offer personalized services that fit each patient's individual health care needs.[15] The American College of Radiology (ACR) proposes this as an initial first step towards becoming a more visible member of a patient's healthcare team. This step also subscribes to the ACR's long-term goal of having radiologists directly communicate the results of imaging tests to patients.[16]

CHAPTER 2: BREAST CANCER SCREENING

Routine breast cancer screening is conducted with the objective of improving timely detection of an invasive cancer so that it may be treated effectively. Breasts are commonly examined through physical examinations and mammography, while laboratory and genetic tests also exist to detect risk-related mutations. Individuals are offered one or more tests based on a medical assessment of their risk factors.[17] Though physical examinations can discover breast lumps, they are diagnosed as benign 80% of the time. Cysts are characterized as fluid-filled benign lumps and are usually found in women under 40. They feel smooth or round. Fibroadenomas, noncancerous breast tumors, mostly affect women in their 20s and 30s, are benign, and have a smooth and firm or rubbery texture. Cancerous lumps, on the other hand, are irregular in shape and they may feel firm and fixed to the breast tissue.[18]

Mammography

A mammography screening exam, referred to as a mammogram, can help physicians with the early detection and diagnosis of breast diseases. It is a non-invasive medical imaging tool that utilizes low-dose x-ray to produce pictures of breast tissue. Screening mammography can detect breast cancers up to two years prior to the disease physically manifesting itself. Patients who may have demonstrated symptoms or obtained abnormal results from their screening mammogram may be recommended for diagnostic screening. If a doctor prescribes a diagnostic mammogram, multiple x-rays will be taken to offer a view of the breast from multiple vantage points. A spectrum of women visibly reap the benefits of imaging: women who are relatively symptom-free as well as women with symptoms such as a lump, pain, skin dimpling or nipple discharge.[10] This thesis, however, will hone in on understanding the process of routine screening and refrain from further investigation of the diagnostic test that may be hypothetically administered afterwards.

Mammography has been considered the gold standard for early detection of breast cancer.[2] Its effects have been studied in randomized trials which reveal 15 to 25% reductions in mortality rates associated to breast cancer, whereas meta-analyses of observational studies show 13 to 17% reductions in mortality rates.[19] Using this breast imaging technique, radiologists can detect small tumors like ductal carcinoma in situ (DCIS) early before they can cause harm to the patient. DCIS describes small abnormal tissue growths in the milk ducts in the breast. Screening mammography can also detect invasive ductal and invasive lobular cancer which are conditions where the cancer has spread to the surrounding breast tissues. While robust concerns about radiation exposure exist, protection organizations insist that the benefits of getting diagnosed outweigh the associated risks, under most circumstances.[10]

Other screening tools including ultrasound and magnetic resonance imaging (MRI) may supplement mammography to improve accuracy in detecting breast cancers. Eligible women are advised by their referring doctor or radiologist to pursue these adjunct screening modalities. Breast MRI targets women who are at high risk for breast cancer due to a strong family history. An additional 14.7 cancers per 1000 women are detected when MRI is used in addition to mammography and whole breast ultrasound.[20] The American Cancer Society recommends it for women defined as high-risk (20-25% greater than that of the average woman) or who haven't undergone genetic testing but are first-degree relatives of BRCA carriers.[21] MRI requires the injection of intravenous contrast to detect differences in blood flow within the breast. A cancer typically demonstrates different blood flow compared to the normal tissue that surrounds it. Although breast MRI has demonstrated high sensitivity, it is not as specific which may lead to unnecessary biopsies. Some physicians may allow patients to obtain mammography and breast MRI in the same visit, while others advise them to separate screenings by 6 months.[7] Ultrasound also benefits women with dense breast tissue, characterized by excess ducts, glands and fibrous tissue and little fat. It is generally harder to visualize tumors in dense breasts via mammography.[10]

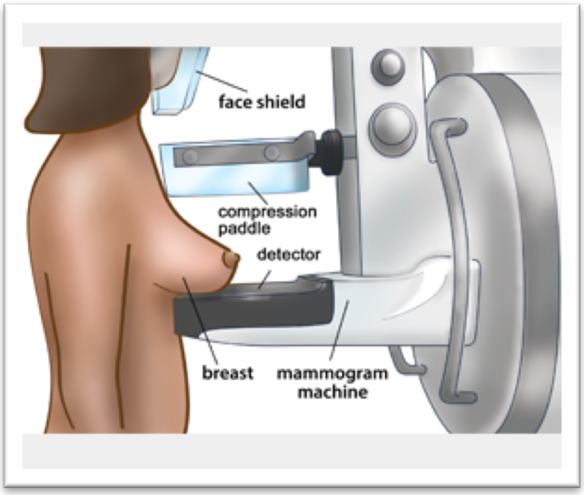

Figure 3. Lateral view of breast positioning during mammography (CancerCareManitoba).

Screening Guidelines

The influence of political actors and stakeholders plays a functional role in constantly shifting the recommended standards of practice. Breast cancer screening guidelines have been at the center of controversy throughout mammography history. Radiologists, at one point in history, were excluded from even joining panels that engaged in the discourse about medical guidelines. To facilitate widespread acceptance of guidelines, however, doctors must be mobilized to recommend periodic screening to their patients. Government and private insurance companies would also need to embrace these new standards in order to cover the costs associated with screening. Perhaps most importantly, women should be encouraged to partake in the 21st century wave of self-advocacy, demanding expanded coverage for medical and screening services.[22]

Breast cancer screening recommendations vary from yearly to biennially according to the organization. Current practice and proposed guidelines from the U.S. Department of Health and Human Services (HHS) and the American College of Radiology (ACR) suggest that women get annual mammograms starting at age 40.[10] Other major consensus groups and organizations in the United States also promote screening at age 40 including the National Cancer Institute, American Medical Association, American College of Surgeons, American College of Physicians, American College of Obstetrics and Gynecology.[7] The American Cancer Society has recently shifted its guidelines to recommend annual screening to women at average risk of breast cancer starting age 45 rather than age 40. They also encourage women to withdraw from this aggressive form of screening after the age of 55 and alternatively pursue biennial screening.[23]

The National Cancer Institute (NCI) advises women to consider screening at an earlier age if they've been previously diagnosed with breast cancer or have a family history of breast or ovarian cancer. Women at high risk for developing breast cancer may consult their providers about obtaining a breast MRI in addition to annual screening mammogram. Most such groups recommend breast cancer screening begin at age 40 and women with a first-degree relative diagnosed with breast cancer begin annual mammography 10 years prior to the age of diagnosis of that relative.[10] The United States Preventive Services Task Force (USPSTF) is currently the only panel of health care professionals that recommends screening every two years beginning age 50 for women at average-risk. It was this very recommendation that sparked a passionate debate regarding optimal screening strategies among organizations.

Limitations of Mammography

As part of an overt strategy to sow the seeds of screening into standard of care, the shortcomings of mammography have rarely been publicly noted. Rather, its potential benefits are inflated, causing many women to overestimate its benefits. Deceiving marketing strategies have involved plastering images of premenopausal women onto campaign ads, misleading women against the well-known fact that they have a higher risk of developing cancer in their later years.[22] Sensational taglines have broadcasted false information to convince women that they have a one in ten lifetime probability of developing breast cancer, historically instilling a sense of panic among women. Although these techniques successfully drove up mammography screening rates by capitalizing on the fears and ignorance of women, they also left many of them lacking adequate patient education about the limitations of mammography.[22] The excessive acclaim over screening has led some women to wrongly view mammography as a resource for preventing the onset of breast cancer.[22] In a study by Domenighetti et al. (2003), 68% of women were under the assumption that mammography lowered their risk of getting breast cancer.[24] Oblivious to their outstanding risk of cancer-associated mortality despite screening, women may experience a wave of outrage or confusion on the off chance they get diagnosed.[22] It may also disincentivize them from actually engaging in prevention efforts such as getting educated on the social and environmental risks that predispose some individuals to breast cancer.

By framing breast cancer screening as a political issue, we can begin to expose the underlying influences behind aggressive screening in the United States. A fixation on early detection and mammography has fabricated a "pink ribbon" culture, gaining endorsement from groups seeking capital gain.[25] A synergy specifically between government and health technology manufacturers has encouraged the ubiquity of pink ribbons as well as facilitated the development of national mammography markets. Well-funded and reimbursed screening programs sponsored by nations in Western Europe, North America, South Korea, and Japan are correlated with mature mammography markets. Mature markets have large investments in infrastructure including mammography units and diagnostic centers and show high demand for upgraded replacement equipment.[26] The U.S. boasts the largest and most advanced mammography market with regards to equipment, technology, and available care. It secured substantial revenue following the elimination of cost sharing under the Affordable Care Act which boosted rates of screening among older women living in areas with the highest quartile of educational attainment.[27] Strong health infrastructure, participation and coverage among the population has triggered a commensurate strengthening of the overall market.

The rapidly growing mammography global market was valued at 1.43 billion USD in 2015. It is projected to have a compound annual growth rate of 10.5% between 2018 – 2025 with revenue contributions made by rising breast cancer cases and growing awareness about preemptive screening.[28] Yet, only a handful of manufacturers in mature markets account for over 80% of global mammography revenues in 2017. Hologic was the largest market share holder, with GE Healthcare and Siemens Healthineers following respectively as the second and third-largest manufacturers. Demand for innovative products that incorporate artificial intelligence, 3D tomosynthesis, and patient comfort has been satisfied by products like Hologic's 3D mammography unit, 3Dimensions, and GE Healthcare's Senographe Pristina.[26] The surging demands behind advanced screening technology surreptitiously hide many public health agency's diminishing support for aggressive screening. Revenues from the breast cancer industry are diffused among the same agencies that have shown unrelenting support for screening starting at age 40. The American College of Radiology owns the trademark for "The Mammography

Saves Life campaign." Siemens and General Electric respectively sponsor the American Cancer Society's Make Strides Against Breast Cancer campaign and the American Breast Cancer Foundation.[25]

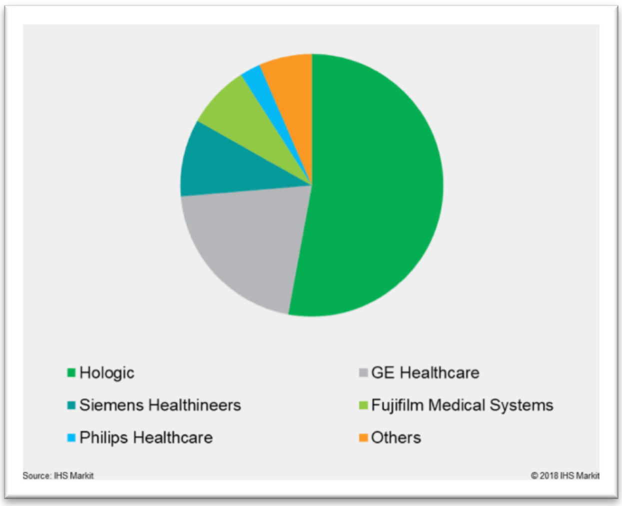

Figure 4. Global market shares for mammography equipment, 2017 (HIS Markit).

Observing how technological change has led to health improvements at the disease level can help illuminate whether medical spending is worth the increased cost of care.[29] Rises in healthcare spending have catapulted our nation into a position where we spend the most on healthcare relative to comparable countries. In 2000, health expenditures hit about $1.4 trillion while doubling to $3.5 trillion in 2017. Figures on spending take into account "healthcare as well as health-related activities (such as administration of insurance, health research, and public health), including expenditures from both public and private funds."[30] Technological change is responsible for a large portion of cost increases over time, as well as many of the benefits that have come from modern medicine including "increased longevity, improved quality of life, less time absent from work, etc."[29] Advancements in the sphere of breast cancer diagnostic tools and therapies have improved overall cancer diagnosis and treatment rates. Chemotherapy regimens have increased in complexity, more frequent surgeries are being performed, outpatient visits are offered for drug treatments, while advanced imaging techniques and increased public awareness also increase utilization of mammography. However, spending on breast cancer screening and treatment has shown that the costs and benefits of these medical advancement are at least of equal magnitude. An analysis by Cutler & McClellan (2001) compares population-based survival improvements with treatment costs using Medicare claims records in conjunction with data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) program. Survival after breast cancer increased by four months on average due to increased detection and innovations in therapeutic treatment. When valuing a year of life at $100,000 and subtracting medical and nonmedical costs of breast cancer, the value of increased survival at least rivalled that of costs incurred by technological change.[29]

Although screening has shown to reduce breast cancer-specific morality, there is a dearth of evidence to show that it reduces overall mortality for people.[31] In a systematic review of meta-analyses of cancer screening trials, 33% showed reductions in disease specific mortality while none showed reductions in overall mortality.[31] The downstream effects of screening caused by false positive results, overdiagnosis of non-harmful cancers, and detection of incidental findings may offset these reductions in disease-specific mortality.[31] A number of studies have reported that some of the cancers detected by mammography would have had no bearing on the woman's health if they hadn't been found. Only ⅓ to ½ of DCIS diagnoses would have presumably led to invasive breast cancer. But the lack of understanding of how to distinguish between harmful and harmless DCIS has led to an increased rate of DCIS diagnoses.[22] As a result, these women are forced to undergo risks associated with treatment.[22] Conflicting studies indicate that the diagnosis of low grade, non-necrotic DCIS lesions occur rarely. Rather, most DCIS detected from mammography screening is high grade and necrotic, and appropriately warrants intervention.[32] The Swiss Medical board has chosen not to recommend mammography given that for every 1000 women who undergo screening, breast cancer deaths only decline from 5 to 4 while non-breast cancer deaths are stagnant at 39 or increase to 40.[33] This finding arrives at several plausible conclusions; screening either increases non-breast cancer deaths or women who are saved from breast cancer die earlier from different causes of death.[33]

Mammography diagnoses are fraught with problems of high false positive rates, characterized by physicians raising attention to findings that aren't actually cancerous. The percentage of women who are given an abnormal reading and asked to pursue further testing is referred to as the screening recall rate.[22] Various studies have shown women to have a 30 to 61 percent chance of getting a false positive result within 10 years of screening if they start at age 40.[1, 3] A biopsy is performed on women with abnormal follow-up mammograms or ultrasounds. There is a 7 to 8 percent chance that a woman will also get a breast biopsy within that first decade, but most biopsies will demonstrate non-significant results.[10] Interestingly, screening recall rates for mammography fare much lower in other countries. This may be explained by the fact that radiologists abroad are faced with fewer threats of medical malpractice litigation than in the U.S.[22]

Women with heterogeneously dense or extremely dense breast tissue may also encounter greater challenges when it comes to yielding accurate diagnoses. These women have a lot of fibrous or glandular tissue (dense tissue) and not as much fatty tissue. While fatty tissue appears dark and transparent on a mammogram, dense tissue presents as a solid white area making it harder for a radiologist to see a breast mass or tumor on mammography which also looks white. As a result, a correlation between increased breast density and higher false negatives is observed. While mammography can already miss up to 15% of cancers, this figure is more exacerbated in women with high breast density.[22] The sensitivity of mammography ranges from 98% in women with fatty breast parenchyma, to 36% in women with dense breasts.[3,4] This biological trait can also increase a woman's risk of getting breast cancer by four to six times.[34,35] Dense breasts are more common among younger women, women with a lower body mass index and women who take combination hormone therapy to relieve signs and symptoms of menopause.[36] Only some states actually require the facility to notify the patient if they have dense breasts. Similarly, there is limited coverage for follow-up ultrasounds if radiologists wanted to obtain a more accurate visual. For this population of women, full field digital mammography (FFDM) has proven to be more sensitive than film-screen (analog) mammography.[37] But despite being designated the new norm, even FFDM has shown limited accuracy among high-risk younger women.

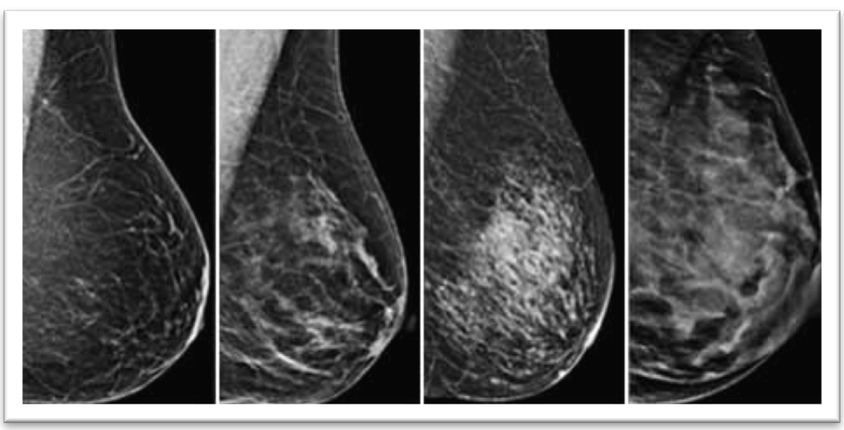

Figure 5. Categories of breast density. According to the BI-RADS reporting system, the levels are (from left to right) almost entirely fatty, scattered areas of fibroglandular density, heterogeneously dense and extremely dense (Mayo Foundation for Medical Education and Research).

Concerns regarding accumulated radiation exposure from digital mammography have been broadcasted by popular press and various medical literature. The average mean glandular dose (MGD) from digital mammography is 3.7 mGy.[38] This is estimated to have a lifetime attributable risk of fatal breast cancer of 1.3 per 100,000 women if women are exposed beginning age 40. This excess risk decreases if a woman is exposed to yearly screening later in life. A risk-benefit ratio demonstrates that for this same group of women, 292 lives would be saved as a result of annual screening.[39] Given a 36% mortality reduction presumed from screening, some researchers argue that the theoretical radiation risk should not discourage women under 50 from yearly screening. Nevertheless, these concerns have driven efforts to create new digital mammography technology utilizing lower radiation doses without compromising accuracy. For instance, spectral imaging or photon counting eliminates 97% of scattered radiation, delivering less MGD to the breast than standard mammography. The FDA recently approved a low dose photon counting mammography that has reached popularity in other countries. It delivers half the dose of MGD relative to standard FFDM.[40]

Moving forward, microscale efforts to promote shared-decision making should be made as well as larger funding of intensive scientific trials to fulfill higher standards of evidence regarding screening's benefits. It is within the parameters of the training and medical obligation of frontline healthcare workers to advocate on behalf of uninformed patients. Hence, transparency and social accountability should be prioritized especially in making sure patients are fully informed of how screening affects overall mortality. Raising higher consciousness on these processes may catalyze rational, shared decision making between doctors and their patients.[31] Responsibility should not completely rest on the shoulders of doctors, however – news coverage should also contextualize and elucidate this information.[25] Additionally, if political will, public support and financial resources could be mustered to pursue larger randomized studies, population-based trends of overall mortality could be explored in relation to screening. It's been suggested that in order to yield conclusive results, 4.1 million participants would need to be enlisted in this trial.[41] Funds should be reallocated from extensive marketing of mammography into supporting screening trials that actively assess its utility.

CHAPTER 3: QUALITY OF CARE FROM THE PATIENT'S PERSPECTIVE

Patient feedback is an important source of data for identifying the factors that deter or stimulate women to participate in mammographic examinations.[42] It may be used towards designing effective strategies to capture under-screened populations as well as an indicator for measuring the quality of healthcare.[43] Previous research has found that interventions to enhance the professionalism, empathy, and cultural awareness of technicians are key towards improving patient satisfaction and compliance.[44] But patient satisfaction is not only correlated with characteristics of the microsystem practice but personal factors as well, such as a woman's characteristics, attitudes, and expectations.[45] In an effort to fully capture patients' experiences with breast cancer screening, data has been abstracted from surveys, online blogs, or direct quotes from eligible women. Giving women a platform to share their mammography experiences has in itself shown to be an uplifting and therapeutic activity, particularly if collection of this information results in improvements of service delivery.

Poor repeat adherence rates are stirring up efforts to popularize annual or biennial screening among women. Studies estimate that less than 50% of eligible women have obtained an annual mammogram for at least 2 years in a row.[46-47] Participants who fail to have any physical manifestations of breast cancer or haven't already been diagnosed may ignore compliance.[44] While access to care and insurance coverage significantly affect a woman's decision to pursue screening, a poor initial experience with mammography may also be a predictor of poor follow-up compliance.[48,49-50] Literature has documented feelings of psychological distress among women undergoing screening. Accordingly, in a survey of 255 women, 30% of participants claimed that their decision to continue to get screening mammograms was influenced by their first mammogram.[51,52] A longitudinal study of 6,898 women found that having poor experiences during screening mammography is negatively correlated with return for futures mammography.[53] If these women relay their dissatisfied mammography experiences to their family and friends, this may induce a ripple effect in further discouraging more women from adhering to screening.[54]

Examining the barriers to breast cancer screening among migrant and minority communities is necessary to support inclusion of these group members in outreach efforts. In 2009, the Victorian Cytology Service (VCS) conducted a survey of cancer screening programs around Australia and New Zealand. Decreased participation was evidenced in the following population groups: indigenous and culturally and linguistically diverse populations, older women, men, lesbian women, disability groups and rural or remote communities.[43] For the purposes of this thesis, a concise systematic review of cancer screening in hard-to-reach populations in the United States was conducted using multiple search engines. Based on the brief results of this search, this chapter aims to shed light on the experiences and attitudes that influence screening behaviors in a diverse group of women including those from the following marginalized groups in the United States: disabled women, African American and African-born Muslim women in New York City, and American Indian/Alaska (AI/AN) Native women living in Kansas and Kansas City.[44,55]

Fear and Waiting Time

Women’s increased fear or anxiety during a screening visit has been associated with the uncertainty of a pending diagnosis. Of the 306 patients who attended a breast clinic, 60% cited having anxiety due to fear of cancer and the outcome of the consultation. Most of these women were first-time patients.[56] The perceived threat of getting screened may also be rooted in misconceptions and a lack of knowledge concerning the screening process. In the Muslim community, cancer is not widely discussed as it is a stigmatized topic. But such stigma can impact the community on the broader social scale by stifling public discourse that attempts to raise awareness about early detection.[57] Negative perceptions of breast cancer have subsequently driven screening to become somewhat undesirable among African American and African-born Muslim women:

"I know it's a bad sickness and it kills a lot of people…, it killed my aunt."

"… Some people think you can contract it because your sister has it or your friend has it."

" … (Muslim women) don't want to do it. They say the radiation makes you get cancer."

"It's shame to say that I got cancer."[58]

A blog written by Professor Annie S. Anderson for the Scottish Cancer Prevention Network articulates a similar narrative embedded in fear, adjusted to her specific identity and experiences.[59] While in the mammography suite, Anderson speculates whether or not the technician would inform her if they noticed any abnormalities on the screen. She is simply told that her results would be mailed to her in two weeks. As anticipated, the "clear letter" arrives in two weeks, finally putting an end to the troubled thoughts turning over in her mind.[59] Anderson has a high regard for breast cancer screening, nevertheless, which she claims stems from having been previously diagnosed with other serious conditions. Coming to the brave decision to persist routine screening despite the looming fear of another diagnosis is understandably very difficult, which Anderson describes in her blog:

> "Twice in my life I have been tested for serious conditions and have had positive results, so I never undertake screening lightly. I know I will accept screening invitations because I know early detection is the key to better outcomes. But, memory and fear are there – and have to be confronted."[59]

Even asymptomatic women without prior history of illness can relate to this heightened sense of distress.[60] Especially, those who are noticeably treated as high-risk patients:

> "[I] have a history of having to have more views each time I come in. Even though you know it is going to happen you are still apprehensive about it. Because you're wondering, what are they going to find today."[61]

Surveys show that an overwhelming share of patients would rather hear the results of an imaging examination from the radiologist at the time of the procedure than to hear them later on from the referring physician.[62] This is logistically easier given that if need be, further diagnostic studies can be performed while they are still at the facility.[63, 64] Women who were originally feeling anxious experienced a significant decrease in anxiety levels post-consultation with the radiologist. These women presumably received negative results.[56] Awaiting the results through postal mail, on the other hand, may draw out patient's nervousness. For one, women may be prompted to rationalize the time it takes to receive their results.[59] Some women presume a longer wait means as that their results are normal versus a shorter wait time suggesting they have a positive diagnosis. Even so, this reaction to waiting for postal results does not apply to all patients. Some women actually prefer the delay in getting informed of their results as they would find it overwhelming to get them the same day as their clinic visit.[63]

Pain and Discomfort

Pain is a subjective sensation and thereby, difficult to quantify or standardize among a set population.[65,66] Women generally have dissimilar experiences when it comes to their tolerance for discomfort and as a result, they experience mammography differently. In line with this statement, the literature shows how patients vary considerably in the sensations they encounter during screening. The percentages of patients who reported general incidence of pain across studies include 73% (n = 187),[67] 66.5% (n = 113)[65] and 57% (n = 1514).[68] The variance between these studies may be explained by discrepancies in data collection methods.[66] Pain was commonly described using the following language: '*constraining*,' '*pinching*,' '*squeezing*,' '*pressing*' and '*unpleasant*.'[65]

Breast compression is a specific source of discomfort correlated with overall satisfaction with mammography. The machine is responsible for producing uneasy sensations by pinching, pulling and stretching the skin.[69] In a study of screening patients, 71% found compression to be uncomfortable while 43% of respondents (n=20) described the plate as painfully cold.[70] Witnessing their breasts being flattened was equally as troubling for the women.[71] The compression machine was referred to as "*sterile*, "*cold*, "*mechanical*," "*threatening*" and "*harsh and unrelenting*."[71] One individual from a cancer support group expressed how "*I thought my breast was going to explode*."[72] When compression was controlled by the patient rather than the technician, women reported significantly less pain and greater overall satisfaction with mammography.[73]

American Indian/Alaska Native women living in Kansas and Kansas City reported feelings of embarrassment in addition to discomfort, given their more conservative views about getting undressed.[44] They explained that for cultural reasons, AI/AN women do not discuss their bodies nor disease. Two women elaborated on how their communities had a heightened emphasis on modesty:

> "Well I've always found, I bet you have too, in our culture our older people are not ready to talk about their private parts. I mean they're real modest.
>
> I think prior to my mother being diagnosed with breast cancer, I hadn't worried about it. No one had ever talked to us about…you know, she's a nurse, she never talked to us about breast self-exams or…but until it happened in our family and now we talk about it with like my girls and even our sons."[44]

Across a collection of studies, women discussed the feeling of being objectified. One woman's experience was akin to being handled like a "*lump of meat*."[71] Others went on to talk about "*exposing body parts that one normally doesn't*" and "*more touching than is allowed by other individuals*."[71] The motions of undressing, exposing the body, and touching of breasts were particularly unsettling for first time mammogram attendees.[74] Nevertheless, a select number of women were not bothered by the process and as it happens, preferred that it took place in an impersonal context.[71]

The expectations women have about mammography have been shown to affect how they perceive pain during the test and the satisfaction they feel afterwards.[44, 75] The source of these expectations about mammography may have been derived from personal anecdotes from family and friends.[44] In a study where 4% of women reported experiencing extreme pain during the examination defended this with "*because mammography is a painful examination*."[68] The study posits that these women may have been persuaded that mammography was inherently an uncomfortable technology. This would have biased their expectations before they even got examined. Alas, women who experience more pain than they expected have shown to be less likely to return for future mammography.[53]

Women with disabilities (WWD) may encounter a unique host of difficulties that may reduce the likelihood of adherence to preventative screening. Individuals with limited mobility were fraught with fatigue at having to stand straight for an extended period of time and spread their arms.[76] Other hardships experienced by disabled women include poor communication with staff or a lack of privacy, particularly among those who experienced accelerated impairments due to aging itself.[77] Health care providers who are emotionally distant and inappropriately stereotype these patients often leave behind a sense of degradation and worthlessness.[78]

Addressing these areas of concern through improved staff attitudes and patient-centered care may help carve out a better experience for WWD and promote their continual participation in mammography.[79]

The technician's attitude can generally help regulate a patient's comfort levels during the procedure.[80] Consolation can be offered to the patient by providing accurate and positive expectations about mammography to address any reservations they may have.[44] Studies have shown an association between receiving information and fewer reports of pain during screening.[67] The results from a survey show that 80% (n = 197) of women who did not engage in conversation with the technician reported pain, as compared to 64% (n=158) of women who did converse with them.[67] Of course, we would need to be wary of the situation's causality. In other words, did the "technician's attitude toward the patient influence the woman's experience itself, or did the pain influence the woman's evaluation of the technician's attitude?"[80]

Interpersonal Attributes: Communication and Support

A woman's experience in the mammography suite is informed by the behavior, attitude, professionalism and interpersonal skills of the technician and radiologist. Patients commonly express a desire to be oriented and continuously informed throughout the screening process. Given that this process is chiefly headed by the technician, they play a central role in shaping the patient's experience.[61,69,72,74] By initiating pleasant conversation, technicians can reduce feelings of anxiety and embarrassment among patients.[69,72,74] Technicians who practiced clear communication and patiently responded to questions were also met with greater patient satisfaction. They excelled at keeping the patient informed and effectively managing their expectations.[61,69,74] Pleased survey respondents, for example, reported that staff "*made you feel* *important.*"[74] AI/AN Women living in Kansas and Kansas City reported better experiences in smaller facilities, having friendly, knowledgeable and respectful technicians. They similarly appreciated being guided through the test procedure. Greatest weight was placed on the technician's technical competence and attitude.[44,80]

On the other hand, some women left the visit feeling disappointed by the technician's limited effort to provide patient-centered care. Their poor attitude and standoffish demeanor left a negative impression. In a study sample of 201 individuals, only 45% felt that the technician engaged them conversationally.[67] Patients reacted in the following way: "*her attitude was bad and it made my time miserable,"* [69] "*didn't seem interested*" and "*you were just another number,*"[72] "*didn't talk, she just shoved and pushed,*" "*if you get treated poorly…you're for sure not going to go back*."[69]

A patient's compliance with screening may also be adversely affected by the lack of respectable contact with the radiologist. According to the American College of Radiology, ½ of Americans cannot distinguish between the roles of a radiologist and technician.[13] In failing to appreciate the medical qualifications of the radiologist, patients show more hesitance to follow the advice given to them at the time of an examination or procedure.[56] Yet, radiologists feel that they have the least communication skills training relative to other specialists.[81,82] Residents who are currently being trained in the field have expressed these same concerns:

> "…attendings often times didn't want you to come in when they are giving patients bad news…a lot of time they think it's better for the patient to have privacy… that (has a) negative effect on our education, just not having the experience."[61]

Let's Talk About Ionizing Radiation

Exposure to ionizing radiation from mammography examinations may increase risk of breast cancer among subgroups of women who are often subjected to more frequent screening or possess risk-increasing genetic variations.[83,84] Women who are obese or have dense breast tissue may be asked to undergo additional evaluations beyond routine screening, rendering them more susceptible to radiation-induced breast cancer.[85–87] Women with large breasts who are under the age of 50 are at twice the risk of developing radiation-induced breast cancer as women with small or average breasts. This is mainly attributed to obtaining screening examinations with more than four views and above average doses per view.[88] Carriers of germline mutations in genes involved in the DNA-damage repair pathway (DDRP) have also been shown to have an increased risk of developing (contralateral) breast cancer after radiation therapy.[89] This has important implications for building a safer system of delivering breast cancer screening and encouraging patient participation in healthcare decisions.

Patients at an oncologic center have mixed beliefs and levels of knowledge regarding the ionizing radiation generated by medical imaging which generally appears to be commensurate with their prior life experiences. A qualitative interview study elicited the views of a diverse oncologic population including patients in active treatment, cancer survivors, parents of pediatric cancer survivors, and participants in a cancer screening program. The sample (n = 30) was primarily female (60%), white (80%), well educated (90% with college degrees), married (50%), and employed (52% working full time or part time). Patients who were survivors of testicular and lung cancer and patients undergoing screening for lung cancer screening were the most knowledgeable about which medical imaging tests involved the use of ionizing radiation. Participants who had breast or colorectal cancer and parents of patients with neuroblastoma were less capable of making this distinction. It was unclear for many participants on whether magnetic resonance (MR) imaging emitted damaging ionizing radiation. Some participants were unclear on how imaging tests measured up to one another and which tests delivered higher ionizing radiation doses.[90]

Attitudes towards cumulative radiation exposure also vary according to a woman's health status, namely if the woman is undergoing screening, active treatment or if they are a cancer survivor. Women undergoing screening mammography prefer the inconvenience of and anxiety of continually obtaining false-positive results if it increases the chance of detecting a potential cancer earlier. In the same survey population of 1528 women predominantly between the ages of 40 and 59, 86% of respondents were willing to be recalled for a noninvasive procedure while 82% demonstrated willingness to be recalled for an invasive procedure.[91] Surveys show that this opinion is more concentrated among individuals without current disease. Patients who have previously reaped the benefits of having their cancers detected by imaging tools were also less inclined to inquire about long-term risks from ionizing radiation. The perception of medical imaging is slightly different among those with active or residual disease. Some patients at an oncologic center expressed frustration at their inability to differentiate between imaging tests and were concerned about the harm inflicted by overutilization.[90] Yet for most of them, immediate survival was a more pressing concern, weakening any lingering interest in the long-term potential risks of ionizing radiation.[90]

Discussions with patients on the benefits and risks of long-term exposure to ionizing radiation are not frequently prioritized among clinicians. Most oncological patients report never having discussed these matters with their provider while only a select few directly questioned their doctor, nurse, or technician about it. Among this small group of patients, a majority were disappointed by the lack of thoroughness and clarity in their responses. Time constraints may be shaping this trivializing behavior, as professionals are forced to hop from one patient to the next.

A testimonial from a radiology resident highlights the frustration they feel towards building rapport with patients under limited time:

> "We…[have] such a snapshot interaction with the patient…on our part sometimes there is this hesitation because we are not familiar with the patient, and so we don't necessarily have the rapport with patient."[61]

Patients who were the most intrinsically motivated to understand the risks of repeated exposure to ionizing radiation were survivors of cancer. They were willing to strike up a benefit-risk conversation as a way to build trust with their provider. Some participants, however, imbued sufficient trust in their provider and did not find it necessary to initiate this type of conversation. For a few, prompting this discussion seemed outrageous and frightening. Most individuals agreed, however, that routine care should at least make benefit-risk information accessible for interested parties.[90] Breast center staff should also put more effort into averting radiation-induced breast cancer by discussing with patients the possibility of delaying screening to age 50 or pursuing biennial screening as an alternative to annual screening. These changes would have a combined effect of lowering patient's risk almost five-fold.[88]

Breast Density Notification

High breast density (BD) is common, 40-50% of women ages 40-74 have dense breasts in the United States.[92,93] It is a risk factor for developing breast cancer and is associated with a higher likelihood of an interval breast cancer in mammography screening.[94] For women with dense breasts, adjunct screening such as breast ultrasound and digital breast tomosynthesis may help detect additional cancers not detected on mammography.[95–97] However, because follow-up screening is considered diagnostic, most states do not require full insurance coverage of supplemental imaging for women with dense breasts. The first law in the country was enacted in

New York which requires insurance companies to cover all screening and diagnostic imaging exams for the detection of breast cancer.[98]

Notifying women undergoing mammography of the risks associated with their breast density is mandated in 32 states.[99] A growing patient advocacy movement pushing for informed decision-making gave vitality to this new legislation. Just recently, the Food and Drug Administration broadened the scope of this law by proposing a new rule that mandates all breast centers nationwide to use specific language to notify women if they have dense breasts and to explain breast density. According to Dr. Jenn Shuren, director of the agency's Center for Devices and Radiologic Health, this would be the minimum requirement, leaving it to the state's discretion to include more information in the notification.[100] Nonetheless, given the associated adverse outcomes of false-positives, significant costs, and the possibility of overdiagnosis from increased supplemental screening, it is debatable whether notifying women on BD confers any net health benefits.[101] This may suggest a need for establishing formal methods to evaluate the effects of enacting BD notification laws.

Clinically integrating the concept of patient autonomy remains a key area of improvement for medical practices. Primary care physicians report lacking the necessary training to address BD-related issues and to make appropriate recommendations to patients.[102–104] Radiologists also appear uncertain on how to manage new legislation and imaging recommendations.[99,105–109] Presumably due to poor information flow between providers and their patients, knowledge of breast density among women receiving routine mammography remains inconsistent. A survey assessing breast density awareness and knowledge was administered to all women following implementation of mandatory breast density notification in Massachusetts. Out of 338 women, 54.7% self-reported having dense breasts but only 61.1% associated their breast density with increased breast cancer risk. Women with dense breasts (63.8%) had a stronger intention to follow-up with their provider as well as seek supplemental screening (45.1%) in comparison to women with non-dense breasts (50.8% and 15.4%, respectively).[110] Many patients, however, faced financial barriers that prevented them from complying with recommendations for follow-up imaging.[111] Larger healthcare organizations which carry more political and economic clout, should be called on to offer support to individual clinics, physicians, and other healthcare providers as they navigate BD notification legislation. Providers should receive formal training on discussing relevant information about breast density and its associated risks with their patients. In recommending next steps, they should also be mindful of financial costs incurred by supplemental screening.[112,110]

CHAPTER 4: CHARACTERISTICS OF HIGH-PERFORMING MICROSYSTEMS

A healthcare organization referred to as the macrosystem is responsible for coordinating and overseeing the smaller microsystem units it is comprised of. The clinical microsystem refers to a functional, replicable unit of the healthcare organization consisting of clinicians and staff. This core team of health professionals works interdependently with a shared clinical purpose of providing care to a population of patients.[113–115] To perform a set of tasks associated with delivering healthcare, certain elements of the microsystem are necessary. These core elements include a specific type of care process, clinicians and support staff to engage in these processes, a specific patient population, an information environment, and technology to support providers and patients.[113]A few examples of clinical microsystems include a family practice, cardiovascular surgical care team, a community-based outpatient care center, an emergency department or a neonatal intensive care unit.[116] Microsystems are flexible, adapting according to the needs of the people they engage with directly. They can also respond to external demands from larger macrosystems.[117] But in order for a microsystem to evolve over time, actors working within these units should be encouraged to innovate and continually build their expertise.

The complexities and obscurities of healthcare institutions not only lead to patient discomfort and harm, they also incur excess costs. An operational microsystem can help stop, prevent or diminish errors that pose a risk to patient safety by increasing the unit’s awareness of its functioning as a microsystem.[6,117] By being mindful of one’s individual purpose within a system, individuals can critically reflect on their work and recognize lapses in service quality. According to Weick and Sutcliffe, becoming more mindful means microsystems are “preoccupied with failure, reluctant to simplify interpretations, sensitive to operations, committed to resilience and deferent to expertise."[118] Briefly, this means becoming alert to front line errors and consistently acquiring new information to nuance their understanding of complex problems. This also means finding innovative solutions to recover from errors, many of which should come from individuals with the most expertise, irrespective of their authority level.[118]

Since the larger macrosystem is only as effective as the units of which it is comprised, organizational level efforts to mitigate error should be carefully tailored to the ecology of the individual microsystem. Organizations that continually develop and organize around the frontline relationships with the clientele they serve regularly deliver high quality services and possess an outstanding reputation among their customers.[117] Hence, frontline innovations can be used to develop high-performing health care systems. This would especially benefit patients who present multiple chronic health problems complicated by various social factors.[119] High-risk patients receiving personalized care obtain more coordinated care and exhibit greater satisfaction.[120]

Microsystem assessment tools have been developed to help team members identify areas for improvement and increase the potential for delivering higher quality and safer care. Their robust frameworks help clinical teams develop a sense of identity as a system and explore ways to incorporate change in how they function. This concept has been derived from statistician and consultant W. Edwards Deming and business school professor James Brian Quinn. Drs. Paul Batalden and Eugene Nelson, professors at Dartmouth College were responsible for extrapolating this work to the healthcare sector.[5] Since then, methodological approaches to examine microsystem performance have been produced giving rise to instruments like the Clinical Microsystem Assessment Tool (CMAT). The CMAT has been commonly used to examine microsystem performance according to the 10 key characteristics: leadership, organizational support, staff focus, education and training, interdependence, patient focus, community and market focus, performance results, process improvement, information and information technology.[121] Similarly, The Malcolm Baldrige National Quality Award (MBNQA) establishes guidelines for organizational quality assessment and improvement. Since its creation in 1988, it has been used by various sectors of the economy including business, healthcare and educational organizations.[122]

In 2002, an assessment tool by Mohr and Batalden emerged from a qualitative analysis of interviews from 43 microsystems in North America. Given its success in thoughtfully incorporating the voices and feedback of individuals who are directly represented in microsystems in the U.S., this diagnostic will be used to thoroughly assess breast centers in this thesis. The common dimensions identified across these microsystems should not be thought of as mutually exclusive, but rather, overlapping and complementary. According to this body of research, *the eight qualities associated with high performing microsystems include* integration of information, alignment of role and training, measurement, interdependence of the care team, supportiveness of the larger system, connection to the community, constancy of purpose, and investment in improvement.[6]

Integration of Information

> "Microsystems vary on how well information is integrated into its daily work and the role that technology plays in facilitating the integration."[6]

Information transfer between the technician and interpreting radiologist has been integral in preserving patient safety especially in the midst of a healthcare imaging evolution. Prior to filmless imaging, staff were positioned in a central working area which enabled frequent in-person contact. These interactions promoted peer-to-peer education and quality assurance of imaging studies through improved communication and joint case review.[123] Radiologists and technicians positioned in this group dynamic also interacted with other medical specialists who had to travel to the imaging center to review their patient's films. The digitization of medical imaging through picture archival and communication system (PACS) historically induced a shift in the design of the workplace floorplan. Radiologists and technicians, no longer dependent on their proximity to diffuse information, dispersed as independent actors to increase their operational efficiency.[123] The technological transition to teleradiology in the late 1990s further ostracized radiologists from their clinical team.[124] A marketplace for outsourcing services in a distributed model was created, upon which a decline in consultations with immediate coworkers as well as referring physicians ensued.[124, 125] Some innovations, however, have impacted work relations in a net positive manner. The Electronic Medical Record (EMR) systems provides an avenue of communication through the digital sharing of patient charts. However, its utility hinges on the radiologist's voluntary will to read the notes and information collected by the technician during the patient's visit.

Although new innovations have become adaptable to the imaging landscape, they have noticeably scarified the technical quality of medical imaging data. The former centralized layout of the radiology department enabled a more quality assurance (QA)-focused environment as it offered a space to gather and collectively review films. The radiologist reading room was positioned nearby the technician's viewing area, promoting frequent consultations regarding image quality. Although the interactions in this space precipitated a friendly and social atmosphere, constructive criticism still had a stronghold over peer-to-peer relations. Staff mutually gained from one another's diverse skill sets and hosts of knowledge.[126] Newly practicing professionals would likely profit most from this training opportunity given that they are the most susceptible to diagnostic inaccuracies. Caseloads were also relatively lower, and reimbursements were generally higher which initially afforded more time and attention to quality assurance practices. Over time, technology vendors centered their research and development efforts on market economics. Productivity became correlated with cost-effectiveness and revenue rather than quality which was not as easy to quantify. The untimely decline in reimbursements further pushed imaging providers to concentrate efforts on increasing productivity.

External sources of interpretive error have been bred out of pressures to comply with high imaging volumes in order to obtain reimbursement by third-party payers.[13] Time-consuming work compounded with already lengthening work-days, has been shown to increase rates of misdiagnosis and compromise the efficacy of mammography. A study documented radiologists' weakening visual accommodation and declining performance by the end of the work-day.[127] Factors such as inattention, fatigue or lack of experience have been correlated to high false negatives.[2] False negative outcomes can jeopardize patient safety by delaying delivery of treatment as prognosis worsens.[2] Distractions and multi-tasking have also been noted as other sources of interpretive error.[128,129] Beyond interpreting images, the job of the radiologist may require them to consult with referring physicians, answer phone calls and return pages.[130] A study by Balint et al. showed that an increase in average phone calls an hour before a preliminary report was due increased the odds that a resident would make an error by 12%.[130] In an effort to control escalating demand for medical imaging, it is imperative that we make a stronger commitment to QA and to incentivize data-driven quality improvements in imaging quality.[126]

Alignment of Role and Training

> "Alignment of role and training suggests that there is a deliberate effort within the multidisciplinary team to match the team member's education, training, and licensure with their role."[6]

Job dissatisfaction and poor employee performance can have far-reaching effects on the quality of patient care and safety.[131] Studies over the years have explored important variables related to mammographic radiologist and technician job dissatisfaction. Radiologists are reportedly demoralized by the risk of malpractice litigation which may drive them to doubt their medical decision-making capabilities. Other unsatisfied radiologists find mammography to be tedious.[132] Technicians' discontentment, on the other end, often stems from a negative relationship with the radiologist they work with or other fellow mammographic technicians.[131,133] Technicians in the UK reported experiencing occupational stress due to difficulty communicating with the patient while the biggest indicator of job dissatisfaction for them was role ambiguity.[133]

Physicians who incorporate a degree of familiarity in their relationship and communication with technicians can help improve the overall performance of the microsystem. Technicians empowered to offer their opinions or take initiative on a protocol makes for a smoother workflow, with fewer interruptions to the radiologist and greater assured patient safety. Radiologists and technicians can strengthen their relationship by building trust, communicating expectations as well as honoring a tech's workstyle. Sharing research projects, passing along positive feedback, and technology tricks to facilitate workflow are additional ways to create a stronger team.[134]

Forming an interdisciplinary team will cultivate a culture of mutual support and respect. Studies show that mutual respect underscores the significance of each team member in the group, making them feel valued and appreciated. This may help undercut the internal and external environmental factors possibly driving insecurity in their professional identity. These individuals are subsequently more likely to be committed, creative and contributory towards the final goal. Not only do team members feel more comfortable fully participating in the group dynamic by raising issues and questioning ideas, they receive constructive feedback in return. Effective interdisciplinary teams also display strong mentorship through formal or informal mentoring. Infusing these practices and values into the social fabric of the microsystem is expected to stimulate personal growth and overall clinical performance.[135]

Measurement

> "Effective microsystems measure what they do and recognize that the measures at the macrosystem level are not always helpful at the microsystem level. Part of the work of the microsystem becomes the development of a set of measures that are appropriate for the goals of the microsystem."[6]

Standards and performance metrics are used to drive up quality.[136] The Mammography Quality Standards Act requires mammography facilities to regularly review medical outcomes associated with diagnostic mammography.[137] Diagnostic mammography is performed as an additional assessment following abnormal screening findings or following the discovery of a palpable lump. The American College of Radiology calls for more comprehensive auditing that entails separate screening and diagnostic mammography data.[138] According to the U.S. Food and Drug Administration, as of January 2019, 99% of currently certified mammography facilities in the United States use digital mammography.[139] A transition from film to digital mammography has swept across imaging centers over the last decade. This has been followed by increased abnormal interpretation and cancer detection rates and decreasing positive predictive value (PPV_2) of a biopsy recommendation.[140]

Performance benchmarks in the United States for modern diagnostic digital mammography are updated annually from the Breast Cancer Surveillance Consortium (BCSC) and describe the range of performance in clinical practice.[140] Six geographically diverse BCSC registries were consulted for data on 401,548 examinations conducted from 2007 to 2013 in 265,360 women linked with cancer diagnoses.[140] The demographics of the population were also collected which included age, race and/or ethnicity, family history of breast cancer, and breast density. Metrics used to gauge performance include the cancer detection rate, abnormal interpretation rate, positive predictive value (PPV) of a biopsy recommendation (PPV_2), PPV of biopsies performed (PPV_3), false-negative rate, sensitivity, and specificity.[138]

The Breast Cancer Surveillance Consortium reported that more than 75% of radiologists met the acceptable ranges for cancer detection rate, abnormal interpretation rate, and sensitivity. Fewer radiologists performed up to par with the accepted standards for PPV_2 and PPV_3. Only 53.1% of radiologists operated within the acceptable range for PPV_3 in their evaluation of a palpable lump while fewer than 70% were within the acceptable range for specificity. Trends in the data show that radiologists are exceeding the recommended limit for false-positive biopsies albeit a majority are effectively detecting cancers.[140]

Relative to the United States, European countries have been successful in achieving higher specificity levels in diagnostic and screening mammography, while sensitivity performance measures remain similar.[141–144] NHS Breast Screening Programme standards are delivered by 80 services across England and are used to screen over 2 million women each year.[136] There are now 17 core standards that cover the screening pathway experienced by a patient.[145] Reports on performance are given at both the service level and individual mammogram reader level. To determine overall performance of the screening, sensitivity and specificity of invasive cancers are most commonly used. Yet, it is difficult to yield an instant assessment of how many women received true positive or negative results immediately after they get their mammogram. Women with interval cancers or next round screen-detected cancers may have their status as true negative or positive validated later on in time. Hence a more accurate estimate of performance, according to the NHS, has been cancer detection rate and recall rate.

A microsystem's commitment to develop clinical performance measures that drive improvement may manifest in unique and innovative ways. In an interview of 43 microsystem leaders, nearly half measured performance levels using clinical, functional or financial indicators. A few used national guidelines and benchmarks to compare their performance. However, one representative spoke out against this technique, claiming it confers tunnel vision:

> "We measure success against ourselves. We try very hard not to measure against benchmarks. Benchmarks can limit you. Sometimes the benchmarking in and of itself becomes the goal."[146]

Other strategies employed by microsystems to monitor clinical performance include tracking the types of protocols used by physicians and their adherence to those protocols. Forty-four percent of microsystems in this study measured patient satisfaction levels while fewer also assessed provider satisfaction. Not every leader interviewed was cognizant of how their performance measured across different indicators, and reasonably so if they lacked formal methods for data collection. Described by some as an arduous task, clinical monitoring requires extensive resources. While some microsystems are discernably committed, others may not value it enough to put in the necessary time and effort.[146]

Interdependence of the Care Team

> "Microsystems with a high degree of interdependence are mindful of the importance of the multidisciplinary team approach to care, whereas those with a lower degree of interdependence are characterized by providers and staff working as individuals with no clear way of sharing information or communicating."[6]

Establishing a collaborative model of care as an extension of integrated care will increase the efficiency, availability and effectiveness of breast clinic services. The division of labor has historically spurred organizations to grow and specialize on separate terms. This has left behind a fragmented system, where complex organizations are working in silos, inadvertently impacting quality, cost and outcomes. Breast centers have evolved significantly since when they were first launched.[14] Previously, these centers were loosely defined on whether they solely offered mammography or offered a wider array of services.[14] Now, many are pursuing innovative models that coordinate care among healthcare providers to provide a continuum of services to their patient populations.[147] The addition of coordinated multidisciplinary teams has considerably improved the quality of delivered services. Teams consist of professionals who specialize in responding to different health and human services, including doctors, nurses, technicians, social workers, etc. They often assemble in meetings termed "pretreatment breast conferences, comprehensive breast conference, tumor board, or simply breast conference"[14] This collaboration demonstrates a holistic commitment to treating an individual and also facilitates a warm hand-off to other healthcare providers in the case that a patient must advance beyond the screening process.

The National Accreditation Program for Breast Centers (NAPBC) is administered by the American College of Surgeons and accredits centers that provide a range of cancer care resources. These centers demonstrate quality in categories as leadership, clinical management, research, community out-reach, professional education and quality improvement. NAPBC-accredited centers embrace the entire spectrum of cancer care, providing women with access to a range of board-certified specialists, including breast surgeons, breast radiologists, medical oncologists, radiation oncologists, breast pathologists, plastic/reconstructive surgeons, genetic counselors and psychosocial support professionals.[148] Accredited centers also offer breast nurse navigators, patient education and support, palliative care programs, survivorship programs and high-risk clinics. To be accredited, a breast center must provide all of these services in one setting or provide most of the services on-site and have referral processes in place for other services.

It is frequently stated that "no one model fits all" and accordingly, it is up to microsystems to use a bottom-up, patient centered approach to implement an integrated care model that enhances their capacity to provide safe and cost-effective care.[149] By capitalizing on the abilities of each team member, clinics can more readily provide comprehensive services including preventative education, screening and diagnosis. Of course, the process of constructing this collaborative model will be dynamic. Each member of the team will have to figure out how they can best contribute or "develop areas of expertise" in improving the patient experience. Technicians are an underutilized resource in delivering comprehensive care, specifically during screening mammography. Because they are at the frontlines of patient care, their services are a determining factor in the patient's satisfaction and subsequent compliance with screening. Hence, while establishing a collaborative model, it is important we take into consideration the great potential of technicians in optimizing patient healthcare delivery. Ultimately, the goal should be to promote quality of care while preserving patient autonomy. This is characterized by ongoing communication between team members, and between healthcare providers and their patients. This not only improves patient satisfaction, particularly in the area of decreasing women's anxiety throughout their visit, but also boosting their sense of self-efficacy.[150] Patients may be more activated to advocate for themselves as they navigate the healthcare system.[151]

Supportiveness of the Larger System

> "The larger organization may be either helpful or "toxic" to the efforts of the microsystem."[6]

A microsystem's ability to provide safer care to its patients may be conditional upon the leadership of the larger healthcare organization it reports to. The Health Care Advisory Board claims that successful organizations follow a "tight, loose, tight" management strategy of their microsystems.[152,153] This would entail having microsystems within an organization position their mission, vision and strategies in "tight" accordance with those of the organization.[6] They are simultaneously given the freedom to evolve in order to achieve their mission of providing safer care, while still under the management of "senior leaders" in the microsystem.[6] Although microsystems are given the freedom to pursue quality improvement efforts, they should also be entitled to organizational support to integrate these efforts into their daily work.[146]

Breast center microsystems and providers are encouraged to comply with screening recommendations from national guideline committees, cancer societies or leagues, and specialty societies. The incongruence between screening recommendations from these organizations may, however, be jarring for providers within the microsystem. There is disagreement over which age mammography should be initiated and discontinued, as well as the optimal screening interval. Other than within the USA, there is no significant difference in the intensity of screening guidelines globally. Mammography recommendations from the American Cancer Society, American College of Obstetrics and Gynecology, and American College of Radiology recommend annual screening with longer screening intervals for patients at average risk. The

American College of Radiology is the sole organization that recommends aggressive mammography annually beginning age 40 for this same population of women, while failing to specify the age upon which women should stop getting mammography.[154]

Despite the USPSTF and ACS recently promoting less routine use of mammography, there has been little documented change in screening practices among patients. Among primary care physicians in 2016, 80% of 871 surveyed participants said they would continue recommending screening to women between the ages of 40 and 44 contrary to the recommended guidelines.[155] Patients' behaviors also showed minimal adjustment to revised guidelines.[156] Some researchers link this obstinate behavior to the fact that patients and physicians overestimate the benefits of mammography in reducing overall mortality. Fear of malpractice litigation due to delayed breast cancer diagnosis in symptomatic patients may also be a contributing factor, as may be the U.S. fee-for-service payment system. Difficulty engaging patients in shared decision-making may also hamper physicians' efforts to offer personalized screening. Women's adherence patterns to mammography are associated with other external factors according to a survey by The Centers for Disease Control's Behavioral Risk Factor Surveillance System (BRFSS). Adjusting for insurance status and frequency of medical checkups, increasing frequencies of screening are correlated to rising age. Women without access to healthcare were not afforded the same privilege of adhering to any recommended mammography screening guidelines.[157] Patients who had not received a medical check-up within the last 5 years were shown to be less likely to adhere to mammography screening.[157] Poor adherence is commonly associated with advanced-stage breast cancer in low-income populations.[158]

Physician's recommendations for screening appear to be correlated with differential alliance and affinity to certain agencies. A survey filled out by general practitioners, internal medicine doctors and gynecologists gauges their confidence in various breast cancer screening mammography guidelines. Of all survey respondents, 26% said they trusted the ACOG breast cancer screening guidelines the most while 23.8% reported trust ACS guidelines; 22.9% trusts USPSTF guidelines. Accordingly, physicians who allied with ACS and ACOG guidelines were significantly more likely to recommend screening younger women as compared to physicians who trusted USPSTF guidelines.[155] This survey suggests that physician adhere differently to guidelines, while other studies have shown that these adherence patterns are influenced by their own society's recommendations. For example, referral rates are significantly lower among family and internal medicine physicians whose USPSTF society recommends biennial screening starting at age 50 years. Obstetricians and gynecologists, on the other hand, demonstrated stable mammography referral rates over time. Their society continues to recommend annual screening starting at age 40 years. Patient who regularly see obstetricians and gynecologists are hence more likely to be encouraged to receive screening mammography as compared to their counterparts.[159]

Connection to the Community

> "Connection to community represents a symbiotic relationship between the microsystem and the community that extends well beyond the clinical care of a defined set of patients."[6]

Under the age of 45 years, African-American women demonstrate higher incidences of breast cancer.[160] Cancer data show that 30-40% of African-American breast cancer patients are younger than 50, compared with 20% of Caucasian-American breast cancer patients.[161]

African-American women are also more frequently diagnosed with late-stage breast cancer.[162] Triple negative/basal-like tumors which are more prevalent among African-American women have poorer prognosis compared to other subtypes of breast cancer within the first 5 years after diagnosis.[163–169] This molecular subtype of breast cancer is also more common among Hispanic women relative to non-Hispanic white women.[170–172] Lifestyle factors can contribute to the higher rate of triple negative breast cancer among African-American women, all of which may explain why African-American women face higher breast cancer mortality rates.[163,173–176]

Evidence of complex socioeconomic, cultural and biological factors may help elucidate the disparities in breast cancer outcomes between African-American and Caucasian-American women.[177–180] It is widely understood that the poor social and economic conditions permeating African-American communities have given rise to health inequities. African-Americans are twice as likely to lack medical insurance or rely on public insurance such as Medicaid compared with Caucasian-Americans. Such barriers to healthcare access have been shown to discourage adherence to routine screening.[158] The underutilization of genetic counseling services also delays breast cancer diagnosis and treatment.[181–183] Additionally, the younger age distribution of African-American breast cancer patients has been linked with the higher prevalence of early childbearing that is observed among African-American women. A short-term increase in breast cancer risk occurs in the postpartum period and is correlated with premenopausal breast cancer risk.[184] A similar concept explored by Palmer et al. (2003) demonstrates how multiparity increased breast cancer risk prior to the age of 45 years but was protective against breast cancer risk after age 45 for African-American women.[185] Findings have suggested that a lack of physical activity and inadequate intake of vitamins and minerals may also contribute to a pre- and postmenopausal breast cancer risk among this demographic of women.[186]

Investing in community outreach to improve mammography utilization rates has been integral in reducing ethnicity-related disparities in breast cancer survival.[174] It's important to acknowledge national data which shows that differences in mammography screening rates between African-American women and Caucasian-American women has been narrowing. Since breast cancer outcome disparities persist, a multi-pronged public health approach may be most effective at reducing associated mortality rates.[174] NAPBC-accredited centers engage in breast disease education, prevention and/or early detection programs in collaboration with other facilities or local agencies. They aim to help women reduce their risk by informing them of healthy lifestyle behaviors and chemoprevention, providing genetic counseling to high-risk populations, and offering screening services and clinical examinations. Patients who turn out to have positive findings are offered follow-up services. NAPBC standards also require that centers provide patients with educational information covering evaluation and management of breast diseases.[148] However, resources should not be exclusively tailored to diagnosed populations but relevant to the needs of women from all populations. Specific outreach to the African-American community can be optimized through survivor advocates, social networks, and church-based support groups.[187–191] The Sisters Network, Inc. is a notable national African-American survivor advocate organization whose mission is to spread awareness on breast health and increase accessibility to clinical trials.[192] Increased participation in outreach programs may also boost the likelihood of research endeavors.[174]

Constancy of Purpose/Investment in Improvement

> "An important characteristic of a microsystem is that the aim… is consistent with the aim of the larger system and guides the work of the microsystem. An investment in improvement comes in the form of resources such as time, money, and training, but above all it involves creating a philosophy of improvement within the microsystem."[6]

To establish new norms in the workplace, clinical teams must be committed to building change into the fabric of their microsystem. Developing an expanded monitoring program may help improve awareness of the team's performance as well as each individual's role within the team. But perhaps even more importantly, improving mindfulness in the workplace can encourage individuals to thoughtfully process their responses to demanding and stressful situations. This reflective process not only facilitates continuous learning, but also helps professionals recognize the external factors driving error like the fact that "the world they face is complex, unstable, unknowable, and unpredictable."[6] They face growing demand for their services alongside declining reimbursements and new technologies that enable increasing productivity. These mounting challenges call for the need to prepare team members to become compassionate towards themselves and resilient in their commitment to provide quality care. Practicing mindfulness can be the first step in making the link between safety and the microsystem.[6]

Dynamic leadership that promotes the use of reflective practices and team-building exercises can help spearhead the crusade for creating a culture of mindfulness. As a form of "tacit knowledge," mindfulness is a state of raised consciousness that is best learned through "observation and practice."[193] Leaders can cultivate mindfulness among staff members by setting an example of how they personally react to chaos and the unknown. Team members may also be engaged through versatile mindfulness interventions that have been created to specifically fit into the routine of individuals working in a healthcare setting. A systematic literature review of brief mindfulness practices for healthcare providers identified virtual interventions including on-line modules, audio CDs or smartphone apps that give people the flexibility to practice at home.[194] Practices vary and can involve a combination of the following activities: "general mindfulness practices such as increasing awareness, presence, or acceptance through breathing meditations, mindfulness-based stress reduction-inspired content, Buddhist Anapanasati breathing meditation or Vipassana meditation."[194] Group sessions can also facilitate team-building within the unit, allowing for the emergence of collective mindfulness. This type of training has been associated with improvements in personal well-being, connection to self and patient, error recognition and medical decision-making.[193]

CHAPTER 5: PERSONALIZED RISK-BASED APPROACH

Shifting the current paradigm from mammography to a more flexible breast cancer screening regimen may be the most effective option for optimizing health outcomes. We should continue to aspire towards producing new and improved breast cancer screening tools. In tandem with this new technology, a personalized risk-based approach is necessary to tailor health decisions and interventions to an individual's unique risk factors. This approach attempts to combine various practices and imaging techniques to maximize specificity and sensitivity while minimizing cost and radiation exposure.[7] This will also predictably ease patient anxiety and concern about radiation exposure which has been shown to decrease compliance with screening recommendations.[195] An example of a standard stratified screening program that uses an array of biomarkers would be as follows: "offer of stratified screening, risk profiling, delivery of screening, communication of results, and further management."[196]

In order to fully implement a personalized risk-based breast cancer screening and prevention program, a host of stakeholders must be mobilized. The medical community has begun to rally around the concept of tailoring screening regimens to a woman's overall risk profile. Medical education for health professions will be necessary to reinforce this screening program as this new approach requires assessments to be made over longer periods of time and hence, foster "greater interaction between service providers and the target population."[196] This way, screening frequency and modality may be adjusted to "potentially optimize the harm-benefit ratio of mammographic screening" for different subgroups of women.[196] In defiance of most recommended screening guidelines in the healthcare industry, the U.S. Preventative Service Task Force (USPSTF) and American Cancer Society (ACS) have boldly displayed their support for risk-based breast cancer screening.[197] As an independent agency, the USPSTF is not implicated in any conflicts of interest.[25] However, currently there is little evidence of prevention advice being integrated in population-based breast cancer screening programs.[196] Prevention refers to both primary prevention and early detection (secondary detection).[198] Figure 6 presents an implementation scheme of a sample risk-based screening and prevention program from the National Institute for Health and Care Excellence (NICE).[199]

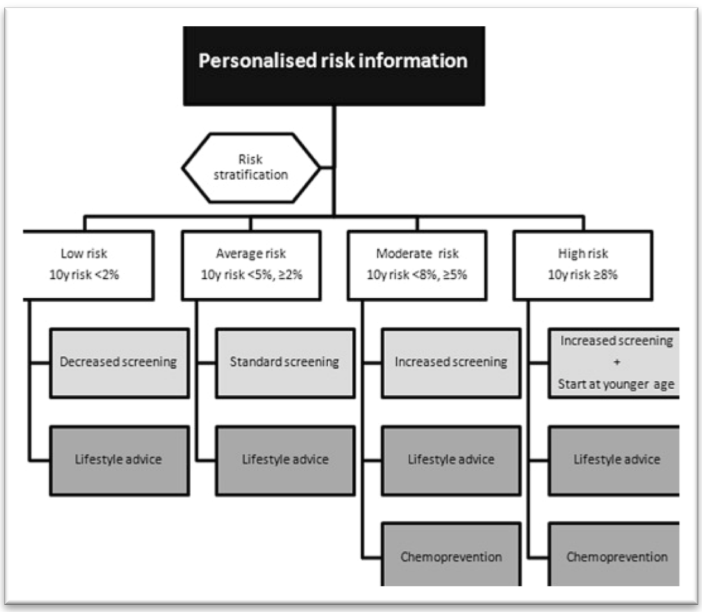

Figure 6. Implementation of a risk-based screening and prevention program (National Institute for Health and Care Excellence (NICE)).

Risk Stratification & Shared Decision-Making

Stratified screening will be offered on the basis of age as well as risk profiling, which has been shown to increase accuracy in discovering higher-risk individuals. This is expected given that our ability to estimate an individual's risk of developing cancer can be exponentially aided by exploring the genetic basis of disease susceptibility.[198] Programs offering stratified screening will have to delineate what information is given to prospective patients and ensure that it is made comprehensible to patients of varying educational and ethnic backgrounds. Most importantly, the program must have a protocol for enlisting the consent of participating individuals. Accommodations should be made for individuals who refuse risk stratification but still have a desire to get screened.[198]

The variations of risk assessment stem from the following core evaluations: genetic testing, assessment of non-genetic risk factors and the integration of genetic and non-genetic information into a risk score/risk category. Genetic DNA will need to be accessed in order to perform sequence analysis and ultimately carry out specific risk assessments. Preceding any invasive course of action will be a thorough discussion of which high-risk variants to include in the risk assessment based on the advantages they would confer to the patient. Deleterious mutations in BRCA1 or BRCA2 are often related to a risk of breast cancer. A strong family history of cancer may prove to be reasonable suspicion for testing for such high-risk alleles. Additional variants may be tested over time as more evidence accumulates. Surely if whole genome sequencing becomes more routine as a prevention tool in the distant future, younger individuals may be enlisted in the program. Genetic counseling may be sought following testing to translate test results, provide support options to the patient and/or appease potential frustration and concerns. Additionally, caution should be taken to securely store samples and data as well as protect them from being abused for reasons not agreed upon by the individual. [198] Non-genetic information to assess risk may also be collected via a questionnaire that elicits reproductive history, past medical history, family history, environmental exposures, and lifestyle information. Because this information is less stable throughout life, it may have to be obtained from the patient at regular intervals throughout their life.[198]

A fruitful and comprehensive risk assessment will generate a risk score by taking into account all of a patient's risk factors. Algorithms that compute these scores will have to rely on the accurate collection of data. Physicians may utilize risk models such as BRCAPRO, Tyrer-Cuzick, and Claus or the Breast Cancer Surveillance Consortium (BCSC) risk calculator which estimates risk in the upcoming five to ten years. Some of these instruments are more accessible than others; the National Cancer Institute's Breast Cancer Risk Assessment Tool (https://www.cancer.gov/bcrisktool/) and the BCSC's Risk Calculator (https://tools.bcsc-scc.org/bc5yearrisk/calculator.htm) are available with ease via the internet. Yet, only the BCSC's Risk Calculator takes into account breast density.[196] In terms of the organizational processes involved, health care professionals will need to be periodically trained on how to utilize risk models. This is especially pressing given the scientific community's inclination towards continually churning out new information on the genetic and environmental risks behind breast cancer.[196]

After extrapolating information from risk tools, providers should engage patients in shared decision-making (SDM) to elicit their views and preferences regarding different options for their healthcare. It's worth noting that in discussing the role of the clinician in this process, this may refer to any health professional at the imaging center or a trusted provider outside of this domain who can help patients deliberate their options. To facilitate this interaction, providers are encouraged to follow a model based on "choice, option and decision talk: a) introducing choice, b) describing options, often by integrating the use of patient decision support, and c) helping patients explore preferences and make decisions."[200] While providers may suggest alternative screening pathways for patients who present unique risk factors, it is crucial that they thoroughly engage patients in a discussion of the benefits and harms of screening. This enables patients to develop informed personal preferences, while also giving them the space to articulate their concerns regarding screening. While providers may be challenged to pursue SDM with patients with low health literacy or low numeracy, by exercising good clinical communication skills, providers can build rapport with patients from all walks of life. This process is particularly important in supporting vulnerable populations who've been historically neglected in the healthcare system. The structural forces that have undermined their efforts to adhere to screening or routine medical care have similarly dissolved their chance to obtain personalized care. SDM preserves the autonomy of patients who have felt marginalized, honoring their ability to follow a self-determined course of action for achieving their personal wellness goals.[200]

Delivery of Screening & Prevention Education

Stratified prevention hinges on the application of risk-based screening coupled with general advice on modifiable lifestyle factors. Differential interventions for high and low risk individuals consider the risks and benefits of the use of certain screening modalities and the frequency of imaging. The pros and cons not only consider implications to the individual's general health but also expenditures as a measure of total health care spending. Consequently, individuals who are at higher risk may be offered a longer period of lifetime screening while low-risk individuals may delay their start date for screening until they reach a later age. Healthcare professionals whether a technician, radiologist or primary care physician, should offer consultations regarding preventative management through chemoprophylaxis or lifestyle habits.

Patients may be offered the option to use alternative or adjunct screening modalities in addition to mammography. Advanced units like contrast enhanced mammography and digital breast tomosynthesis are being designed to eliminate the downsides of standard mammography. Contrast enhanced mammography can evaluate blood flow in breast masses similar to MRI, improving reader sensitivity and performance when compared with standard mammography and ultrasound.[201] This technology requires injection of iodinated contrast. An FDA approved version in the U.S. was made in 2011. Digital breast tomosynthesis or 3D mammography has been designed to better visualize overlapping breast tissue and accordingly, decrease the rate of false positive and false negative findings. This is ideal for women with dense breast tissue as it allows the radiologist to visualize small breast cancers. During mammography, the breast is compressed which may cause tissue in the upper and lower breast to overlap. This would create a misleading appearance of cancer.[202] 3D mammography avoids this issue by passing X-rays through the breast at different angles, acquiring “slices” of the breast. Relative to standard mammography, digital breast tomosynthesis exposes a breast to on average 8% higher MGD per acquisition.[203] Another limitation of tomosynthesis is a decreased sensitivity for detection of microcalcifications. Tomosynthesis is currently FDA approved as strictly a supplement to standard mammography.[7]

Automated Whole-Breast Ultrasound System (AWBUS) Sonography is used as a follow-up to ultrasound or for high-risk women or women avoiding exposure to ionizing radiation. It is generally accessible, incurs minimal costs, and does not utilize contrast like MRI. Hand held screening breast ultrasound has demonstrated significant benefits in helping radiologists acquire enhanced visualization of breast tissue. A study published in the Journal of the American Medical Association reported a 5% chance of a biopsy being performed following ultrasound. The positive predictive value (PPV) which indicates the proportion of women who truly are diagnosed was 11%.[20] On the downside, the quality of the captured image is heavily reliant on the technologist's skill and experience. This poses difficulty in standardizing ultrasound examinations. Two-dimensional AWBUS purports to find a solution by producing consistently high-quality examinations through robotic machinery. A standard ultrasound probe is guided over both breasts through automation.[204] It detects cancer at the same rate as standard ultrasound but has a higher PPV of 38%.[205]

Computer-aided detection (CAD) systems were introduced to reduce the rate of missing and incorrectly interpreting visible lesions at digital mammography. These errors contribute to at least 25% of detectable cancers that are missed due to poor human detection performance.[206–208] Some studies assert that the use of CAD will eliminate the demand for double reading.[209–212] Many European countries employ this dual scheme of interpreting mammograms which has shown greater success in the number of cancers detected relative to single readings.[213–218] Yet, it has also reportedly resulted in the recall of more women[215,217–220] and use of greater resources.[221] The use of double reading of examinations may create a heavier workload for all radiologists and threaten their productivity.[222] In the United States, mammograms are regularly interpreted by a single reader accompanied by computer-aided detection. Few studies have highlighted its benefit over single reading alone due to the low specificity of most traditional CAD systems.

Artificial intelligence (AI) is the newest undertaking of the digital imaging market and has shown promise for aiding radiologists in cancer detection without requiring additional reading time.[223] A new generation of artificial intelligence systems which are deep learning-based CAD systems improve both diagnostic performance and efficiency.[223] A systematic review of the implications of AI shows that there is a general consensus of its potential to improve "diagnosis, clinical decision making, patient outcomes, and workflow areas in breast imaging."[224] Human interactions with computer behavior are still a necessary element of the clinical decision-making process, submitting AI to the jurisdiction and management of the interpreting radiologist. The physician is appointed to oversee any interpretative error made by the AI before it can result in an unsafe medical recommendation for the patient. Errors may originate in mistakes in the patient's clinical history or poor image quality. Hence, success of AI has been mainly concentrated among task-based activities rather than decision-making.[225] Generally, studies report that it has improved the workflow of radiologists and increased accuracy in diagnosis. Future directions in breast imaging AI include developing advanced algorithms that account for the variables inherent to human behavior such as "human touch, the physician-patient relationship, and accumulated medical knowledge and experience."[224] Until then, AI may be most appropriately used as an adjunct to radiologist interpretation of imaging studies.[225]

Communication of Results & Follow-Up

Microsystems should develop formal methods for communicating results and coordinating follow-up for those with abnormal test results.[198] Patients should be consulted before-hand to determine how they'd prefer to be communicated their test results, as well as relayed periodic reminders about their upcoming screening appointments. Individuals who've obtained abnormal mammogram results may be asked to return for follow-tests which may begin with less invasive tests like a diagnostic mammogram or breast ultrasound. In some instances, additional tests such as breast MRI or biopsy may be recommended.[226]

Leveraging professional relationships within the clinical team will help yield successful results in coordinating a patient's care across multiple settings. Microsystem service and support staff should collectively approach this situation with compassion, helping patients alleviate cognitive stress related to their test results. Healthcare professionals should thoroughly inform diagnosed patients of the different characteristics of their cancer and management relevant to its severity. They may also refer them to appropriate specialists. The collective and deliberate efforts of the microsystem and its affiliated multidisciplinary team will ultimately help these patients transition across the continuum of care.

Concluding Thoughts

The first step in implementing a risk-based breast cancer screening prevention program is galvanizing the individuals who operate within the breast center into action. Innovation should be made at the frontlines of healthcare by workers who are observing the challenges of healthcare delivery head-on. To advance this mission, organizations should operate in a way that provides microsystems with the resources and support to take on clinical redesign. Microsystem service and support staff should also situate patients at the center of innovation. By using patient safety and autonomy as a driving force towards quality improvement, they can move closer towards achieving "improved care, continuity, communication and coordination, and cultural competency."[227]

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