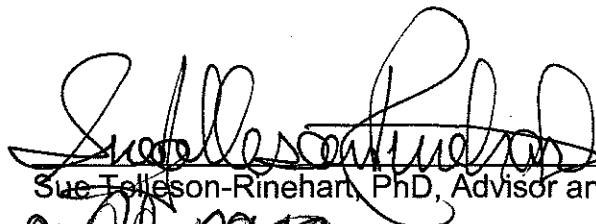


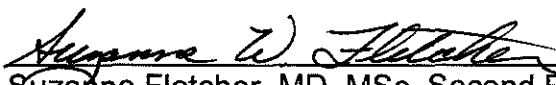
Full-Field Digital Mammography for Breast Cancer Screening: An Example of Evidence, Lost in Translation

By
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Abstract

Screening mammography is the gold standard for early breast cancer detection and a cornerstone of preventive medicine. Traditional mammography is currently being replaced by newer, more eloquent digital technology. Clinical trials have not proven that digital mammography reduces breast cancer mortality or burden of suffering. Nevertheless, the technology has spread according to Everett Roger's "Diffusion of Innovation" pattern. The purpose of this Master's Paper is closely to examine the process by which breast cancer screening in the United States has evolved from screen film mammography to full-field digital mammography. This is a qualitative, iterative analysis that triangulates analyses of the medical literature, elite interview responses, and media coverage to cultivate a storyline about the development and dissemination of digital mammography. The technology has spread because of our national hunger for computers and innovation, our eagerness to support the "war on cancer," public perceptions about the technology's theoretical advantages, and ongoing efforts of advocacy groups to maintain health care equality. Although digital mammography is significantly more expensive than is screen film mammography, cost-effectiveness considerations have been deferred by many health care leaders. Regulating technologies such as digital mammography, which are extremely expensive but do not confer better public health outcomes, is a necessary component of fixing our health care system.

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Preface

This paper is meant to be a critical analysis, written from the perspective of a student of public health, medical literature, public policy, and social change. I chose a topic about which I am passionate, which is cancer prevention, screening, and mammography. I chose to examine digital mammography because, when I began the work, I did not have a strong, predefined opinion about whether this is the appropriate direction for breast cancer screening. The reader should know my hypothesis when I began this project: The adoption and dissemination of digital mammography has followed a trajectory similar to that of other medical technologies in the United States. That is, digital screening mammography has not been introduced to the health care system in a systematic, synchronized, or evidence-based manner. Rather, leaders and groups with vested interests in the success of digital mammography have been most significant in the technology's disorganized development and introduction.

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Introduction

...this has sort of been an interesting issue around evidence-based medicine. It's sort of what happens, and particularly in an environment where you have a strong, significant advocacy group... the public has driven this, and it sort of went right by where the evidence was.

-- Carl Ravin, MD, Chairman, Department of Radiology, Duke University Medical Center (DUMC)

In September 2007, the University of North Carolina at Chapel Hill (UNC) became the first hospital in North Carolina to transition completely from screen film to all-digital mammography. These two screening modalities both use X-rays to obtain breast images. Screen film images are captured on film, but digital images are deposited in computer software. Thus, digital images may be manipulated to adjust contrast, brightness, or magnification. We have been eager to implement digital mammography because of its potential to improve the diagnostic accuracy of traditional, screen film mammography. This potential, if realized, would be enormously positive for the fields of preventive medicine and oncology.

Many of our current medical technologies were also introduced into the health care system because of their potential to improve public health. Unfortunately, too many of these have turned out to be extremely expensive without contributing significantly to improved clinical outcomes. The medical profession has recently, however, become more attuned to using evidence as a guide for individual practices, and a method for improving both effectiveness and cost-effectiveness of interventions. In the case of digital mammography, several large clinical trials have compared the technology with screen film mammography. Overall, these trials have not demonstrated considerable diagnostic advantage of digital screening for the majority of the population. Nevertheless, as Dr. Ravin said, we have gone "right by where the evidence was."

The purpose of this analysis is to conduct a critical examination of digital mammography by identifying the variables most likely to explain its emergence and rapid adoption. Popular culture encourages Americans to buy the most expensive and innovative things on the market, whether they are electronics, automobiles, or health care devices. Doctors may choose to adopt uncertainly supported practices because of available resources, personal experiences, or even political loyalties. At the health system level, adoption of new technologies is fragmented because separate parties are responsible for developing, approving, funding, marketing, and distributing products. In this disorganized process, no one has the advantage of a completely balanced, "big picture" understanding of new medical interventions. Moreover, no entity has the authority to regulate technologies using this "big picture."

Above and beyond these baseline forces that seem to impel the adoption of technology, digital screening mammography has been introduced into the system against a backdrop of ongoing national discussions about breast cancer screening and prevention. Participants in this discussion include government organizations, cancer and women's advocacy groups, innovators of digital technology, breast imaging specialists, private vendors of digital equipment, and third-party payers. All these interests have had stakes in digital technology's dissemination. In this complex process, the evidence has been muffled, manipulated, misunderstood, and even completely forgotten by both groups and health care leaders.

Nowhere can these various perspectives be better explored than through interviews with elite stakeholders and analyses of media coverage of digital mammography. Therefore, this qualitative analysis is iterative, relying on a triangulation of analyses of medical literature, respondent interviews, and media accounts to draw conclusions about influences on the adoption of digital screening mammography. The fruit of this triangulated analysis is a storyline of

digital mammography, which provides one account of its development and introduction.

Prior to beginning the story of digital screening mammography, we need to make clear two major limitations on this type of study. First, the study relies on a modest amount of data from which to extract relationships and draw conclusions. To compensate for the small sample size, I have collected information from elites with different perspectives in health care and unique areas of expertise. The media analyses are based on a review of articles from the nation's major newspapers. Second, qualitative and iterative research cannot be used as a vehicle to prove causation. Although this analysis is presented in a stepwise fashion, the data cannot support any one action/event directly causing another. One of the purposes of triangulating methods, however, is to collect data from multiple sources and impute strong relationships between interests and events. To the degree that different methods converge on a single answer, the methods have provided some cross-validation of one another, and the answer is likely to be more robust.

Qualitative Methods: Elite Interviewing and Newspaper Analyses

Two standard methods of gathering social science data are through analyses of interviews and documents.¹⁻³ I extracted data from interviews and newspaper articles using a dynamic analytical process in which I generated, tested, and refined hypotheses about the most significant social factors affecting the adoption and dissemination of digital mammography. I used the well-recognized social research process of coding to both develop and support hypotheses from my field work.^{2, 3} I acquired skill in document coding through intensive training at the Odum Institute for Research in Social Science (University of North Carolina at Chapel Hill)³ and by reading three reference books about qualitative research: Bogdan's *Introduction to Qualitative Research Methods*, Bailey's *Methods of Social Research*, and Berg's *Qualitative Research Methods for the Social Sciences*.^{1, 2, 4}

Briefly, I coded both interview responses and newspaper articles using the following parameters: (1) most important topics, as determined by length of interview discussion or word counts in newspaper articles, (2) areas of apparent consensus, for example agreement among interviewed radiologists about the similar subjective experience of women receiving a digital versus film mammogram, and (3) areas of disagreement or contradiction, such as different opinions about the role scientific evidence in the adoption of digital mammography. I also coded each newspaper article according to its publication date, words used in the title, key words and/or phrases used in the article's text, presence of medical evidence citations, and overall tone of the article. Summaries of the coding schema for the interviews and newspaper articles are found in Appendices 1 & 2. Ideally, the codes I developed for data extraction should be reviewed and verified by another social science researcher to bolster their validity and reliability. Due to limited resources and time constraints, however, no second coder was able to review my data at the time of this writing.

The purpose of interviewing elite stakeholders is to gather information and perspectives that cannot be obtained from surveys or other public documents. Elite interviewing focuses on how leaders frame their views and how they make connections or reveal disjunctions between their opinions. In her work with elite interviewing, Hochschild says the purpose of such interviews is to contextualize issues from the perspectives of those involved in shaping them.⁵ In the case of mammography, elite interviewing is appropriate because leaders from various fields have essentially spearheaded the national push for digital screening in the absence of mandates compelling such a transition. Understanding their views of the process is, in significant ways, to understand the process itself.

Over the course of one month, I conducted a total of ten interviews with twelve elites in the fields of radiology, breast cancer screening, hospital administration, and public policy. I received permission from UNC's Institutional Review Board (IRB) to conduct these interviews, and obtained verbal consent from each participant to record, transcribe, and include their responses in my analysis. I transcribed all interviews, which varied in length between 15 and 45 minutes, in the "naturalist" style including notations of pauses, incomplete statements, and other non-verbal communication. The IRB-approved interview questions and a list of respondents are located in Appendices 3 & 4.

The media have always been a powerful agenda-setter in our country. John Kingdon, in his classic work *Agendas, Alternatives, and Public Policy*, found the media have a significant role in magnifying issues.⁶ In theory, professional journalists maintain a "wall of separation" between news pages and editorial pages. Often, however, the media report in ways that actually shape and structure issues.^{6,7} Kahn and colleagues analyzed breaches in the "wall" and found that newspaper reporting is affected by the political views of editors, who alter the tone of the news coverage about incumbents.⁷ In the case of digital mammography, the media likely served two purposes: spreading information

about digital technology to the public and framing the public's perception of the technology.

My media search included the top twenty-five circulating United States newspapers, according to A.C. Nielsen's spring 2007 assessment (Appendix 5). Although newspaper readership among the U.S. lay public has declined with our increased preference for television and internet news, policy makers and medical elites continue to read and contribute to newspaper articles. Also, the results of newspaper searches are very reliable indicators of media coverage, since the choice of stories in other media is reflected, and often even stimulated by, what newspapers choose to cover.

I accessed the majority of newspapers electronically through the UNC Libraries website; however, *USA Today*, *The Wall Street Journal*, and *The L.A. Times* were not directly available through the website. I used LexisNexis® to access *USA Today* articles and Procite® to access *The Wall Street Journal* and *The L.A. Times*. I searched each newspaper database using key terms "digital mammography" and excluded reprints, brief financial statements, articles that did not contain the words "digital mammography" together in context, and articles that only mentioned digital mammography as a peripheral subject (ie. in obituaries or biographies). The initial media search yielded 500 articles, of which 215 met inclusion criteria.

Weighing the Evidence: Review of the Medical Literature

Approach to Reviewing the Literature

The strongest evidence-based approach to evaluating digital mammography would involve answering the following question: "Does digital mammography screening decrease breast cancer mortality rates more than does screen film mammography?" This fundamental question of comparative effectiveness should be addressed prior to adopting any new screening tool. In addition, it is critical to review the literature regarding relative harms and costs of digital as compared to film mammography. This chapter addresses both the comparative effectiveness and cost-effectiveness of digital mammography. A subsequent chapter, entitled *Perceptions with Real Consequences*, investigates the potential hazards of adopting digital mammography as the standard breast cancer screening method.

The purpose of any screening test is not simply to detect disease, but to help people live longer lives with higher quality because they are treated for the disease intended to be detected at an early stage by screening. Thus, screening tests are only effective if they detect diseases that can be successfully treated. In the case of digital mammography, researchers have conducted randomized and paired-comparison trials to study the diagnostic accuracy of digital versus film screening for breast cancer lesions. These types of studies are necessary to ensure that digital mammography does not miss breast cancers that would have been detected by screen film mammography. The inherent problem with these studies, however, is that they cannot demonstrate which modality is a more effective screen for relevant breast cancers, or those that can be treated to enable women live longer lives with less morbidity.

In general, screening examinations are more likely to detect indolent forms of any disease because of length-biased sampling. In other words, patients with less lethal forms of disease are more likely to be identified on screening exams

because they remain in the pre-symptomatic, screening-detectable phase of disease for a longer time. The natural history of indolent breast cancers, such as low-grade ductal carcinoma in situ (DCIS), is variable. Although digital mammography may enable more breast cancer diagnoses, these diagnoses could include a significant number of indolent breast cancers. These cancers may be detected earlier on full-field digital mammography, but could have been detected later on film mammography with no change in clinical outcome for the woman. Alternatively, many digitally detected breast cancers may never have become clinically apparent. Women with these sub-clinical cancers may be exposed to painful and unnecessary treatments, such as surgery and chemoradiation. In scenarios such as this, digital screening mammography does not serve its intended purpose of helping women live longer and/or more healthfully.

The best way to evaluate the value of digital versus film mammography for breast cancer screening would involve a randomized controlled trial (RCT). The investigators should randomize women to receive either digital or film mammography, and follow them over years (or even decades) to determine which group experienced lower breast cancer mortality rates and also which group had the greatest number of false positive and/or negative screens. Although having data from such an RCT would be ideal from the perspective of evidence-based medicine, designing the trial would be difficult for several reasons. First, the relationship between screen film mammography and decreased breast cancer mortality is already well-documented in the literature. Restarting mortality trials with the digital “upgrade” would require tremendous funding and other resources to monitor patients over time.

In addition, any relationship between breast cancer screening and mortality is undercut by advances in cancer therapy. Because cancer therapy will improve alongside any trial to compare screening modalities, it would be difficult to distinguish between the effects of digital screening and the effects of more

sophisticated therapies on breast cancer mortality. To explore this phenomenon, Berry and associates used mathematical models to estimate the distinct effects of screening, chemotherapy, and tamoxifen on breast cancer mortality reduction since 1975.⁸ The models provide estimates of how much mortality reduction is attributable to cancer screening versus therapy. The models attribute breast cancer screening with reducing breast cancer mortality by a range of 7.5% to 22.7%, with a median value 15.3%, over the past 25 years. The proportion of the overall decreased breast cancer mortality attributable to screening, as compared to chemotherapy and/or tamoxifen, ranged between 28% and 65% with a median value of 46% since 1990.

As becomes clear, systematically reviewing the literature for effectiveness evidence about digital screening mammography is complicated by several factors. Studies examining the influence of digital screening on mortality are not available, and studies examining the accuracy of digital screening are subject to length-time bias. Despite these limitations, I proceeded with a systematic literature review to answer the following question: “Among women seeking breast cancer screening, does digital mammography have greater diagnostic accuracy than film mammography?” Studies which evaluate the diagnostic accuracy of digital and screen film mammography must be rigorously analyzed for high-quality, transparent reporting of methods and results as outlined in the Standards for Reporting of Diagnostic Accuracy (STARD) criteria.⁹ Thus, I only reviewed articles that included calculations of sensitivity/specificity of the screening tests, described the study population and participant recruitment, outlined the data collection process, explained the expertise of radiologists reading mammograms, and explicitly reported statistical methods.

Systematic Review

I searched MEDLINE for trials published over the last ten years, using the MeSH term “mammography” and keyword “digital,” with the limits of English, Humans, Women, Clinical Trial, Randomized Controlled Trial, Comparative Study, and

Controlled Clinical Trial. This initial search yielded 103 articles. I only reviewed studies of asymptomatic women undergoing breast cancer screening. The study interventions were full-field digital mammograms, the comparisons were screen-film mammograms, and the outcome of interest was breast cancer detection. For purposes of this review, breast cancer includes both DCIS and invasive disease. Because my focus is on the real-world effectiveness of digital mammography as a tool to improve breast cancer outcomes in the population, I specifically excluded studies that considered breast tissue calcification(s) a “positive” screening test, because detection of only breast macro- and micro-calcifications is often an ambiguous indicator for a breast neoplasm. I also excluded studies using biopsy specimens or phantom images for comparison between digital and film modalities, and studies that relied primarily on computer-aided detection (CAD) devices for diagnosis or computed radiography (CR) systems for image acquisition.

Four major studies met these inclusion/exclusion criteria: (1) Lewin and associates’ 2001 comparison of full-field digital and screen film mammography, (2) the Oslo I Study, (3) the Oslo II Study, and (4) the Digital Mammographic Imaging Study (DMIST). An abbreviated summary of each trial’s design and major findings is located in Appendix 6.

Figure 1: Summary of Clinical Screening Trials Comparing Film and Digital Mammography

Statistically significant findings appear in **bold**

Trial	Lewin and colleagues	Oslo I	Oslo II: Ages 45-49	Oslo II: Ages 50-69	DMIST: All ages	DMIST: Age <50
Study Design	Paired-comparison trial	Paired-comparison trial	RCT	RCT	Paired-comparison trial	Paired-comparison trial
Ages Included	>40yo	50-69	45-69	50-69	All	<50
Sites	2	1	1	1	33	33
Number of exams	6,736 exams in 4,489 women (1,665 enrolled once, 291 enrolled twice) *Repeat exams separated by >11 months	3,683	Film: 7,607 Digital: 3,012	Film: 10,304 Digital: 3,985	Film: 42,745 Digital: 42,570	Film: 14,355 Digital: 14,355
Cancer Detection Rate	Film: 0.49% Digital: 0.37% p>.01	Film: 0.76% Digital: 0.62% P=0.23	Film: 0.22% Digital: 0.27% p=0.686	Film: 0.54% Digital: 0.83% p=0.53	Film: 0.40% Digital: 0.43%	Film: 0.22% Digital: 0.33% p<.003
PPV*	Film: 3.3% Digital: 3.4% p>.30	Film: 21.9% Digital: 13.7%	Film: 7.4% Digital: 7.1% p>.05	Film: 22.1% Digital: 21.6% p>.05	Film: 5%*** Digital: 5%***	Film: 2%*** Digital: 3%***
Recall Rate**	Film: 14.9% Digital: 11.8% P<.001	Film: 3.5% Digital: 4.6% p=0.21	Film: 3.0% Digital: 3.7% p>.05	Film: 2.5% Digital: 3.8% p<.05	8.4%***	10%***
Overall Conclusions	Conclusions limited because of high number of lesions examined with both screening modalities	Lack of statistically significant results and limitations to external validity reduce applicability of study	Randomization improves internal validity of the study; however, overall lack of significant findings		Although high external validity, study was limited by non-significant findings and low internal validity	Suggests truly higher sensitivity of digital mammography in one subgroup of women
Quality (Good, fair, poor)	Fair/Poor	Fair	Fair	Fair	Fair	Fair

*Percentage of abnormal mammograms leading to breast cancer diagnosis (by one reader)

**Recall after consensus meeting, based on abnormal mammographic findings

***Values were extrapolated from data presented by DMIST authors

Lewin and associates, 2001:^{10, 11} This was the first large study comparing the effectiveness of film versus digital mammography for screening purposes. Women over forty years who presented at one of two mammography centers were included, for a total of 6,736 paired examinations of film and digital mammography. Overall, the study found no significant difference between the modalities in terms of cancer detection rates or positive predictive values (PPVs). The authors did not design this analysis for hypothesis generation, and could not conduct statistically meaningful subgroup analyses to compare accuracies of each modality among different age groups.

The major, statistically significant result discussed in this study was lower recall rates for patients receiving digital (11.8%) than for patients who had had film mammography (14.9%). The authors attributed these lower recall rates to fewer false positive results with digital mammography. Interpreting radiologists were not masked, though, and could therefore have been more meticulous about recalling film than digital cases.

The primary threat to the validity of this study was the mammography image interpretation process. One radiologist read each film, but (s)he was permitted to use previous screen film mammograms for comparison. Thus, radiologists could have introduced interpretation bias as they based their diagnoses on previous images. In addition, many indeterminate cases emerged during the study as radiologists found suspicious lesions on one imaging modality but not the other. Radiologists discussed these discordant findings at "discrepancy conferences," where teams used both digital and film images to make a final diagnosis. These indeterminate cases comprised over half the total abnormal findings in the study, but were counted as either digital-detected or film-detected lesions for analysis. This is problematic because the high volume of cross-reading diluted the actual distinction between diagnostic performances of each screening modality.

Oslo I:¹² The Oslo I trial, conducted by Skaane and associates, was published two years after the study by Lewin and colleagues. Oslo I took place at one site, and was designed as a paired-comparison study with 3,683 women aged 50-69 years receiving both film and digital mammograms. The study found no significant difference in the two modalities' rates of cancer detection, PPV, or recall. Since the Oslo I did not include women in their forties, the trial's findings are not applicable to this subgroup of women.

Despite not finding significant differences, the Oslo authors did improve upon the experimental design of Lewin's study. Each image was reviewed by two independent radiologists, who were not given previous screen film images for comparison. The radiologists discussed indeterminate breast lesions in teams, but the teams were only allowed to use original images to make final diagnoses.

Oslo II:¹³ The main differences between the Oslo I and II studies were that Oslo II had a larger study population of 25,263 women, it included women aged 45-49 years, and it randomized participants to either film or digital mammography. The authors found no overall, significant difference in cancer detection rate or PPV between screening modalities. Notably, both Oslo I and II found higher recall rates for digital mammography than for screen film mammography. These results reached statistical significance in the Oslo II study. The higher recall rate for digital imaging is the obverse of the trial results by Lewin and associates, who found a significantly lower recall rate for digital mammography. This difference may be partially attributable to more frequent mammography recalls in the United States as compared to Europe.¹⁴

Although Oslo II was a randomized trial, it has some limitations in its design and external validity. First, the soundness of randomization cannot be determined for this study, as the authors do not give detailed information about their methods of randomization, masking, or concealment of allocation. Also, only Norwegian

women participated in both Oslo studies. This population is more homogeneous than the population in the United States, where women of different races, ethnicities, and even socio-economic classes have distinct screening patterns and presentations of disease. Finally, the Oslo studies only used one type of digital machine (General Electric's Senographe 2000D®). The authors therefore could not explore different manufacturers, which may influence cancer detection rates.

One major contribution from both Oslo studies was the documentation of cancer types detected by each screening modality. This information is important, as histopathology of cancer estimates of the cancer's clinical aggressiveness. Histopathology can serve as an intermediate outcome, or marker for cancer mortality. Unfortunately, the Oslo I study only detected 31 malignancies, so the authors could not draw any significant conclusions about the diagnostic performance of either screening modality. A total of 120 cancers were detected during the Oslo II study; however, the study was not powered to find very small differences in detection of DCIS versus invasive cancer. Therefore, although the Oslo studies measured histopathology, neither study was able to draw significant conclusions about which screening modality detected more invasive and/or curable cancers.

DMIST:^{15, 16}. The DMIST design improved upon the external validity of previous studies because it included an enormous sample size, a large number of study sites and participating radiologists, a more diverse study population, and five different types of digital machines. The DMIST enrolled 42,760 women who underwent both film and digital mammography, which powered the study for hypothesis generation and subgroup analyses. Because of the potential to assign false statistical significance with multiple subgroup comparisons, the authors applied the Bonferroni correction equation and considered P-values less than .002 to be statistically significant.

Overall, the DMIST found no significant difference between digital and screen film mammography. The authors did, however, find significantly higher Area Under the Curve (AUC), sensitivity, and PPV of digital mammography among women younger than 50 years old who are pre- or peri-menopausal with dense breasts.¹⁷ This subgroup included 7,315 women, or 17.1% of the DMIST study population. The AUC among this subgroup of women was 0.791 for digital mammography and 0.544 for screen film mammography [p=.0015]. The sensitivities were 0.591 for digital mammography and 0.273 for film mammography [p=.0013]. Finally, the PPV of digital mammography was 0.033 and the PPV of film mammography was 0.015 [p=.0005] among these younger, dense-breasted women. It should be noted that the specificities of the screening modalities were not significantly different within this subgroup of women.

One major concern about the DMIST, raised in editorials in *The New England Journal of Medicine*, was that digital mammography may not perform as well as film mammography for women older than 50 years. This concern was addressed in the DMIST follow-up analyses of subgroups. Among women older than 65 years with less dense breasts, screen film mammography was more accurate than digital mammography in terms of AUC, sensitivity, and PPV. The AUC for film mammography 0.877 and for digital mammography was 0.705 in this subgroup of women [p=.0025]. The sensitivity of film mammography was 0.694, versus sensitivity of 0.532 for digital mammography [p=.031]. Because of the Bonferroni correction, these results just barely missed statistical significance.¹⁷ Nevertheless, the near-significantly better diagnostic accuracy of screen film mammography than digital mammography among older women without dense breasts raises the possibility that digital mammography could actually be more harmful than film mammography in this large subgroup of women.

Another weakness of the DMIST was, as in Lewin's study, interpreting radiologists were permitted to use previous screen film mammograms for comparisons. Also, if an attending radiologist found a suspicious breast lesion

on either a digital or a film image, (s)he was permitted to evaluate images from both modalities during the patient's work-up. Thus, Lewin's study and the DMIST introduced similar image interpretation biases.

Like the Oslo I and II authors, the DMIST authors also recorded histopathology of cancers detected by each screening modality. The DMIST, however, did not detect enough cancers to make statistically sound conclusions about which screening modality was more accurate for detecting specific types of breast lesions. The authors conclude the "histologic findings and stage of the breast cancers detected by the two methods were similar."¹⁶

The DMIST was designed to have superb external validity and generalizability, as the trial was the largest and most widespread comparison of digital and screen film mammography to date. The trial results do suggest better diagnostic performance of digital mammography among one subgroup of women. These results must be interpreted with caution, given the trial's threats to internal validity and inability to measure mortality endpoints.

Cost-Effectiveness of Full-Field Digital Mammography

Although reimbursement rates for mammography are different throughout the United States, Medicare pays about \$86 for screen film and \$135 for digital mammography. Since this price differential has important health policy implications, it is appropriate to consider cost-effectiveness analyses for population-wide use of digital mammography. Tosteson and colleagues performed one such analysis, from the perspective of third-party payers, in the *Annals of Internal Medicine* in January 2008.¹⁸ The authors used a validated, computer-based model which incorporates the DMIST data and accounts for breast cancer natural history, screening and detection patterns, treatment, and competing-cause mortalities. Tosteson and associates considered multiple population-wide screening scenarios, and concluded that digital screening does

not offer sufficient health gains to warrant its increased cost unless its use is limited to younger women. Specifically, age-targeted digital screening for women in their forties cost \$26,500 per quality-adjusted life year (QALY) gained, and age- and density-targeted digital screening for women in their forties cost \$84,500 per QALY gained. Among women over 65 years, density-targeted digital screening cost \$97,000 per QALY gained. Overall, the cost for all-digital mammography relative to all-film mammography was \$331,000 per QALY gained.

The primary limitation of this cost-effectiveness study was its reliance on models. Although the models were externally validated, they were based on predictions of breast cancer risk and treatment patterns, which change significantly over time with new medical developments. In addition, Tosteson and colleagues do not include costs of anxiety and fear that women experience when receiving mammograms or being called back for work-up of suspicious breast lesions. These transient hardships are difficult to capture in a cost-effectiveness analysis, but the authors do consider a “personal visit time” cost for breast cancer screening. These allowances, which range from \$3 for a woman who has a true-negative exam to \$106 for a woman with a true-positive exam, may be gross underestimations of what women truly pay during breast cancer screening.¹⁹

Conclusions: Digital Mammography for Population Screening

In the best of worlds, three questions would be answered with a “yes” before we implemented any wide-scale prevention strategy: “Can it work? Does it work? Is it worth it?” In theory, digital mammography can work as a population screening tool for breast cancer. The clinical trials indicate all-digital screening is certainly plausible, and is diagnostically comparable to screen film mammography.

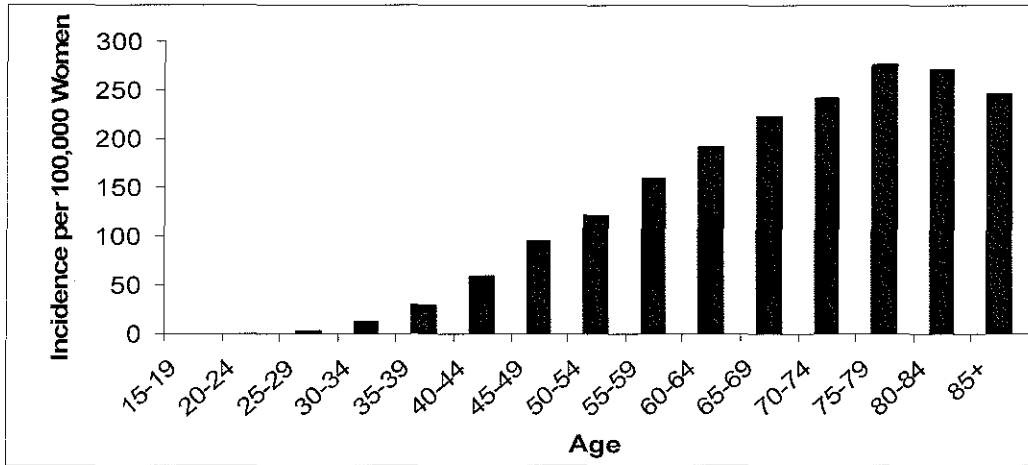
Several limitations restrict the trials' ability to answer the second question: “Does it work?” From a public health perspective, we are most interested in knowing if digital mammography “works” to decrease breast cancer mortality or provides

earlier detection of aggressive, treatable disease. The literature does not provide evidence that digital mammography “works” in this sense. The DMIST does show higher sensitivity of digital mammography in women less than 50 years old, who are pre- or peri-menopausal with dense breasts. Therefore, it can be approximated that more breast cancers could be detected, and burden of suffering could decrease, by using digital screening in just this subpopulation.

The recent trend toward all-digital mammography makes it appropriate to examine the population-wide burden of breast cancer suffering that could be relieved with digital technology. This will shed light onto the final question: “Is it worth it?” Burden of suffering is estimated by considering (1) how many people in a given population are affected by a disease, and (2) how severe a disease is among those who have it.

The majority of women diagnosed with breast cancer are over 50 years old. For an average woman, the risk of breast cancer doubles between ages 40 and 50, or increases from 0.4% to 0.8% 5-yr risk.²⁰ Figure 1 shows that younger women, who could theoretically benefit from all-digital mammography, represent only a small percentage of breast cancer cases.

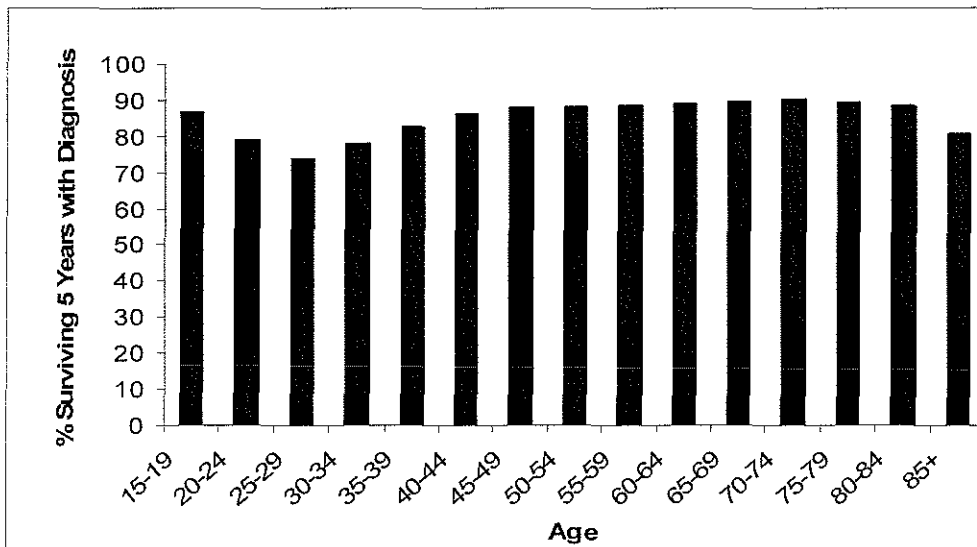
Figure 2: SEER Incidence of Invasive Breast Cancer by Age²¹



Source: SEER database, National Cancer Institute, Cancer Statistics Branch

Five-year survival rates provide an indicator of disease lethality, which is the second burden of suffering component. These survival rates, by age at breast cancer diagnosis, are presented in Figure 2. The graph shows that women in their forties may have slightly lower, but not significantly lower, 5-year breast cancer survival rates than do older women.

Figure 3: SEER 5-Year Survival Rates of Invasive Breast Cancer by Age²¹



Source: SEER database, National Cancer Institute, Cancer Statistics Branch

Figures 1 and 2 make clear that women in their forties are not the majority of breast cancer patients, and they do not appear to have significantly more lethal forms of breast cancer. Screening only this population with digital mammography could be cost-effective, at a theoretical \$26,500 per QALY gained. However, it is inappropriate and not cost-effective to use digital screening mammography for the entire population.

The research community cites expense and resources as major obstacles to comparing the long-term outcomes of digital versus screen film mammography.

The Principal Investigator of the DMIST said in her interview:

...the reason why we did what we did exactly was because we only had so much money. If we had more money, then we could have followed women. We could have gotten more years of data collection and had more information about annual screening mammography, and that would have been a stronger study. With infinite resources, which you don't have, we might have studied mortality as an endpoint. But, those things are impractical. I mean, it's just too expensive. We had one year of data collection, we had one year of imaging results ... and then a year to follow-up. So, we had a total study length of three years and it still cost us twenty-six and a half million dollars.

Despite the reluctance to fund a stronger study because of cost concerns, our health care system has been eager to invest \$331,000 per QALY for all-digital mammography. In population-wide terms, the US Census Bureau estimates the number of women appropriately aged for breast cancer screening, or women between ages forty and seventy-nine, at about 62,186,555.²² If half these women received a digital mammogram in one year, at \$135 per study, the total cost would be \$4,197,592,463. This estimate is \$1,523,570,598 more expensive than would be film mammography for the same population over one year. Thus, using all-digital mammography for breast cancer screening could cost the health care system an additional 1.5 billion dollars per year. This added expense is more than fifty-seven times the cost of DMIST. We have therefore created a paradox between our refusal to fund large-scale trials to prove effectiveness and our willingness to pay for implementation of all-digital

mammography. This paradox is one of many inconsistencies that have framed the introduction of digital mammography to our health system.

“An Idea Whose Time Has Come”

...I say openly, to the world, that we're not doing well. Still 40,000 women are dying a year. It's not criminal, but it's not low enough. There are still too many people dying. We have to acknowledge that we're finding breast cancer in some women when it's too late. We're doing the best we can. People get all defensive about it... Some of the radiologists, they get all defensive about it: "How dare you attack us? We're doing the best we can; we're working our asses off; we're really working hard on this." Yes we are, but our tools aren't good enough.
-- Etta Pisano, MD, Principal Investigator of DMIST

Digital mammography was born into a time of great potential for any new breast cancer screening technology. In the late 1990's, our “war on cancer” was fully waged, with advocacy groups acting as commanders of the siege. The effectiveness of breast cancer screening is, however, limited because of the imperfect sensitivity and specificity of mammography. While the breast cancer lobby has been very successful in summoning enthusiasm and infrastructure for their cause, we have remained frustrated with breast cancer screening because, as Dr. Pisano stated, “our tools aren't good enough.” Therefore, we may consider digital mammography an “idea whose time has come.” John Kingdon states, in American politics, “an idea whose time has come is so powerful that it pushes aside everything that might stand in its path.”⁶

The War On Cancer

Deborah Stone argues that “war” is ingrained into policy language because it invokes our desire to survive.²³ Despite decreasing incidence and mortality rates, breast cancer remains the most commonly diagnosed cancer among women. General apprehension among healthy women about developing breast cancer contributes significantly to its burden of suffering. The anxiety-provoking nature of breast cancer screening was described by the Chairman of Duke's Radiology Department:

... women coming in for screening mammography are our most difficult patient population, because they come in and they're anxious, and sort of nothing great could happen. The two things on the decision tree are: one, you've got an abnormality that's got to be followed up... which makes

everybody unhappy... or two, you're OK this year, we'll see you. It's not like "you're cured, you're healthy, go away." And all the women are familiar with it, and everybody's got at least friends who have had biopsies done. So they're very anxious, and because they're anxious and healthy, they turn out to be a more difficult population.

In addition to the ambiguous nature of screening, breast cancer is also worrisome because it is not strongly associated with individual choices and habits. Popular knowledge teaches women to feel safe from lung cancer if they are non-smokers and from cirrhosis if they are non-drinkers. The tendency for breast cancer to invade a woman's life without warning or clemency perhaps contributed to the development of the "war on cancer."

Advocacy groups, however, have been instrumental in popularizing this "war." Breast cancer advocacy is a relatively new political movement, as Betty Ford was one of the first women to speak openly about her disease in 1974. This encouraged other women with breast cancer to discuss what had previously been an utterly private and even shameful diagnosis.²⁴ Betty Ford and others opened the floodgates of popular awareness and advocacy, and it was not difficult to tie breast cancer awareness and research to other goals espoused by the Women's Movement at the time. The Susan G. Komen Foundation was founded in 1982, and other advocacy groups, including the National Breast Cancer Coalition and Breast Cancer Action, were founded in the mid 1990's.

These groups have been influential agenda-setters for Congress, which increased funding for breast cancer research from \$40 million per year to over \$200 million per year through the 1990's.²⁵ In the year 2007, funding for breast cancer included \$572.4 million from the National Cancer Institute and \$127.5 million from the Department of Defense, for a total of about \$700 million for breast cancer research through federal organizations.^{26, 27} Breast cancer advocacy groups also championed the passage of the Mammography Quality Standards Act in 1992, which requires all mammography centers to be licensed by the FDA.²⁸ In 1993, President Bill Clinton designated October 21 as "National

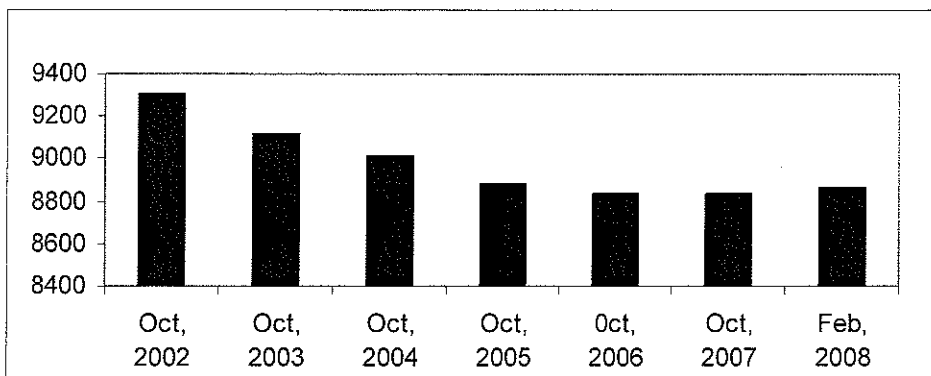
Mammography Day” to encourage women to make yearly mammography appointments.²⁹ A senior policy analyst at the Susan G. Komen Foundation summarized the role of advocacy groups in placing breast cancer screening on the national agenda when he stated:

I think the greatest success in screening is the... availability of mammograms and the education effort that's taking place... and the partnerships between federal and state governments and private organizations like ours, the Susan G. Komen Foundation for the Cure, and others... the American Cancer Society and others to get the word out that mammography is the gold standard in screening for breast cancer, and that you really have your chances of survival increase by having breast cancer detected early...

Advocacy groups have been so successful in their efforts to “get the word out” about the “war on cancer” that women have historically felt overly vulnerable to the disease. In her book *Gender and American Politics*, Sue Tolleson-Rinehart found women in the mid 1990’s overestimated their risk of breast cancer by up to twenty-fold.²⁴

The public’s tendency to be excessively nervous about breast cancer was epitomized at the beginning of this century, with a wave of concern about closing mammography centers and scarcity of mammograms. The actual number of screen film mammography centers has been well-documented by the FDA since 2002. This declining number of film mammography centers is not particularly impressive, especially considering many all-digital mammography centers were opening during these same years:

Figure 4: National Screen Film Mammography Facility Count



Source: MQSA National Statistic Archive, FDA Center for Devices and Radiological Health

The media were responsible for amplifying the perceived mammography shortage, as reports of women crowded into mammography centers appeared especially in the northeastern newspapers. The *Boston Globe* published an article in October 2000 headlined "Radiologists are quitting, making women wait longer to find out if they have breast cancer."³⁰ The article cautioned readers about an upcoming mammography shortage, since the number of women seeking mammograms doubled between the years 1985 and 2000. In 2002, a *Newsday* article headlined "A Long Wait for Mammograms" warned New York women they would wait between one and three months to receive mammograms.

At the same time the media were popularizing a mammography shortage, they were also maintaining the "war on cancer" through digital mammography coverage. Of 215 digital mammography articles analyzed, 44 used the following war-related terms in either their headlines or opening paragraphs: weapon, war, struggle, fight. Among interview respondents, six out of twelve used the terms "fighter," "war," and/or "save lives," with four respondents repeating these words multiple times over the course of the interview.

The earliest media accounts of digital screening incorporated "war" language in a very concrete way, because the technology was developed through cooperation between intelligence and medical communities. Articles with catchy titles like

"Medicine from Space," "CIA lets loose of technology for health use," and "From bombs to breast cancer aid" appeared in papers across the country.³¹⁻³³ In October 1993, the *Sacramento Bee* described digital mammography as "a real-life example of turning swords into plowshares."³⁴ Several articles referenced the Regan Administration's "Star Wars" Defensive Initiative, stating technologies from this campaign would be used to enhance digital mammography.³⁵⁻³⁷ In 1994, the government created the "Missiles to Mammograms" program to foster cooperation between digital mammography innovators and the intelligence community.³⁸ The expectation for "Missiles to Mammograms" was that "space, defense and intelligence technology allow the unprecedented mapping of the landscape of the breast."

These initial descriptions of digital mammography could appeal to the public on several different levels. First, the media accounts attract our sense of fantasy and "the unknown" in a very real way, as digital mammography was connected with outer space and even the Search for Extra-Terrestrial Intelligence (SETI).³² In addition, the notion of combining wartime technologies with a potentially life-saving technology could be pleasing for both peace-lovers and ironic satire-lovers. Professor Jo Anne Earp believes these original accounts could have been purposefully marketed to adorn screening mammography, a uniquely female experience, with more masculine qualities:

When you invest innovation with verbiage that surrounds it with tougher, more manly kind of sales aura... such as war, or technology, or space... then I think as an ad person, you think that's going to sell your sort of softer, "breast, women, and lower status"... kind of take it away from that kind of softer, more feminized, gendered image to a more masculine, more "war toys," technology, masculinized image... where the money has been and the technology has been and the resources have been and the control has been. So I think it probably was no coincidence that it was sold that way.

Regardless of which sentiments these articles invoked among their readers, the original representations of digital mammography essentially secured its status as not just a new medical technology, but a new weapon in the "war on cancer."

The State of Breast Cancer Screening

The FDA's approval of digital mammography in January 2000 represented the first upgrade in breast cancer screening for over forty years. Dr. Robert Egan adapted high-resolution industrial film for mammography in 1960, and that apparatus had remained essentially unchanged until the introduction of digital technology. Figure 5, on the next page, provides a timeline of significant dates in the history of breast cancer screening.

Figure 5: Important Dates in the History of Breast Cancer Screening & Digital Mammography

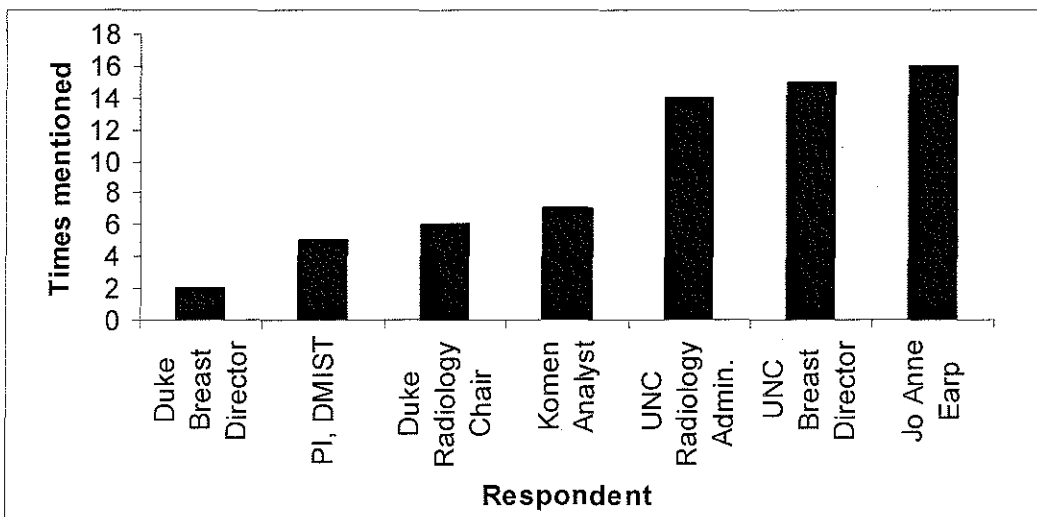
<p>1895 – Wilhelm Roentgen develops the X-ray process³⁹</p>
<p>1960 – Dr. Robert Egan adapts high-resolution industrial film for mammography, allowing simple and reproducible mammograms with improved image detail⁴⁰</p>
<p>1963 – Initiation of the first randomized controlled trial of breast cancer screening by the Health Insurance Plan of New York. Data from 18 years of follow-up indicates 25 percent reduction in breast cancer mortality among women over 50 years who received screening mammography^{40, 41}</p>
<p>1974 – Betty Ford speaks openly about her breast cancer diagnosis²⁴</p>
<p>1982 – Susan G. Komen Foundation for the Cure founded²⁵</p>
<p>1986 – American Cancer Society and American College of Radiology develop breast cancer screening accreditation program⁴⁰</p>
<p>1992 – Mammography Quality Standards Act requires all mammography facilities to be licensed by the FDA²⁸ *NCI designates digital mammography "the imaging technology with the highest potential" for detecting and diagnosing breast cancer⁴²</p>
<p>1993 – Suzanne Fletcher and colleagues publish evidence review, "Report of the International Workshop on Screening for Breast Cancer," which acknowledges unknown benefit of screening for women aged 40-49⁴³ *President Bill Clinton designates October 21st as National Mammography Day²⁹</p>
<p>1994 – "Missiles to Mammograms" program launched by Public Health Service's Office on Women's Health, with the purpose of digital technology sharing between the intelligence community and mammography innovators^{38, 44, 45}</p>
<p>1997 – NIH Consensus Development Conference on Breast Cancer Screening for Women Ages 40 to 49 does not recommend universal mammography for women in their forties; decision met with great resistance from breast cancer screening enthusiasts and politicians⁴⁶</p>
<p>1998 – NEJM article reports cumulative risk of false positive mammogram at 49.1% after 10 mammograms^{47, 48} *FDA approves ImageChecker for mammography double-check^{49, 50}</p>
<p>2000 – FDA approves G.E.'s digital mammography machine, the Senographe 2000D®⁵¹</p>
<p>2001 – National Cancer Institute awards team of investigators, headed by Dr. Etta Pisano, \$26 million grant to study digital mammography⁵² *Medicare coverage for digital mammography increases to 150 percent of traditional mammography reimbursement rates⁵³</p>
<p>2002 – Tommy Thompson announces federal guidelines, which strongly recommend mammography for women aged 40-50 years²⁸ *BlueCross, BlueShield North Carolina begins reimbursing for digital mammography at the same rate as screen film mammography⁵⁴</p>
<p>2003 – FDA starts providing accreditation to mammography facilities which only use digital technology⁵⁵</p>
<p>2005 – DMIST results show digital mammography more effective for younger, dense-breasted women</p>
<p>2007 – UNC converts to all-digital mammography⁵⁶</p>

Other radiology tools, such as CT, MRI, and PET scans, have been digital since their inception. These sophisticated technologies have paved the way for popular concepts like “the digital revolution” and “wireless medicine.” For example, a January 1998 article in the *Dallas Morning News* reported, “More radiologists and hospital administrators seem to be dreaming in digital these days because a new generation of digital technology promises to enhance clarity, reduce costs and improve convenience.”⁵⁷ Film mammography, which requires a dark room for image development and a view box for analysis, seems archaic compared to other radiology technologies. Duke’s Director of Breast Imaging described the state of breast cancer screening in somewhat hyperbolic terms:

The entire rest of the radiology department has been on soft copy display – that means CAT scans, MRI, even X-rays of big toes... for many, many years. So, as radiologists we’ve had experience using soft copy displays when we get our call.

The importance of digital mammography as “technology” was demonstrated in other interviews, as the following respondents mentioned either “computers” or “technology” several times throughout our encounter:

Figure 6: Keyword Frequency: Computer/Technology



The most remarkable feature of this keyword count is respondents affiliated with UNC Hospitals generally mentioned “computers” and/or “technology” more

frequently than did respondents affiliated with Duke University. The trend is telling: UNC converted to all-digital technology early, and has a stake in embracing the technology in which it has made a substantial early investment. Duke, on the other hand, is only now overhauling its screen film systems and does not evince the language of early adopters.

The media have also been attuned to the innovative aspect of digital mammography, and have used concrete, simple metaphors to help explain the technology to the public. These include comparing digital mammography to word processors rather than type-writers, fax machines rather than snail mail, and digital cameras rather than traditional cameras. In fact, 10% of reviewed articles likened digital mammography to digital cameras, and about two-thirds of articles that explained the mechanics of digital mammography used the analogy of either a digital camera or a word processor. A *Newsday* article published in September 2005 provided one such typical description of digital mammography: "Both digital and film mammograms require the use of X-rays to produce an image. But digital mammography, which is similar to taking pictures with a digital camera, allows doctors to view the mammogram on a computer and to change the contrast on their screens to view suspicious areas."⁵⁸ The digital camera metaphor, which is even being used by clinicians, makes digital mammography very palatable for the average woman and also draws on our fondness for the newest and most convenient technologies.

Breast imaging specialists also like new technology, especially when it may lead to higher status and more reimbursement. Breast specialists have perceived themselves to be underpaid and subject to higher rates of lawsuits, compared to other radiologists. The Director of Breast Imaging at UNC described the inherent humility associated with reading mammograms as follows:

I'll just tell you that the history for breast imaging and mammography... that Medicare and all insurance systems are typically low for reimbursing for mammograms... That's another reason why a lot of people don't even want to go into it. It's not just the liability, but it's not a very thankful, high-

paying reimbursement... by them (digital mammograms) having a little bit higher reimbursement, it's just starting to make the tables... in my opinion, from my side of the fence... a little bit better. The reimbursement for mammography... for what people pay... it's just so low.

Media have also reported on the relatively lower compensation and higher liability for breast imaging.⁵⁹ Numerous articles have described mammography as a money-loser, and the *New York Times* even quoted a renowned breast imaging specialist who described fellowships in mammography as a "lousy career move."⁶⁰ Other articles have described breast imaging specialists as the "most highly sued radiologists."

Between August 1985 and 1995, the Physician Insurers Association of America (PIAA) tracked over 125,000 medical malpractice claims for missed breast cancer diagnoses, and found breast cancer-related claims yielded higher settlements than did any other malpractice suits except for those arising from cases of brain-damaged infants. These findings led the American College of Radiology (ACR) to support regular screening mammography for women in their forties, supposedly to decrease the number of missed breast cancers.⁶¹

The perception of higher numbers of lawsuits against radiologists who read mammograms was reaffirmed by several interview respondents, including Dr. Earp, who commented:

Breast cancer is the first... among those diseases that cause lawsuits. I mean, there are papers out there that show, of the suits that happen... breast cancer was the first cause of lawsuits.

Partially in response to these widespread malpractice concerns, the *St. Petersburg Times* conducted research into malpractice history for breast imaging specialists in Florida, and found no significant difference in number of lawsuits or malpractice insurance rates for radiologists between 1991 and 2002.⁶² Nevertheless, government officials in Florida and other states proposed legislation specifically to protect radiologists from lawsuits for missed breast cancers. This example of policy change based on perception of lawsuits, rather

than evidence about the actual amount of litigation, may be considered a litmus test for the political strength of breast imagers and screening advocates. It is not surprising that these groups were very influential in launching the adoption and widespread distribution of digital mammography.

In addition to digital mammography's potential to advance what might be thought of as the "social status" of breast imaging, the technology also brought great hope for more accurate diagnoses. Digital mammography came to market during a time of intense debate, among professional organizations and cancer specialists, about the true value of breast cancer screening. In October 1993, the *Journal of the National Cancer Institute* published the "Report of the International Workshop on Screening for Breast Cancer." Investigators reviewed eight major randomized controlled trials of breast cancer screening, and found a one-third reduction in mortality for screening women ages 50-69, but no benefit for screening women in their forties.⁴³ In 1994, the American Cancer Society (ACS) and the National Cancer Institute (NCI) engaged in a fierce discussion about mammograms for women in their forties, with the ACS supporting screening and the NCI concerned about potential harms of false results.⁶³ In April 1998, even more public attention was drawn to the potential for false positives when the *New England Journal of Medicine* published an analysis estimating the cumulative risk of a false positive result at 49.1% over the course of 10 years, or 10 mammograms.⁴⁷ False negative screenings have also drawn media attention, as an article published in the *Houston Chronicle* explained: "It (mammography) misses 20 percent to 25 percent of cancers in women under 50 and 8 percent to 10 percent in women over 50...⁶⁴"

Many interview respondents reiterated these longstanding concerns about the diagnostic accuracy of screening mammography. The senior policy analyst at the Susan G. Komen foundation named "false positives" as the greatest threat to breast cancer screening. The Chairman of Radiology at Duke also lamented the inaccuracy of screening mammography, and its effect on patients:

So the number of false positives... if you look at the data on how many biopsies and things we do, that turn out to be normal... The patients don't usually get horrendously upset, in the sense that, in the world of women, having a breast biopsy is fairly commonplace. In a way, doctors always say... "three quarters of these are going to be normal, so don't get yourself too excited." The other side of that though, is if only three-quarters of those are normal, couldn't we do a better job about figuring that out before you have to worry for days?... and needles... and all that kind of stuff. We should be doing a better job.

The uncertain analyses of screening mammography have been accented by several definitive, though not necessarily evidence-based, statements by public health officials. For example, in March 2000, the United States Preventive Services Task Force (USPSTF) developed a guideline for screening mammography in women over 40 years old. The USPSTF gave their guideline a "B" recommendation, indicating fair evidence in favor of screening mammography. Despite the "B" recommendation, Tommy Thompson emphatically announced to American women that benefits of screening mammography outweigh potential harms. Thompson said the federal government was sending a "powerful and clear" message to women: "If you are 40 or older, get screened for breast cancer with mammography every one to two years."⁶⁵

Despite Tommy Thompson's declaration, confusion and debate have continued to surround breast cancer screening. One reporter for the *Chicago Tribune* perhaps phrased it best in October 2004 when she wrote: "Many women are confused about mammography, and it's no wonder. For years, doctors have been debating and changing breast cancer screening guidelines. It seems like our bras last longer than mammography recommendations do."⁶⁶

Conclusion

Digital mammography, "an idea whose time has come," entered health care as a technology that could potentially relieve the uncertainties and frustrations inherent with screen film mammograms. It could provide a new "weapon" for the

advocacy groups' "war on cancer," update the mammography process, boost the prestige and profitability of breast imaging, and provide greater diagnostic accuracy in screening mammography. The *New York Times* described these popular hopes for digital technology in a January 2001 article entitled "Mammography's Next Step is Assessed:"

...its (film mammography) imperfect record is one of the great frustrations of cancer professionals and women alike. So it is no surprise that the Food and Drug Administration's approval of the first digital mammography unit early this year was met with much hope and enthusiasm.⁶⁷

The FDA as a Gatekeeper

We are a "gatekeeper" ... and we need to assure that things on the market are not going to hurt people. Once we can assure ourselves of that, then I think we need to allow technologies on the market with the understanding that we will get more information as time goes on.

-- Daniel Schultz, MD, FDA Director, Center for Devices and Radiological Health

General Electric's Senographe 2000D® full-field digital mammography unit was approved by the United States FDA in January 2000. As with other medical technologies, FDA approval was crucial for distribution of digital mammography because it allowed General Electric, and other private vendors like Hologic, Fischer, and Fuji, to begin widespread marketing to patients and clinicians. In addition, FDA approval was a necessary step before the federal government could increase its Medicare reimbursement of digital mammography to 150 percent of screen film mammography reimbursement.⁵³

The FDA's approval happened at an ambiguous time in the accrual of effectiveness data for digital mammography. In January 2000, none of the major trials comparing digital with screen film mammography had been published. The study by Lewin and associates was not published until March 2001 and the Oslo I and II studies were published in 2003 and 2004, respectively. The DMIST did not even have funding until one year after the FDA approved digital mammography. Dr. Schultz summarized the approval process as follows:

... as with many technologies, we were able to provide reasonable assurance of safety and effectiveness, which is the standard that we use and that Congress has given us to approve new medical devices. So, what that means is that in many cases we don't know everything that there is to know and we fully expect that additional information will be gathered over time.

Only a patchwork picture of the approval process may be discerned from media accounts and interview respondents affiliated with the FDA and/or digital mammography. Several respondents acknowledged the necessary connection between public and private sectors during the FDA approval process. The

Administrative Director of UNC's Radiology Department described Dr. Pisano's cooperation with both private companies and the FDA:

Etta helped some companies achieve their FDA clearance. She's also had a role in advising the FDA on what was reasonable, to assess the turnover... what was acceptable for the FDA to approve digital imaging.

Given the critical roles of innovators and private companies in technology development, it is not accurate to consider them "external entities" trying to impose their agendas on the FDA. Nor is it appropriate to expect FDA staff of Advisory Committee members to evaluate new medical devices without input from these innovators and private companies.

In the case of digital mammography, both breast imaging specialists and technology development companies were eager for rapid approval. UNC's Administrative Director of Radiology described the environment prior to buying digital equipment:

Now, when it gets closer to, you know, hitting the market and the vendors were so excited about the eminent FDA approval...and then postponed, postponed, postponed. The vendors were trying to stage the equipment. In some ways, we were willing to purchase, but if it's not FDA approved... we don't go for it... but we will continue clinical research work on the fringe, until it is approved. And then the vendors got to the point where they were so anxious to sell... that they got a little bit reluctant, because they thought FDA was right around the corner. As soon as they got FDA, they'd be able to sell.

The administrator's language in this passage, particularly his use of the words "excitement," "anxious," and his repetition of "postponed," captures the great anticipation with which private companies must have awaited FDA approval. Private companies, however, may not have been as eager for approval as were breast imaging specialists. Dr. Pisano expressed frustration with the process from her perspective as an innovator:

So, I just feel... one of the things that frustrates me about the pace of the change is I've been in this field for 19 years now, and look at how many new tools we've gotten, and digital is the most promising one... and it took a long time to get it. And there are new ones on the horizon and it's going to take a long time to get them, and we have a generation of women

dealing with breast cancer. My generation, your generation... So I feel really a huge pressure to try and move things forward and get things done more quickly. It really bothers me that it takes so long... and that we're making such slow progress. I wish the breast cancer community would focus on that, because the FDA... it's not just the FDA, it's the companies, it's radiologists, it's everybody.

Dr. Pisano's dissatisfaction with the approval process, which almost took on the tone of a personal mission in this excerpt, has been echoed by other groups of breast imaging specialists. One group of radiologists wrote a statement of concern about the digital mammography approval process for *Diagnostic Imaging* in December 1999. Their statement was also published in a *USA Today* article entitled "Going digital Proponents say it's time the FDA updates mammography system."⁶⁸ The group sent the following joint message to the federal government: "We believe that the review process, which has extended for more than three years, is unduly prolonged and complicated."

Dr. Schultz acknowledged pressures from private vendors and breast specialists during his interview: "Um, there's always pressure from companies to approve their products as quickly as possible. I mean, that is a given in what we do." Dr. Schultz also noted that in the case of digital mammography, pressure from technology developers was so great that the agency needed to "take a stand:"

There was a lot of pressure, and a lot of it actually was coming from very prominent clinicians, and even academic clinicians, who felt that the mere fact that the image was... appeared to be... a higher-quality image... should in fact be enough for us to approve the technology, as we had for other types of digital technologies. And I think this was a case where we really needed to sort of take a stand and say that, you know... the fact that it's a better picture, or what appears to be a better picture, is not enough.

The digital mammography approval process was thus caught between the agendas of renowned innovators and the FDA's mandate to ensure public safety. The process was not driven by ensuring digital mammography could maximize positive health outcomes for American women. Rather, it became more about finding mechanisms to satisfy the different stakeholder groups affiliated with the technology.

Conflicting interests even spilled into the FDA's internal discussions about the technology. While certain FDA members pushed for rapid approval, others called for more extensive, head-to-head comparisons of digital and film mammography. A *USA Today* article reported specific information about dueling perspectives of the agency members, certain top FDA officials, and the advisory committee.⁶⁸ The article reads:

The agency wants manufacturers to conduct screening trials that would compare digital and film mammography head-to-head. Such a trial would need thousands of patients and cost millions of dollars.

"This is not an industry that's used to those kinds of costs," says David Feigal, top medical devices official at the FDA.

But the advisory committee, fearing that patients bear the cost of a screening trial, urged the FDA not to require one of G.E.

The end result of these conflicts, both between the FDA and "outside" groups, and among FDA members themselves, was a compromise. After a three-year review process, the FDA had sufficient evidence to convince itself of digital mammography's safety and effectiveness. Dr. Schultz described the compromise:

It was one of those situations, I think, where nobody was totally happy with us. So I think we were probably in close to the right place.

In retrospect, the FDA was actually "close to the right place," because clinical trials have now demonstrated similar diagnostic accuracies of digital and film mammography. Data collection for the actual approval process, however, appears to have been far messier. Specifics are unclear about which data were collected, and what evidence was gathered, before the Senographe 2000D® was approved in 2000. In our April 2008 interview, Dr. Schultz gave one account of the FDA's protocol:

...I think what we were able to do over time, with a lot of input from our statisticians and working with companies... we were able to design studies that were more in the range, I believe, of 1,000 to 1,500 or something like that... that were enriched with additional cancer patients that allowed us to approve the devices with the assurance that I told you about... you know, that we were not... that clinical performance would not be adversely

affected and still get that kind of clinical information, without the large trials that were originally proposed.

The *Dallas Morning News* reported slightly different data collection in February 2000, although Dr. Schultz was cited as the newspaper's key informant. The article stated: "In studies of 625 women, a printout of the mammogram from the digital machine was as effective in detecting breast cancer as standard film mammograms."

These descriptions by Dr. Schultz and the *Dallas Morning News* are vague, particularly with regard to the number of investigational cases used to compare screen film and digital mammograms. Uncertainties were mirrored in press reports, as the *Dallas Morning News* article warned readers: "Digital mammograms appear as good as – but not better than – regular mammograms in detecting breast cancer..."

Ultimately, digital mammography won FDA approval on the basis of these uncertain data. The FDA's approval legitimized the subsequent increase in Medicare reimbursement for digital mammograms, which undoubtedly catalyzed the spread of the technology. Higher reimbursement rates made the upgrade from film to digital technology invisible, from a cost perspective, for many medical practices. In addition, the more generous Medicare reimbursement set a new standard for private insurance companies to increase their payments for digital mammography. Details about the justifications and reasoning behind higher Medicare payments for digital mammography are uncertain. At the time of this writing, no Medicare officials were available to comment on funding appropriations for digital mammography. The 2001 increase in Medicare funding for digital mammography, however, was certainly dependent on the technology's FDA approval.

Since Medicare almost immediately started reimbursing more generously for digital than screen film mammography, free market forces were prevented from

entirely determining the fate of the technology. Also because of compromises, however, providers did not have rigorous evidence to offer a convincing demonstration of digital mammography's effectiveness. The FDA approval process resulted in an allocation of public funds for an ambiguously effective intervention. The FDA, which is inextricably linked with private technology developers and innovators, opened the floodgate and allowed the Senographe 2000D® to flow through health care.

Perceptions with Real Consequences

*So, not to my surprise, but a little bit to my surprise, we get rid of all-film screen and we go to all-digital when there's not data to show that's effective. But I understand why because one of my most favorite of all aphorisms, sentences... I attribute it to W.I. Thomas, sociologist in the 1920's, who said: "Things that are perceived as real are real in their consequences."
-- Professor Jo Anne Earp, ScD*

As with many of our new technologies, the widespread distribution of digital mammography has been catalyzed by anecdotal success stories and even misinterpretation of facts by leaders in health care. This phenomenon is likely because, as Deborah Stone writes, "...facts do not exist independent of interpretive lenses, and they come clothed in words and numbers." Facts about digital mammography have been disseminated in a disorganized way, with the media and even key stakeholders in breast cancer screening receiving their information second- or third-hand rather than directly from the DMIST results section. Certain attributes of digital mammography have been inappropriately magnified, leading some decision-makers to justify their actions with incomplete data.

The Fate of the Evidence

Two popular perceptions about digital mammography have led the general public and radiologists to accept its superiority over screen film mammography. First, positive findings from the DMIST and other trials have been overstated by the medical literature, digital mammography enthusiasts, and the media. Second, people have exaggerated the theoretical and logistical advantages of digital mammography.

Both these perceptions can be traced to the presentation of digital mammography in medical literature. For example, in the DMIST abstract, authors report: "The overall diagnostic accuracy of digital and film

mammography as a means of screening for breast cancer is similar, but digital mammography is more accurate in women under the age of 50 years, women with radiographically dense breasts, and pre-menopausal or peri-menopausal women.”¹⁵ This favorable presentation of digital technology could have been motivated by publication bias, or more publication opportunities for trials with positive, significant results. Dr. Pisano explained her rationale for UNC's adoption of all-digital mammography as follows:

In fact, I was pushing for it before DMIST was even out, because I felt like, “we know what the results are, it would be irresponsible not to do it.” I felt that... we knew it would be better for these dense-breasted women, and therefore we were going to have a hard time serving 60% of the population until we... you know, we had no digital equipment except for in the diagnostic center before we converted.

Although Dr. Pisano knows the DMIST well, her statement was not entirely congruent with the trial's results. Subgroup analyses of the DMIST results were published in *Diagnostic Radiology* in February 2008. The analyses show digital imaging is only statistically significantly better than screen film imaging for one subgroup of women with all the following characteristics: 40-50 years old, pre- or peri-menopausal, and with dense breasts. No other subgroup, including older women with dense breasts or younger women with non-dense breasts, showed a significant diagnostic advantage of digital over film mammography. The subgroup of women who actually had a statistically significantly better cancer detection rate with digital mammography only comprised 17% of the DMIST study population.¹⁷ This percentage does not match Dr. Pisano's suggestion that 60% of women screened would actually benefit from digital mammography.

Dr. Earp addressed this apparent disjunction between actual trial results and the representation of results when she stated:

Etta used to say to me, “we don't need all digital. It didn't work.” She's not saying that now, she's Dean now, and she's saying we have to have it for everybody. She's very conscious, you have to be, of what the legislatures think, what the people think, what the payers think, what the insurance companies think... versus what the science says. I mean, it's a tough role. I don't envy her.

Notably, in past press releases, Dr. Pisano has also given more neutral evaluations of digital mammography, stating it is “not a magic bullet.”⁶⁹ She has advised women “not to rush out and get a digital mammogram.”⁷⁰ The overall message passed from the medical literature to the public, however, is that digital mammography confers diagnostic advantage over film mammography for a significant proportion of women.

The media have been major vectors of information between the research community and the general public. Both the Chairman of Radiology and the Director of Breast Imaging at Duke recognized the importance of media in Duke’s decision to convert from film to digital screening. The Chairman of Radiology explained media influence as follows:

My understanding about what that study showed was that essentially digital had an advantage, really in women with denser breast tissue, but sort of in the 40 to 50 age group.... Now when the press put that out, it came out sounding a little bit different than that... so what happened was women reading this stuff said, “Oh gosh, I’ve got to have the digital ones. It’s better.” So fortunately for us, we had some digital equipment... but unfortunately not enough at the time to take care of all women who wanted to be screened.

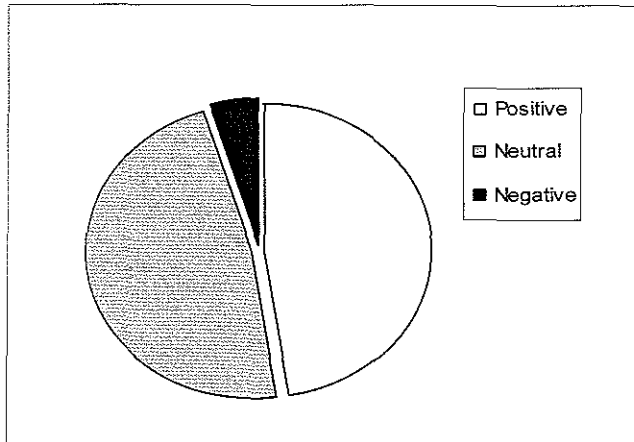
Duke’s Director of Breast Imaging echoed the Chairman’s view about digital mammography being inaccurately presented to the general public:

The message that has gotten out, through no fault of the ACRIN (American College of Radiology Imaging Network) folks, but because it’s easy... it’s complicated stuff... so it’s easy for CNN to report digital is better. And that’s the message that’s gotten out. Even though I think the message is more nuanced than that. It’s better for some, not better for others, and it’s probably equivalent for many.

Although both Duke radiologists point to the media as a potential source of the public’s misinformation, findings from my analysis of media accounts were not consistent with their hypotheses. Rather, it appears the media served to amplify messages from both the medical literature and elites in digital mammography, who gave an overall neutral to positive evaluation of the technology. Of 215

newspaper articles reviewed for this study, 21 articles were written with the purpose of presenting DMIST results. The majority of these articles had either positive or neutral tones in their headlines and opening paragraphs, with the exception of one article:

Figure 7: Newspaper Portrayal of DMIST Results

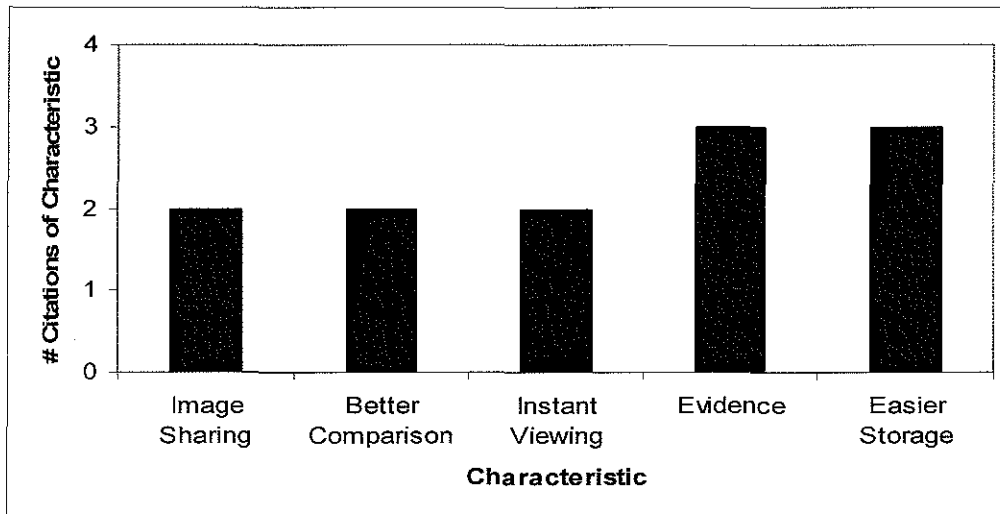


An example of a positive *Wall Street Journal* article's headline read: "Digital Mammograms Excel in Study."⁷⁰ A more neutral *Chicago Tribune* article's headline read: "Digital screening for breast cancer gets mixed review - More accurate for young, but not overall."⁷¹ Finally, the negative digital mammography article in the *Washington Post* was headlined "Finding more Cancer is not the Answer."⁷² Although the 21 DMIST newspaper articles accurately reflected the neutral to positive tone with which primary investigators represented their results, readers of the media were probably more impressed with the positively-toned articles. Women's tendency to be more influenced by the positive articles is perhaps attributable to social factors including public desire for dichotomy, with news situations being either "good" or "bad."

Each of the 21 newspaper articles presenting the DMIST results also mentioned additional, theoretical advantages of digital mammography. These advantages originated from the DMIST article, and include "easier access to images and computer-assisted diagnosis; improved means of transmission, retrieval, and storage of images; and the use of a lower average dose of radiation without a

compromise in diagnostic accuracy.”¹⁶ Enthusiasm for the theoretical benefits of digital technology was also expressed during interviews. The chart below presents responses to the interview question: “What is the main advantage of digital mammography?”

Figure 8: Best Characteristics of Digital Mammography as Identified by Interview Respondents



Respondents affiliated with UNC were more likely to cite evidence from DMIST as the main advantage of digital mammography, whereas respondents without a connection to UNC were likely to mention other advantages. This phenomenon is likely because UNC was the central organizing center for DMIST, and respondents were more heavily invested in the study’s positive findings. The Director of Breast Imaging at Duke shared his understanding about the relative importance of evidence for digital mammography:

...So, do I think it’s medically the best thing for all patients to be all-digital? No! I think that Etta’s data and the ACRIN data are pretty clear that that’s not the case... So, no, I don’t think anyone can really make the argument that patients are medically better served by being all-digital. But there’s more to medicine than being 100% purist about the exact right test... So practical considerations have to be taken into account...

The problem with “practical considerations,” as presented by the media and interview respondents, is that many of these considerations are only supported

by theory and anecdotal evidence. The following are examples of digital mammography characteristics that have been touted as advantageous; however, on closer examination, these advantages are not as real as they are perceived to be.

Less pain, less radiation. Out of 215 media articles reviewed for this analysis, 38 mentioned digital mammography's ability to reduce pain and/or radiation exposure. For example, a 1998 article in the *Chicago Tribune* was titled "Remodel Mammography? It couldn't hurt." The article predicted digital mammography might relieve women from the discomfort of the "slam-o-gram."⁷³ A later article in the *Detroit Free Press* entitled "A New Day for Women" claimed digital mammography could decrease breast compression time, and therefore radiation exposure and pain, by 15-20 minutes. This article quoted one recipient of a digital mammogram who said she felt "no pain at all."⁵³

These characteristics of digital mammography, if accurate, would indeed be very advantageous for women. Radiologists, however, do not validate them. All radiologists interviewed confirmed no difference between digital and screen film mammography in terms of a woman's subjective experience. The Director of Breast Imaging at Duke commented on this discrepancy between women's expectations and the procedure's actual mechanics:

We have had patients say that, "the exam was much more comfortable because it was digital," and I think that's placebo effect. They're really, basically mechanically extremely alike.

Radiologists also agreed that radiation dose delivered during digital mammography would not be appreciably lower than during screen film mammography. The Chairman of Radiology at Duke confirmed digital could potentially deliver less radiation, but at the expense of image quality:

... because it turns out that if you turn up the dose a little then the image looks even better, and the film doesn't... if it were film it goes black. But if it's digital it doesn't go black. And so we saw in everywhere we had digital detectors, radiation dose creep.

Lower recall rates. Many early newspaper articles about digital mammography emphasized its potential for lower recall rates than screen film mammography.⁷⁴

⁷⁵ For example, an October 2000 article in the *Chicago Tribune* featured a breast imaging specialist saying:

“Now we can manipulate the digital mammogram on the computer rather than manipulate the women... We can zoom in on an area, lighten it or darken it. Before, the only way to zoom in was to bring the woman back.”⁷⁶

Although the public has perceived lower recall rates with digital technology, both the medical literature and the radiologists interviewed have indicated no overall, significant difference in recall between screening modalities. In the study by Lewin and associates, authors found a significantly lower recall rate for digital mammography than for screen film mammography. Specifically, Lewin and colleagues found an 11.8% recall rate for digital mammography and a 14.9% recall rate for screen film mammography ($p < .001$).¹¹ In the Oslo II study, however, women aged 50-69 had a 3.8% recall rate for digital mammography and a 2.5% recall rate for screen film mammography ($p < .05$).¹³ No significant difference in recall rates were found in either the Oslo I study or the DMIST.

The Director of Breast Imaging at Duke believes the public's misunderstanding regarding lower recall rates could be attributable to a different system for reading digital versus screen film mammograms:

...And we do some what we call “batch screening” where the patient gets their 4 views and goes home. And we review them, generally the next day, in “batch mode”... you know, we read 60 mammograms at a time and send them a letter saying either “it's fine” or “give me a phone call to come back.” With digital, you can't really do the “batch mode,” because we only have one reading station... those all get read “online.” We know there's a difference in recall for patients right there. It's much easier to just say, “ah, let's just press that out, whatever it is...” As opposed to, you have to call the patient back from an hour away, or a half hour away....

The hypothetically lower recall rates for digital mammography could therefore be a function of the system radiologists use to interpret digital images, rather than superiority of the technology itself. A recent *New York Times* article reported, as clinics switch from film to digital technology, many more women are actually being recalled than the accepted volume of 10% with screen film mammography.⁷⁷ Since articles like this have arrived late in the diffusion of digital mammography, however, they may not deter the technology's continued growth.

Image sharing. One of the most intriguing aspects of having mammograms on computer is the possibility for long-distance image sharing. The media seized this idea of distance medicine, or telemedicine, in their early coverage of digital mammography. In April 1997, the *St. Petersburg Times* quoted a very optimistic breast imaging specialist who thought: "A radiologist could sit in a nice, cool office over here and read mammograms from the Andes Mountains ported over by satellite."⁷⁸ In September 2002, an *Orange County Register* article proclaimed that, since digital mammograms are recorded on "computer code," they could be "downloaded and sent to staff doctors down the hall or to specialists across the country."⁷⁹ A December 2003 article in the *New York Daily News* described digital mammography as having the ability to "send high-resolution images anywhere in the world to be read by specialists."

Despite the public's enthusiasm for image sharing, radiologists have been more tentative about the logistics of using digital technology as a vehicle for transferring mammograms. The Chairman of Radiology at Duke cautioned that image sharing is not likely to result in detecting more breast cancers:

The unfortunate problem is... that, particularly in screening is, to share the images...if you just said, "well, I'm out here and here's a puzzling case, let me get an expert opinion." It's usually not the puzzling cases that are the problem. It's where you just miss the finding. So the question is: Would those physicians who are doing it on the outside just begin to shift their images to us? I don't think so. Could they share an interesting case? Absolutely. Would it be easier to share? Absolutely. Um, but that's not what we see happening most of the time. If they have what they think is a

difficult case, they do. But I'm more concerned about the ones that they just flat out miss.

In addition to these concerns about the utility of image sharing, infrastructural challenges are also prohibiting transfer of digital mammograms. In fact, digital images are only easy to share because, as articulated by UNC's Director of Breast imaging, "...it's much faster to ship something smaller than large packages of films... um, it'll be cheaper postage too because you can put more information on a CD..." Respondents indicated that infrastructural challenges will continue to be the greatest obstacle for image sharing. These challenges are unique for different institutions and health care providers. The Director of Breast Imaging at Duke, for example, shared his frustrations with digital communication set-up:

...send an image here? I don't see that happening any time in the foreseeable future. I mean, you could easily foresee how it would be possible. But right now it would require someone else's PACS (Picture Archiving and Communication System) to talk to my PACS. We can barely get our PACS to talk... you know, it's difficult enough to get it to talk to our ultrasound machine down the hall... getting it to accept images from across the country is certainly technically possible, I just don't see it being likely.

In addition to infrastructural issues, UNC's Director of Breast Imaging cited confidentiality as another barrier to transferring an individual's mammogram between locations:

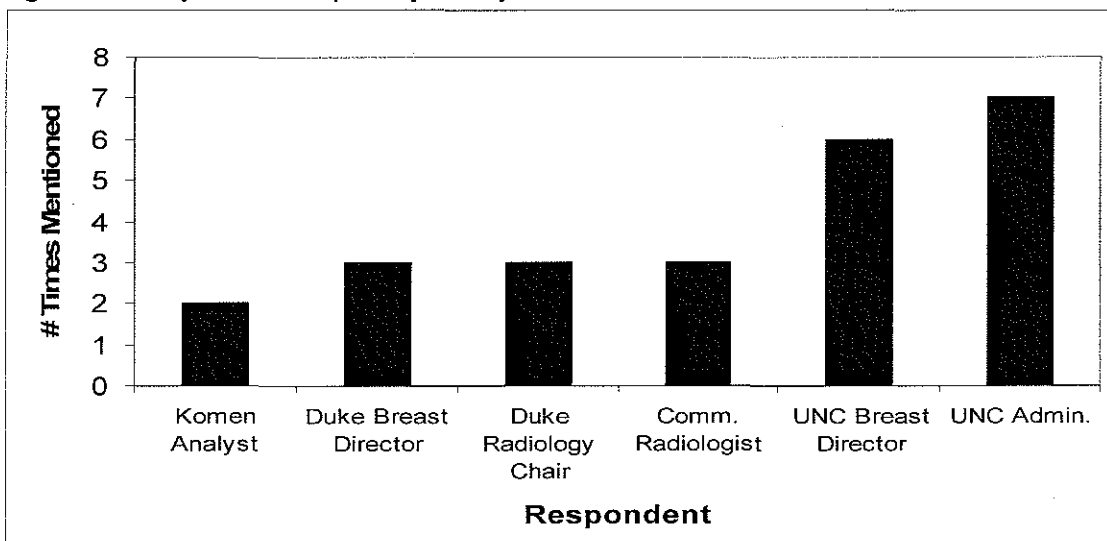
Emailing you can't do with the images because of the federal... the HIPAA (Health Insurance and Portability Accountability Act) laws with patient privacy. You can't really just email 'em.

After speaking with radiologists, the idea of image sharing does not seem as feasible or promising. The most realistic application of digital image transfer is telemedicine, where satellite clinics electronically transport their mammograms to central processing facilities. This arrangement is uncommon, however, and data are not available to prove the effectiveness of telemedicine. The public's naïve

idea about digital image sharing is not likely to happen in the near future, but this perception has been instrumental in our adoption of digital mammography.

Efficiency. Both radiologists and non-radiologists seem to agree that increased clinical efficiency is possible with digital mammography. The Director of Breast Imaging at UNC praised digital mammography for enabling radiologists to leave their roles as “one-armed paper hangers” and retrieve images with “just the click of a mouse.” Other interview respondents mentioned keywords “easy,” “efficient,” or “fast” in their descriptions of the technology:

Figure 9: Keyword Frequency: Easy/Fast/Efficient/Instant



The most striking aspect of this keyword analysis is the tendency of UNC affiliates to mention “efficiency words” more frequently than did other respondents. Again, this could be attributable to UNC’s early adoption of all-digital mammography, and the desire of leaders at UNC to reaffirm the hospital’s role as a leader and innovator. Even the radiologists affiliated with Duke, however, mentioned “efficiency words” multiple times during their interviews.

The media have also presented anecdotal data suggesting greater efficiency of digital mammography. For example, in January 2001, the *Houston Chronicle* interviewed Baylor's director of breast imaging, who praised digital mammograms as being available "anytime and anywhere."⁸⁰ In February 2004, the *New York Post* put a celebrity spin on digital mammography's effectiveness by quoting Mayor Bloomberg at a press conference:

"Early detection is crucial, and digital mammography dramatically speeds up the screening process, cuts waiting times and saves lives."⁸¹

The problem with these popular claims about efficiency is lack of data showing higher patient throughput with digital systems. Radiologists striving to implement all-digital systems often experience the exact opposite of efficiency before their systems are fully functional. Departments continue to install digital systems, though, because they hope digital will eventually become faster. The Director of Breast Imaging at Duke acknowledged his discouraging experiences with digital technology thus far:

Well, I gotta tell ya... at first we had no improvements in work flow in the one room that we had digital. That was a disaster for us, that room has been a disaster... So the supposed improvement in patient throughput that you're supposed to see... we experienced just the opposite. We had a net decrease in patient throughput because the room wasn't operating. Um, once we got the room stabilized... that only took about a year and a half... once we got the room stabilized, now we are seeing much better throughput.

It is uncertain, based on the Director's account, whether Duke's "better throughput" is "better" as compared to screen film mammography or "better" than their throughput prior to stabilizing the room.

At the other end of the spectrum, radiologists who have already implemented all-digital mammography are also speaking about the system's efficiency, but only in terms of personal experience. The Director of Breast Imaging at UNC recognizes the problem of anecdotal evidence, and has designed a study to compare speeds of digital versus film mammography interpretation times.

Regardless of what studies are conducted to examine efficiency, it will be difficult to statistically prove only slightly shorter digital mammography interpretation times. The perception that digital technology is more efficient, however, will continue to drive costly infrastructural changes at institutions across the country.

Conclusion

People have to be convinced that a new intervention, or new way of doing things, is better before they will embrace change. The public has been told digital mammography improves accuracy of breast cancer screening and has other benefits, such as less painful exams and shorter waiting times. On closer examination, many of these perceived advantages are neither evidence-based nor completely accurate. Nevertheless, the public and many health care providers have been eager consumers of the new technology. As digital mammography is rolled out across the county it is becoming evident, as stated by Dr. Earp, that our perceptions are very real in their consequences. The most tangible of these consequences will be investment of precious health care resources in digital technology.

Diffusion of Innovation

Our mammographers have not pushed to get to digital. So it's not like they feel like, "Oh my gosh, we've got to do this..." Other than they know, sooner or later, we have to do it.

– Carl Ravin, MD, Chairman, Department of Radiology, DUMC

Digital mammography, like other medical technologies before it, has followed Everett Rogers' "Diffusion of Innovation" pattern. Rogers' diffusion curve is bell-shaped, with innovators and early adopters representing the first 16% of the population, and laggards at the other tail comprising 16% of the population. The middle section, or early and late majorities, make up 68% of the adopting population.⁸² Interview respondents have ranged from great digital mammography innovators to representatives from the majority who feel that, "sooner or later, we have to do it." Although innovators and early adopters are necessary for initiating diffusion of innovation, the bulk of actual technology distribution is through the early and late majorities.

Innovators & Early Adopters

Innovators, who represent 2.5% of the population, are characterized by their senses of adventure and fascination with novelty.^{82, 83} The Principal Investigator of DMIST, Dr. Etta Pisano, is a well-recognized innovator at UNC Hospitals. Dr. Pisano's eagerness to implement all-digital mammography has been shared by her peers. Thus, unlike traditional innovators, Dr. Pisano did not have to "leave the village" in order to distribute her ideas. The Hospital's Vice Present for Cancer Services believes implementing all-digital mammography was an essential component for achieving the Hospital Mission Statement:

...I think that, if you want to be the best academic, public cancer center in the country, you must have this. And so our hope is that all of these things will come together and will help us become that, because you know our strategic mission is to be "the best academic health care system"... you can't be the "best system" if your premier cancer center doesn't have what it needs to be able to service the people with elite care....

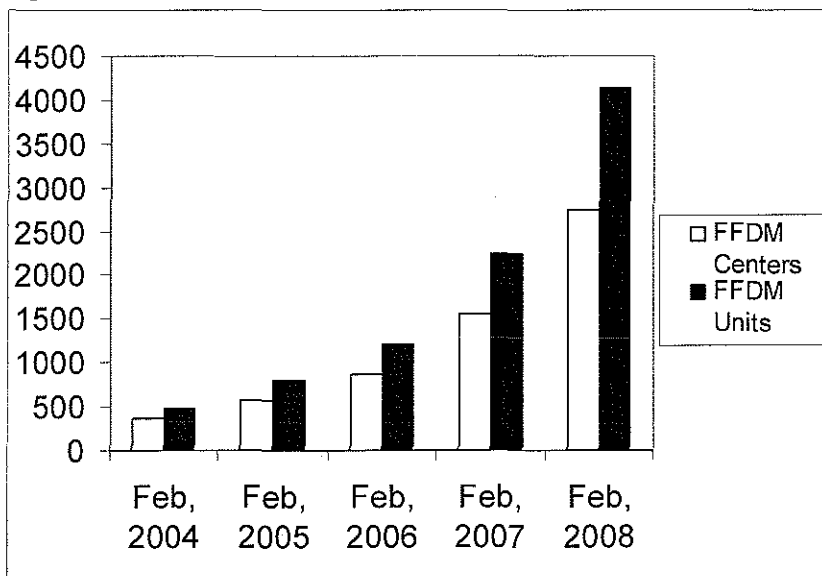
In addition to digital mammography's symbolic, theoretical advantages for the Cancer Center, UNC also implemented all-digital mammography because of very real allegiances. First, UNC Hospitals is proud to be affiliated with Dr. Pisano and is interested in spearheading the acceptance of her technology, which has perceived potential to revolutionize breast cancer screening. Second, although digital infrastructure was very expensive for the hospital, the technology was supported by several key members of the budget committee. The VP of Cancer Services commented on budget concerns as a rate-limiting step:

Now, fortunately for us, there are a lot of women in the operations that approve this budget... including somebody who is a big proponent who had breast cancer... so we got it through, but it was not easy.

Early & Late Majorities

On the national level, digital technology has followed the “curve of adoption” also described by Everett Rogers. This curve has an S shape, with a slow early phase, a rapid middle phase, and another slow third phase.^{82, 83} The spread of innovation eventually reaches a point, usually between 15% and 20% adoption, after which it is difficult to stop further spread. The FDA has kept official counts of digital mammography machines in the United States over the past four years:

Figure 10: National Full-Field Digital Mammography (FFDM) Trends



Source: MQSA National Statistic Archive, FDA Center for Devices and Radiological Health

This curve illustrates the early to middle phases of technology adoption, as described by Rogers. Digital technology grew relatively slowly during 2004 and 2005, but has grown exponentially from 2006 until 2008. The nation has probably surpassed, or will soon surpass, Rogers' benchmark of 15% to 20% technology adoption. This low "tipping point" percentage is partially attributable to the self-perpetuating, localized nature of technology dispersion among the majority.

Donald Berwick describes the majority as "local in their perspective," and "learning about new technologies from people they know."⁸³ Therefore, the process of majority adoption began with women asking their individual providers for digital mammograms. Providers have generally satisfied these patient demands, partially out of self-interests in the potential for digital imaging to advance the field of breast imaging. Private digital vendors have also responded to growing public demand for digital mammography. These vendors, however, have necessarily injected both competition and profitability into the technology's dissemination. Finally, because a sufficient majority of women have started receiving digital mammograms, the lack of digital mammography among underserved populations has become obvious. Thus, advocacy groups are beginning to take on the cause of digital mammography, a resource which could be more available to underserved populations.

Patients as Customers

Media and interview respondents have pointed to patient demand as a local, driving force behind the majority's adoption of digital mammography. The first women preferring digital mammograms were generally educated, and therefore aware of the published, perceived benefits of digital technology. Dr. Earp said she experienced a knee-jerk preference for digital mammography, as a promising new breast cancer screening tool. Retrospectively, though, she acknowledges the lack of evidence for digital mammography among her subpopulation of women:

I demanded... I insisted that I have only digital mammograms. From the moment when we only had one machine, when I knew the DMIST trial was coming out in the *New England Journal*, I knew Etta had been working on it, I knew it was not for me. I knew I was not in a subpopulation with dense breasts and younger women and so on.... And they would tell me that. And I would say, "Sorry, that's what I'm gonna have." And they would say "no" and I would say "yes, yes." And I knew individually, I might get some false positives... but I wanted it.

This desire to "want it" despite the evidence has also been reflected in media accounts. In November 2005, *The New York Times* quoted one radiologist who stated:

"We have callers who say: 'I simply want the best tool. When can I schedule an M.R.I.?' Others say they had their usual mammogram screening last month, and it was clear, but now they want a digital mammogram, too, 'just in case.'"⁸⁴

The circulating desire for women to "want the best screening tool" has resulted in pressure, at local levels, for implementation of digital systems. Dr. Earp described this pressure on the system as "demand from below." Providers and third-party payers have responded to the "demand from below" by implementing digital systems.

Providers and Payers Follow Suit

Many radiologists and breast imaging specialists have been eager to adopt digital technology. Some radiologists, however, are more critical recipients of digital technology evidence. These late majority or laggard providers have conflicting interests in following the evidence, pleasing the "customers," and potentially advancing breast cancer screening with digital tools. For example, although Duke's Director of Breast Imaging was highly critical of digital mammography evidence, he was more nonchalant when he described plans to implement the technology: "Do I think it's fine to be all-digital? Sure. If someone gave me 6 digital units, would I install them? Yeah."

This type of late majority attitude, characterized by “sure’s” and “yeah’s” rather than fervent opinions, has also come to dominate third-party reimbursement discussions. Not every Blue Cross – Blue Shield (BCBS) in the United States has always agreed to pay for digital mammography. BCBS Michigan initially refused to pay for digital mammograms, citing “lack of evidence” for its superiority over screen film mammography. The backlash of protests from enrollees, advocates and doctors became so fierce that the company changed its policy just one month later, and agreed to reimburse for digital at the same rate as traditional mammography.^{85, 86}

Interview representatives from BCBS North Carolina similarly recollected “no good politics” behind their decision to begin covering digital mammography in 2002. Rather, the Senior Medical Director of BCBS NC gave the following account of the company’s decision for reimbursement:

...the physician community was contacting us and letting us know that they were converting to digital mammography... [inaudible] “How much you’re going to pay me pay for it?” So, you know, it’s been an interesting conversation since then... sitting on the sidelines and watching the literature come in... we ended up kind of jumping out ahead of that, and rather than retracting the coverage that we had already committed to...you know, we’re a prominent payer with a big target on our backs...

BCBS NC’s position as a “prominent payer with a big target” on their backs may have prompted them to appease patients and health care providers, rather than attempting to wait for evidence, as did BCBS Michigan. Both “Blues” were sensitive to public pressure. BCBS Michigan and North Carolina reimburse at the same rate for digital and screen film mammograms. This is distinctly different from the higher Medicare reimbursement for digital. By offering equal reimbursements for both modalities, BCBS has satisfied providers seeking reimbursement for their digital mammograms and women who think they want the technology, but has also made the payments invisible to the company from a cost perspective.

As digital mammography becomes more prevalent, and women under 50 years begin to seek more breast cancer screening, companies like BCBS may be pressured to reimburse for digital mammograms at a higher rate than for screen film mammograms. The Senior Medical Director of BCBS NC stated such an increase in payment would not be financially feasible, given the ambiguous benefit of digital screening in breast cancer detection. The Medical Director stated: "...if there was going to be 10 times the benefit from something that was 3 times the cost, that might be worth it." At this time, it is logical for digital and screen film mammography to receive equal reimbursements. As screen film mammography is phased out by digital technology, however, it seems likely that payments for digital screening will increase significantly among private insurers.

The Role of the Market

Several private companies, including General Electric, Hologic, Fuji, Siemens and Fischer, have been involved with digital mammography's development and marketing. These companies have met the majority's increasing demand for digital. The vendors have, of course, been very attentive to suggestions from radiologists about improving the technology. The Director of Breast Imaging at UNC showed satisfaction with vendor responsiveness when she stated, "the different companies, whether they be Fuji, G.E., Hologic... have really listened to the radiologists, who develop their project to help the patient."

Some policy analysts, however, have been more skeptical about the true intentions of vendors and radiologists to "help the patient." *The New York Times* addressed this issue of private market forces influencing health care in a July 2004 article entitled "Is What's Good for G.E. Good for Health Care?"⁸⁷ The article specifically points to the company's medical technology marketing as a leading contributor to "runaway health care costs." Policy analysts indicated doctors and hospitals are "eager customers" of medical technology. The analysts believed, since insurance companies and other third-party payers have "squeezed" reimbursement for traditional office visits, providers must adopt

technology for additional revenue generation. Thus, although the collaboration between vendors and providers may be partially motivated to “help the patient,” these two entities also enjoy higher profits from their working relationship.

Despite the apparent benefits of collaboration between radiologists and mammography vendors, many radiologists have also been frustrated with digital companies. These frustrations stem from the nature of free market, where separate companies have developed slightly different products. Each company competes with one another to develop the fastest machines with the clearest images. Therefore, digital equipment from several years ago has become obsolete in comparison with some of the newer, more efficient and sophisticated digital equipment. The Director of Breast Imaging at Duke expressed his dissatisfaction with older digital mammography machines, and his hopes for newer models:

... so we've gone with a different vendor for the two additional rooms that we're installing because we want something that is robust. And the one thing that we've heard about this new vendor is that it's sort of “plug and play.” We can't afford... and I don't mean financially, but just headache-wise, we can't afford the hassles of machines that weren't working on a regular basis.

The Director could, however, encounter another logistical “headache” in his decision to purchase equipment from a “different vendor.” Unfortunately, companies have developed separate machines, which are often incompatible for image transfer. This incompatibility between systems has obviously been a major barrier for image sharing and telemedicine. Even more concerning, though, is that women switching between providers may not have their previous mammograms available for comparison. Dr. Pisano addressed this matter in her article “Digital Mammography: What's Next?”:

First, the most important recommendation is the group's clear statement regarding the desirability of adherence to uniform display standards for digital mammography so that all images can be displayed equally well on any digital mammography soft-copy system... To date, vendors have not shared these algorithms openly and in fact have treated this all-too-important feature as a “black box.” They tout and sell “upgrades” to their

software packages without providing data supporting or justifying the new algorithms. Patients and physicians deserve more transparent information regarding the utility of new algorithms.

Several vendors have responded to these concerns by making their equipment more compatible for image transference between systems. UNC Hospitals has installed a universal mammography display system called "AXA," which allows radiologists to install digital mammograms from any company onto the UNC PACIS. Not every general radiologist, however, will be able to install these universal display systems in their practice.

Overall, the private market has been responsive to feedback from radiologists in the development of digital mammography. At the same time, digital vendors have competed with one another to render many systems either obsolete and/or incompatible with other systems. Digital companies will probably continue to develop their products and make faster, more advanced equipment. Many waves of digital mammography re-adoption could wash over the nation as private vendors continue to develop technology in a stepwise fashion.

Equality

To the extent that Medicare pays for the majority of breast cancer screening, mammography is a public good that should be evenly distributed. Digital mammography is, however, another resource that is more available to wealthy citizens. The first centers to adopt digital mammography also had the richest workforces and the most highly specialized physicians. This regional variation of digital mammography accentuates health care disparities, as described powerfully by Dr. Earp:

... in the past there was sort of the early adopters, or there were the special people, or the people who were close to the decision-makers, or those who were in-the-know... the elites... but we don't want to wait while the elites have theirs! Trends happen first among the elites, and then they give it to the poor people and to the ordinary people.

Media have also picked up on the inequalities associated with digital mammography. Of 215 articles reviewed for this analysis, 39 described the need to provide digital technology for uninsured women. Most of these reports have been published recently, or between 2005 and present. In October 2007, the *Chicago Tribune* used digital mammography as a poignant example of the city's segregated health care system.⁸⁸ The article's data showed hospitals in rich, white neighborhoods had significantly more digital mammography units and breast imaging specialists than hospitals in poor, minority neighborhoods.

Breast cancer and other advocacy groups have been among the first to tackle this problem of unequal digital mammography distribution. The senior policy analyst from the Susan G. Komen Foundation described this role of advocacy groups as follows:

...As digital mammography becomes more commonplace, it's really going to be incumbent on advocacy groups like ours and federal and state decision makers...to do some things to ensure that the costs are affordable and the technology is available, especially to underserved populations.

Advocacy groups have been very successful in multiple arenas, including policy and fund-raising, for installation of digital equipment in underserved areas. The Komen Foundation is winning digital mammography funding through the National Breast Cancer and Cervical Cancer Early Detection Program (NBCCEDP), which provides breast cancer screening for uninsured women who do not qualify for Medicaid. The senior policy analyst commented on the Susan G. Komen lobby for NBCCEDP funds:

At the federal level, every year we're going to Congress, to the Appropriations Committee, and you know all of our supporters and activists are going to their individual members of Congress and asking for more money for that program... On the state level, you know, we're working through our affiliates... because we have 122 affiliates across the country who have good, strong relationships with their local governments and their state governments.

In addition to this enormous political lobby, the media have been publicizing other advocacy activities and fund-raising events. Digital mammography vans have been particularly popular news items, as the *Sacramento Bee* (May 2006), *New York Post* (March 2007) and *Dallas Morning News* (April 2007) have all run articles covering recent purchases.⁸⁹⁻⁹¹ All these articles praised mammography vans for being able to screen about 5,000 women per year who would not have otherwise been screened, either due to their rural location or lack of health insurance. Fund-raisers for digital equipment have included everything from luncheons with keynote speakers to Christmas ornament sales, tennis tournaments and, of course, races for the cure.^{92, 93} The majority of fund-raising events were either sponsored by or affiliated with the Susan G. Komen Foundation.

Although advocacy groups have successfully mobilized resources for digital mammography in underserved areas, some question the true need for this type of technology in rural medicine. Dr. Earp, an expert in rural breast cancer screening patterns, commented:

... I think by and large rural health care doesn't need more machines, higher technology. I think it needs more middle-level practitioners, whether they're nurse practitioners or physician assistants or general internists. I think that 90% of what goes on between a doctor and a patient has everything to do with the history taking and the talking, and relatively little to do with the labs and the technology.

Although others express similar skepticism about the true value of digital mammography in underserved areas, these opinions have not slowed the momentum of advocacy groups. This is potentially because questioning voices have arrived after digital mammography has already been accepted by the majority as the new breast cancer screening standard. Also, digital mammography equipment provides a very concrete, tangible symbol of advocacy group efforts to improve access.

Conclusion

Digital mammography has followed Rogers' "Diffusion of Innovation" pattern. The majority's adoption of digital technology, however, has been complicated by the imposition of several outside interests on the process. Originally, digital mammography was perceived to have several theoretical advantages over screen film mammography for both patients and providers. The majority of women have come to regard digital mammography as the new standard for breast cancer screening, and radiologists have responded to these "demands from below." At the same time, many radiologists have capitalized on the potential efficiencies and profitability digital mammography could bring to their practices. Private vendors, in turn, have competed with one another to make digital equipment increasingly sophisticated, requiring costly upgrades. Finally, advocacy groups have taken up the cause of digital mammography and launched campaigns to make the technology available for everyone.

At this point, we must take a step back and re-examine the evidence. Digital mammography is a technology with uncertain public health benefits; however, the hubbub of patient demand, market forces and advocacy groups are all heavily engaged with the technology's dissemination. As the majority comes to adopt digital technology, it seems likely that the voice of evidence will become even more muffled. New digital mammography-related interests will enter into the national discussion and use particular pieces of evidence to support their own positions.

The Shifting Cost Burden

Is it the right thing to do? Yes. Not everything is designed for profit, and we realize that.

-- Michael DeGennaro, Administrative Director of the Department of Radiology, UNC Hospitals

Cost has been the singular negative aspect of digital screening mammography upon which both media accounts and interview respondents have converged. Newspaper articles pinpointed cost concerns, as 66 out of 215 articles described the drawback of cost in either headlines or opening sentences. For example, the *Detroit Free Press* published an article in June 2003 called "Digital Breast Exam Eclipsed by its Cost." The article reported findings of a Michigan health advisory board that had concluded the costs of digital technology far outweighed its benefits. The article quoted a medicine professor from the University of Michigan who said, "We can no longer give everything that works to everybody."⁹⁴ Also, after the DMIST results and initial cost-effectiveness analyses were published, the *Cleveland Plain Dealer* published an article titled "Mammography Going Digital: It's More Expensive, but Cost-Effective for Some" (January 2008). The reporter noted that although digital mammography would only be appropriate for a subgroup of women, the technology "like all other medical screening technologies before it, is going digital - whether or not it produces the most cost-effective images."⁹⁵

Interview respondents generally agreed that higher costs are the greatest disadvantage of digital screening. Seven out of twelve respondents named cost as the most prohibitive aspect of digital mammography, and an additional three respondents believed cost to be one of the greatest challenges for digital screening. Perhaps the Director of Breast Imaging at Duke, a self-proclaimed "purist" who "belongs in academic medicine," described the cost of digital technology most directly when he stated:

They (Medicare) shouldn't reimburse more, and there has certainly been some political chatter about ending that. Again, given the ACRIN results,

showing overall... for all-comers, for everyone who walks in the door for a mammogram... no overall difference in cancer detection between digital and analog. Why would they pay more for digital? It doesn't make sense.

Interview respondents diverged in their own reasoning for the higher digital costs. No one, through, has taken personal responsibility to control the price of digital mammography. The following are examples of the ways in which patients, health care providers, and even health system leaders have inappropriately justified and/or dismissed digital mammography costs.

Cost Considerations at Patient-Provider Level

Although individual patients and providers have been significant forces behind developing and marketing digital mammography, they are not invested in the technology's cost-effectiveness for the health care system. The Chairman of Radiology at Duke described the insignificance of digital cost to the patient:

Of course, digital costs more. Not that most people care, because they've got insurance.

Health insurance has essentially detached individual "customers," who act as price controls, from the digital mammography market. Many radiologists also contextualized digital mammography costs from the perspective of their own, individual practices. At the local level, digital mammography is cost-effective. One radiologist practicing in Appalachia stated, although digital mammography may not be cost-effective for the system, "I didn't lose any money... the government had a differential payment... it paid for itself to go ahead and buy the digital." Dr. Pisano also emphasized this point, saying the cost-effectiveness study by Tosteson and colleagues "was done from the perspective of third-party payers rather than the perspective of a practice."

Cost Considerations at the University Level

Many breast imaging specialists at tertiary medical centers are also disconnected from digital mammography cost considerations. The Director of Breast Imaging at Duke commented on digital mammography price as follows:

...you would have to ask someone with a finance background. I've seen arguments made... I've never calculated it out myself. One of the beauties of academic medicine is I don't have to, someone else can do that... but that's not my area.

The Director of Breast Imaging at UNC also acknowledged the disadvantage of digital mammography costs, but immediately thereafter emphasized the technology's potential for downstream cost savings:

Um... the only downside to begin with is that it costs more for the equipment. The initial start-up is more... and obviously the benefit is you get rid of the processor, you get rid of the dark room, you get rid of your costs for film, you get rid of the costs for your chemicals, you get rid of... unfortunately, the people who service the processor because you've got service contracts, people come out and clean it, make sure they're functioning appropriately. You get rid of the problem of having to have physical, large amounts of storage for folders and films. You know, you get rid of that potential of losing films.... So, the initial start-up costs are more... but downstream, digital I really think pays for itself.

The Director of Breast Imaging gave eight possibly cost-efficient qualities of digital mammography in this response. Hospital financial analysts, however, do not expect to collect any savings with digital mammography. Specifically, the Administrative Director of Radiology at UNC cited the enormous cost of digital image storage, which requires more electronic power than does film storage:

Conventional mammography, for example, would cost somewhere in the \$80,000 range... a digital mammographer is somewhere around \$500,000. What you save, perhaps, on chemistry and processing is nothing compared to storage... the digital storage costs.

Overall, university radiologists have felt professionally disengaged from the problem of digital costs and have embraced unrealistic optimism about downstream digital mammography savings. These perspectives of university leaders are problematic because smaller practices often follow academic medical centers in technology implementation. This creates a domino effect, and digital mammography expenses are eventually passed to the federal government or other third-party payers.

Cost Considerations at the Health System Level

On a system-wide level, digital mammography can be contextualized as either insignificantly expensive or necessarily expensive. Dr. Pisano, for example, contextualized digital mammography costs as another expense in our already expensive and complicated health care system:

You know, people look at technology and say “Oh, that’s the reason that we spend a lot of money.” Well, I challenge you to look at the profits of insurance companies versus digital mammography. I assure you, it’s a drop in the bucket compared to how much is skimmed off in profit.

Dr. Pisano named other health care expenses as far greater threats to the system than digital mammography. Although such concerns are certainly valid, her response purposefully drew attention away from the cost-ineffectiveness of digital mammography.

Other interview respondents pointed to the health care system as the reason behind digital mammography’s higher price. For example, the Administrative Director of Radiology at UNC blamed some American health regulators for driving higher digital mammography prices:

...if you look what’s happening in Europe, a lot of this technology is going more mainstream. They don’t have some of the gatekeepers of technology there, and as a result the cost model is shifted... [I am] talking about the FDA and perhaps Certificates of Need, which have both been cited elsewhere as increasing the cost of digital technology.

Digital mammography costs have even been dismissed by federal health care governing bodies. This is partially attributable to system design, because the FDA and Medicare are separate entities. The FDA’s Director of Devices and Radiological Health, Dr. Schultz, commented about technology cost considerations:

OK, well since you mentioned cost... cost is not something that we factor into our analysis. You know that. We don’t look at cost, we look at safety and effectiveness... and health benefit, but we don’t look at cost. So, in terms of how many people can avail themselves of a technology because of cost issues... I mean, I’m not saying that that’s not a very important

question and it's not a very important issue from a health policy standpoint, but it's not part of our mandate at FDA.

Although cost-effectiveness is not part of the "mandate at FDA," Medicare certainly considers FDA approval status in their decisions to reimburse for new medical interventions. In this arrangement, neither federal entity is completely informed about the rationale behind the other's decisions. Furthermore, cost-effectiveness data are difficult to accrue and use for decision making. Thus, it is counterintuitive that our nation's technology approval and technology funding bodies are so completely separate.

Conclusion

Although both media accounts and interview respondents have recognized the problem of cost, digital mammography prices are dismissed at all levels, from that of the individual patient to the level of federal regulators. Some respondents emphasized the relative cost-effectiveness of digital mammography, from the perspectives of individual providers. Other health care leaders have described digital mammography cost as an inevitable byproduct of our complex, expensive system. Finally, many leaders seem to have adopted the colloquial "it's not my problem" stance. These hands-off approaches to cost have resulted in no action to ensure that digital mammography, or other future medical technologies, are subject to more rigorous cost-effectiveness analyses before they can be distributed.

Lessons from Digital Mammography

I tell you, I think the whole point a moot question, because I suspect that within 5 years, patients will all be getting digital tomosynthesis. And the whole analog versus digital question will be obliterated. The difference in sensitivities of digital versus analog are probably real but slight... I suspect that it's going to be a quantum leap up to tomosynthesis.

-- Jay Baker, MD, Director of Breast Imaging, DUMC

The necessity for evidence-based medicine is more clear than ever before, as our health care technologies, therapeutics, and costs continue to escalate. Much literature has focused on how to make evidence both accessible and sound, or based on measures that are equal, valid, and reliable. Despite fine progress by expert and disinterested groups such as the USPSTF, we continue to adopt and invest in some medical practices for reasons other than evidence. In the case of digital mammography, the evidence has been manipulated and/or forgotten in the national arena because of our collective excitement about the technology's possible advantages. Between our "war on cancer," the potential for digital technology to advance breast imaging, the perceived advantages for women, the forces inherent in diffusing innovation, market forces, and the drive for health care equality, digital mammography adoption has been a disorganized process. Perceptions, rather than facts, have propelled the distribution of this new, expensive medical technology with questionable public health benefits.

The next breast cancer screening technology, which has already been met with great enthusiasm by researchers and radiologists, is tomosynthesis. One interview respondent described tomosynthesis as "like a CT of the breast," which produces three-dimensional images rather than the traditional, two-dimensional images from screen film or digital mammography. Seven interview respondents, including four radiologists, named tomosynthesis as the next step for breast cancer screening.

Many of the same interest groups that have propelled the spread of digital mammography will also drive our adoption of tomosynthesis. Radiologists are already eager for tomosynthesis, as articulated by the Director of Breast Imaging at Duke:

...my hope was that tomosynthesis would be approved faster than it's been approved... and it's just no end of frustration to me that G.E. has dragged its feet on getting FDA approval. I'm very thankful that Hologic has come along and put a fire under the whole modality... I know there's a lack of data to prove it now... but I do think that tomosynthesis is going to be the way to go. I may be wrong, I haven't totally bought into it, but the cases I've seen are pretty compelling.

This excerpt illustrates the pressure for approval of tomosynthesis by both radiologists and private vendors, both inextricably linked to the FDA. As we see, this academic medical center Director of Breast Imaging is already voicing strong enthusiasm for the technology based on his anecdotal evidence rather than data from clinical trials.

Some of the original perceived benefits of digital mammography have now become the projected benefits of tomosynthesis. Specifically, the Chairman of Radiology at Duke cited potential for lower recall rates and better images as two advantages of tomosynthesis:

So with the tomosynthesis you're able to look at it, if you want to think, slice-by-slice... But, you know, it may be the new thing... if some lady gets called back from a screening mammogram for a finding, to be able to go through the breast. Is it just overlapping of tissue? Is it something real, is it really a mass?

Also like digital mammography, hospital administrators are expecting significant costs associated with overhauling the current infrastructure and replacing it with tomosynthesis equipment. The Administrative Director of Radiology at UNC projects tomosynthesis will be a "big cost in transition." The Director, however, immediately qualified that view by adding "some of these machines are being sold so that they're capable... you know, digital with tomosynthesis."

Over the coming decade, tomosynthesis is likely to become the next generation of breast cancer screening. Although information about the technology is not yet prevalent in mainstream media accounts, interview respondents working to further tomosynthesis adoption are very optimistic about its potential. Before the entry of tomosynthesis into the health care market, though, we must dispassionately evaluate its true advantages from a public health perspective.

Such an evaluation could take place through a federally-supported program to regulate new medical technologies. Dr. Earp described such an agency as a “whistle-blower” who would need “federal legislation to protect them because, almost inevitably, there’s a movement to wipe them out.” The Institute of Medicine recently called for a new, single program with “authority, overarching responsibility, sustained resources, and adequate capacity to ensure production of credible, unbiased information about what is known and not known about clinical effectiveness.”⁹⁶ Although the creation of this program could help clinicians practice evidence-based medicine, I believe the proposal should be expanded.

We need one federal regulatory program mandated to evaluate medical evidence, and then approve and/or assign funding for new medical technologies based on evidence appraisal, perhaps similar to the National Institute for Clinical Effectiveness in the United Kingdom. Evaluators would necessarily include elites in the fields of medicine, technology and finance. These people would collaborate to consider the relative effectiveness, harms, and costs of every new, proposed medical intervention. The program could feasibly be created from an existing bureaucracy such as the USPSTF, the FDA (for which this role had already been discussed in Congress during debate over the latest reauthorization of the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act [PL 110-85]), or even the Centers for Medicare & Medicaid Services. These organizations would require some redefinition of their

Congressional mandates in order to become more influential gatekeepers of medical technologies.

The program would require tremendous resources to function effectively, but could eliminate many of the apparent miscommunications between federal programs that presently allow ambiguously effective technologies, such as digital mammography, to become standards of care. For example, having one regulatory program responsible for appraising medical literature and approving new technologies could reduce the uncertainty in many of the FDA's decisions, which are based on limited "safety and effectiveness" data. Furthermore, connecting the technology approval process with decisions about funding would allow more effective technologies to be more generously reimbursed. Over the long term, such a centralized program could help contain health care costs by ensuring that only effective medical interventions enter the health care market and receive Medicare/Medicaid reimbursement.

The main threats to this proposed health regulatory program are inefficiency and potential for political manipulation. Both these threats may be resisted by assuring the program has sufficient autonomy and resources to maintain efficiency and integrity against partisan interests. Also, in terms of efficiency, creating such a program would necessarily invoke a paradigm shift among technology patrons, such as those of digital mammography, who were eager for product approval and funding despite limited evidence. These patrons must come to understand the importance of having clinical trials prior to approving new medical technologies for mainstream use. Thus, the program could potentially, and in many cases appropriately, further delay approval of many new technologies.

The ability of health care researchers and providers to develop complex technologies, such as digital mammography and tomosynthesis, is one of the greatest attributes of our health care system. Our propensity to improve

technology and reward innovation has enabled clinicians to share information, enhance patient quality of life, and improve survival times. At the same time, however, it is important to balance acceptance of new technology with shrewd appraisal of the evidence. Achieving this balance will continue to be an extremely difficult, although absolutely necessary, component of fixing our health care system.

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67. Laurie Tarkan. An Upgrade That Matters? Mammography's Next Step Is Assessed. *New York Times, The (NY)*, 2001: 5.
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69. Rob Stein Washington Post Staff Writer. Digital Mammograms Find More Cancers. *Washington Post, The (DC)*, 2005: A5.
70. Kranhold Kathryn. Digital Mammograms Excel in Study. *Wall Street Journal*, 2005: A5.
71. Judy Peres Tribune staff reporter. Digital screening for breast cancer gets mixed review; -; More accurate for young, but not overall. *Chicago Tribune (IL)*, 2005: 10.
72. H. Gilbert Welch Lisa Schwartz and Steven Woloshin Special to The Washington Post. Finding More Cancer Isn't the Answer. *Washington Post, The (DC)*, 2007: F2.
73. Elizabeth Owens-Schiele. REMODEL MAMMOGRAPHY? IT COULDN'T HURT. *Chicago Tribune*, 1998: 3.
74. Phat X. Chiem Chronicle Staff Writer. Image Is Everything With Digital X-rays; - ; Technology allows them to be enhanced, transmitted. *THE SAN FRANCISCO CHRONICLE*, 1997: B1.

75. Jon Van Tribune Staff Writer. PRECISION MAMMOGRAPHY; -; RESEARCHERS ARE STUDYING DIGITAL IMAGING AND OTHER CUTTING-EDGE TECHNOLOGIES IN HOPES OF IMPROVING THE EARLY DETECTION OF BREAST CANCER WHILE AT THE SAME TIME REDUCING THE NEED FOR WOMEN TO HAVE BIOPSIES. *Chicago Tribune*, 1998: 1.
76. Bob Condor Tribune Staff Writer. EARLY ARRIVAL; -; NEWS RESEARCH FOR DETECTING BREAST CANCER DOESN'T RESEMBLE A MAMMOGRAM, BUT STILL EMPHASIZES THE SOONER THE BETTER. *Chicago Tribune*, 2000: 3.
77. Denise Grady. Sharper Digital Breast Exams Can Add Anxiety. *New York Times, The (NY)*, 2008: 1.
78. Sue Landry. Women are avoiding screenings for breast cancer. *St. Petersburg Times*, 1997: 1D.
79. Bernard J Wolfson. SPECIAL REPORT - RACE FOR THE CURE // Perfect? No, but mammograms are still best method of detection // The past year has seen a series of conflicting studies, but the tests remain the gold standard. Here's a look at some developments. *The Orange County Register*, 2002: B.
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89. Nancy Churnin Staff Writer nchurnin dallasnews.com. Tears of joy for the mammogram van; -; Hospitals take testing to underserved communities. *Dallas Morning News, The (TX)*, 2007: 3G.
90. Jasmin K Williams. LOCAL HERO - BRINGING VITAL CANCER DETECTION TO THE STREETS. *New York Post (NY)*, 2007: 052.
91. Dorsey Griffith, Bee Medical Writer. Crowd for a cure; -; Thousands join the fun to fight breast cancer. *Sacramento Bee, The (CA)*, 2006: B1.
92. Valerie Sudol Star-Ledger Staff. Two Rivers show aids cancer center. *Star-Ledger, The (Newark, NJ)*, 2001: 78.
93. Paul E. Kandarian. People. *Boston Globe, The (MA)*, 2007: 9Reg.

94. Patricia Anstett Free Press Medical Writer. DIGITAL BREAST EXAM ECLIPSED BY ITS COST. *Detroit Free Press (MI)*, 2003: 1A.
95. Mary Vanac Plain Dealer Reporter. Mammography going digital It's more expensive, but cost-effective for some. *Plain Dealer, The (Cleveland, OH)*, 2008: B1.
96. Medicine Institute of. *Knowing What Works in Health Care: A Roadmap for the Nation*. Washington, DC: National Academies Press; 2008.

Appendix 1: Coding Summary of Interview Responses

War terms used: Number of times respondent mentioned the words “fighter,” “war,” and/or “save lives” during the encounter.

Subjective experience, Radiation Dose, Recall Rates: Four radiologists commented on these parameters during the interviews. Subjective patient experience refers to the painfulness and length of study for digital versus screen film mammography. Radiation dose refers amount of radiation delivered to patients during digital versus film mammography. Recall rate refers to the volume of patients requiring further work-up after digital versus screen film examinations.

Cost disadvantage: All interview respondents except one discussed digital mammography costs. Respondents either indicated cost was the “greatest” disadvantage of the technology, acknowledged cost as one disadvantage (“yes”), or did not acknowledge cost as a disadvantage (“no”).

Tomosynthesis: Interview respondents who cited screening tomosynthesis as the most promising future avenue for breast cancer screening.

Respondent	# War Terms Used	Subjective Experience Different? (Y/N)	Less Radiation? (Y/N)	Less Recall? (Y/N)	Cost Disadvantage	Tomosynthesis: Next Step?
Matthew Moore	2	N/A	N/A	N/A	Greatest	-
Cherie Kuzmiak, MD	1	No	No	No	Yes	Yes
Jo Anne Earp, ScD	5	N/A	N/A	N/A	Greatest	Yes
Carl Ravin, MD	1	No	No	No	Greatest	Yes
Jay Baker, MD	0	No	No	No	Yes	Yes
Marlene Rifkin	3	N/A	N/A	N/A	Greatest	Yes
Michael DeGennaro	0	N/A	N/A	N/A	Greatest	Yes
Daniel Schultz, MD	0	N/A	N/A	N/A	Yes	-
Mills Antley, Jr, MD	0	N/A	N/A	N/A	No	-
Etta Pisano, MD	3	No	No	No	Yes	Yes

Eugenie Komivies, MD	0	N/A	N/A	N/A	Greatest	-
Jackie Wynn, RN	0	N/A	N/A	N/A	-	-

Appendix 2: Coding Summary of Media Review

*****War language:**

Of 215 digital mammography articles analyzed, 44 used the following war-related terms in either their titles or opening paragraphs: weapon, war, struggle, fight. The following are only articles that used war-related terms in their titles.

Headline	Outlet	Date
Using Defense Know-How for Health Care - Technology to Hunt Warheads May One Day Find Tumors	Washington Post	2-Jul-04
Defense technology may be used to help detect breast cancer	Wall Street Journal	12-Oct-94
Crowd for a cure -- Thousands join the fun to fight breast cancer	The Sacramento Bee	14-May-06
U.S. Weapons Lab, Firm Unite in War Against Breast Cancer -- Lawrence Livermore Partnership Aims For Better X-Ray Device	The Sacramento Bee	7-Oct-93
Breast-cancer detection may employ 'star wars' technology - MEDICINE: A digital mammography machine could provide sharply improved images of early cancerous tissue	Orange County Register	28-Nov-93
Breast cancer fight hopeful, frustrating	Houston Chronicle	19-May-02
Weapon in war against cancer/Spy technology will soon be trained on breast tumors	Houston Chronicle	5-Apr-95
Spies In The Sky VS. Breast Cancer High-Tech Wizards Spotting Tumors Missed By Doctors	New York Daily News	31-Oct-99
Foundation keeps word to a friend -- \$5 million donation to fight breast cancer sets record for area	Chicago Tribune	2-Oct-98
Scientists enlist Star Wars tech in battle against breast cancer	Chicago Tribune	28-Nov-93
Digital detection -- Make full use of new weapon against breast cancer	Detroit Free Press	20-Sep-05
The move: From bombs to breast cancer aid	Detroit Free Press	31-Oct-97
NASA high tech may help fight breast cancer	Detroit Free Press	18-Oct-94

Missiles to Mammograms: New Uses for Technology	Plain Dealer, The (Cleveland)	18-Aug-97
Health Watch - Helping to fight breast cancer - Military equipment, other high-tech tools may aid in detection	Atlanta Journal-Constitution, The	12-Apr-95
CIA offers computer-image technique to aid in early breast-cancer Military target finder may help save women	Dallas Morning News, The	5-Apr-95
Space, defense technology being used to fight breast cancer	Star-Ledger, The	17-Aug-97
Hillary Clinton hurts the fight on breast cancer	Newsday	4-Apr-00
Star Wars Secrets Yield Weapon for Breast Cancer	Newsday	19-Dec-95
From Sword to Scalpel Partners develop breast cancer detector	Newsday	2-Jun-94

***Digital cameras/word processors as vehicles to explain digital mammography:

Articles that explained digital technology using the metaphor of cameras and/or word processors:

Total # of articles	(A) Articles explaining digital mechanics	(B) Articles mentioning digital camera or word processor in explanation	B/A*(100)
215	31	20	64.5%

***Articles explaining DMIST:

Analysis of the tones of titles/opening sentences of newspaper articles explaining results of the DMIST.

Total articles: 21

Total negative articles: 1

Total positive articles: 10

Total neutral articles: 10

Headline	Outlet	Date	Tone	Other digital advantages mentioned?
Finding More Cancer Isn't the Answer	Washington Post	10-Apr-07	Neg	Y
heart disease High blood sug....	Washington Post	27-Sep-05	Neu	Y
Digital Mammograms Find More Cancers	Washington Post	17-Sep-05	Pos	Y
Digital imaging improves mammograms before 50	USA Today	16-Sep-05	Neu	Y
Digital mammograms are better, but scarce	USA Today	19-Sep-05	Neu	Y

Digital Mammograms Excel in Study	Wall Street Journal	17-Sep-05	Pos	Y
Are Mammograms Right for Everyone?	NYT	1-Nov-05	Neu	Y
Study Weighs The Two Types of Mammogram	NYT	17-Sep-05	Neu	Y
Technology targets breast cancer -	Houston Chronicle	26-Jan-06	Neu	Y
Research, technology improve breast cancer treatments - Gene essays, digital imaging, aid in detection	Houston Chronicle	20-Oct-05	Pos	Y
Digital mammograms spot cancer better, study finds	Houston Chronicle	17-Sep-05	Pos	Y
Digital screening for breast cancer gets mixed review - More accurate for young, but not overall	Chicago Tribune	17-Sep-05	Neu	Y
Latest reseach, new tests	Detroit Free Press	22-Oct-06	Neu	Y
Breast cancer awareness during 5 years, cost of mammograms has steadily risen in state	Detroit Free Press	23-May-06	Neu	Y
Digital detection -- Make full use of new weapon against breast cancer	Detroit Free Press	20-Sep-05	Pos	Y
Proof's in on digital breast test: it's better	Detroit Free Press	17-Sep-05	Pos	Y
The power of detection Study gives digital mammography the advantage in spotting cancer in women younger than age 50	Newsday	17-Sep-05	Pos	Y
Researchers call breast density a cancer risk too long ignored	Boston Globe, The	12-Feb-07	Neu	Y
Study sees new hope for finding breast cancer	Star-Ledger, The	17-Sep-05	Pos	Y
Image is everything	Star-Ledger, The	17-Oct-05	Pos	Y

Digital mammograms found better for younger women	San Francisco Chronicle	17-Sep-05	Pos	Y
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*****Reduced pain and/or radiation:**

Out of 215 media articles reviewed for this analysis, 38 mentioned digital mammography's ability to reduce pain and/or radiation exposure. The following are some examples of articles that addressed pain and/or radiation exposure in their titles or leading paragraphs. Note the references to less pain and/or radiation are in **bold**:

Headline	Outlet	Date	Key Excerpt
Remodel mammography? It couldn't hurt	Chicago Tribune	4-Oct-98	Women forever dreading what some call the " slam-o-gram " may find some relief in the future, or at least more reliable results than in the past, thanks to two developing techniques.
Women get a new mammogram option digital x rays are faster and more comfortable	Detroit Free Press	17-Jan-01	Digital mammography -- a computerized X ray -- cuts in half the approximately 15-20 minutes usually needed to perform mammography. That means women don't have to stand as long with their breast compressed tightly between heavy plastic devices -- a common complaint among women that some say deters them from getting mammograms.
Imaging and other cutting-edge technologies in hopes of improving the early detection of breast cancer while at the same time reducing the need for women to have biopsies.	Chicago Tribune	30-Nov-98	After decades of relying on X-rays and film to detect breast cancer, physicians are working to create a new world of high-technology mammography that promises less painful testing , fewer false readings and a smaller necessity for biopsies.
Research, technology improve breast cancer treatments - Gene essays, digital imaging, aid in detection	Houston Chronicle	20-Oct-05	Radiologist Dr. Larry Grissom of Houston Northwest Medical Center has been using digital mammograms since 2002. Grissom said the advantage of digital mammograms can be likened to computer-based digital photo programs.... "And the amount of dosage with digital is up to one third less because you manipulate the image instead of having to repeat the mammogram."
New Digital X-Rays Offer a Clear Picture That Patients Also See	Wall Street Journal	3-Mar-00	The digital mammogram is just one of a slew of new digital X-ray technologies slowly appearing in hospitals and dentists' offices around the country.... But doctors and radiologists say the digital X-rays offer benefits, including time savings, better visibility for the person reviewing the X-ray and, in some cases, less radiation exposure.

*****Inequality:**

Of the 215 articles reviewed, 39 described unequal distribution and/or the need to provide digital technology for the uninsured. The following are some examples of articles that address inequality through their titles (chronological order):

Headline	Outlet	Date
Race For The cure a sorority of survivors	Houston Chronicle	30-Sep-99
Mammograms called best option - Review backs more research, better access for the uninsured	Dallas Morning News, The	9-Mar-01
X-ray van stays in S.F.	San Francisco Chronicle	16-Dec-01
Elmhurst Gets 550G for Mammogram Van	New York Daily News	31-Mar-04
Tennis tourney a cancer fund-raiser	Atlanta Journal-Constitution, The	8-May-04
Rell's Treatment Highlights Hurdles For Screenings Faced by Many	NYT	9-Jan-05
Digital mammograms are better, but scarce	USA Today	19-Sep-05
Crowd for a cure -- Thousands join the fun to fight breast cancer	The Sacramento Bee	14-May-06
Tears of joy for the mammogram van -- Hospitals take testing to underserved communities	Dallas Morning News, The	10-Apr-07
Local Hero - Bringing Vital Cancer Detection to the Streets	New York Post	21-Mar-07
More Mammograms	NYT	20-May-07
Breast cancer panel decries city's 'segregated' system	Chicago Tribune	18-Oct-07

*****Cost as Disadvantage:**

Newspaper articles pinpointed cost concerns, as 66 out of 215 articles described the drawback of cost either through their titles or opening sentences. The following are only those articles that addressed cost concerns through their titles:

Headline	Outlet	Date
Breast cancer awareness during 5 years, cost of mammograms has steadily risen in state	Detroit Free Press	23-May-06
Cancer test costs rise as waits fall -- reimbursement rates lag at many of state's mammography centers	Detroit Free Press	17-Jun-03
Digital breast exam eclipsed by its cost	Detroit Free Press	7-Jun-03

Mammography going digital: It's more expensive, but cost-effective for some	Plain Dealer, The (Cleveland)	1-Jan-08
Health Costs Underestimated, Experts Say	NYT	30-Nov-00

Appendix 3: Digital Mammography Interview Questions

Please note 3 different interview formats for participants, based on their participation in affiliation with UNC, Duke, or other women's health organizations.

UNC Hospitals:

In your opinion, what were the most important factors leading to UNC's adoption of digital mammography in September, 2007?

What types of issues arose in switching from plain film to digital? What were the debates and struggles that had to be settled before the switch? Have any new, unforeseen issues with cost, quality, or logistics arisen since the transition?

How has infrastructure had to change during the switch from plain film to digital mammography? What has been required of radiologists and technicians? What were the costs? What was sacrificed in order for UNC to make the switch?

Now that we have implemented digital mammography as standard of care at UNC, how do you think we should measure the successes and shortcomings of digital mammography in the future? What is your hope for digital mammography?

Dr. Pisano's 2005 "Diagnostic Performance of Digital versus Film Mammography for Breast-Cancer Screening" in the NEJM DMIST Trial emphasizes the superior diagnostic accuracy of digital mammography in detecting breast abnormalities in women under 50yo and pre-/peri-menopausal women. At the same time, the literature shows digital and plain film mammography to be roughly equivalent in their diagnostic accuracy for the majority of women we currently screen (age 50+). What are your thoughts on how digital mammography will affect breast cancer screening?

In deciding to convert to digital mammography, did UNC consider what the switch would mean for the rest of the state? {What do you mean? Did you think about what would happen in the rest of the state as a result of UNC going completely digital?}

In your opinion, how has digital mammography been received by patients, physicians, technicians, and support staff at UNC?

Digital mammograms are much more expensive than are plain film mammograms. {Give the \$ value} Could you give me your opinion on how a cost-effectiveness argument can – or can't – be made on behalf of digital mammography?

Questions for Radiologists:

In your opinion, how will the switch to digital mammography affect quality?

Some radiologists feel that digital mammography will increase potential for image sharing and therefore increase breast imaging accuracy. What are your opinions on this? Will digital mammography relieve some of the litigious burden of reading mammograms?

What types of challenges are associated with comparing old plain film mammograms with new digital images?

Duke University Medical Center:

In your opinion, what is the current role of digital mammography at DUMC?

The literature shows digital and plain film mammography to be roughly equivalent in their diagnostic accuracy for the majority of women we currently screen (age 50+). However, digital mammography has proven superior to plain film in breast imaging for women aged 40-50 and pre/peri-menopausal women. What are your thoughts on how digital mammography might affect breast cancer screening?

Would you say that DUMC paid any attention to UNC's recent transition from plain film to digital mammography for breast imaging and screening for breast cancer? In your opinion, is it the right time to transition from plain film to digital? What would or would not have to happen for a similar transition to happen at DUMC?

Medicare reimburses ~90 dollars for plain film and ~150 for digital mammography. At the same time, the new equipment and training to capture/interpret digital mammography are tremendously expensive. How do you think cost factors will influence the decision the switch from plain film to digital mammography, both in the academic and private sectors?

Some public health officials have expressed concern that transitioning from plain film to digital mammography is a "slippery slope" which creates an atmosphere where more expensive screening tools, such as MRI, will become more commonplace. What is your opinion on this?

In your opinion, what should the future hold for digital mammography at DUMC?

Questions for Radiologists

Many radiologists have been very enthusiastic about the potential of digital mammography. Many believe advancements in technology could eventually make digital far superior to plain film. What are your thoughts about this? What are the potential diagnostic advantages of digital mammography?

Some radiologists feel that digital mammography will increase potential for image sharing and therefore increase breast imaging accuracy. What are your opinions on this? Will digital mammography relieve some of the litigious burden of reading mammograms?

Other Leaders/Experts in Breast Cancer Screening:

In your opinion, how well are we doing with breast cancer screening in general?

Is everyone who needs to be screened getting screened?

Are some people, who don't need to be screened, getting screened?

What have been the greatest successes in breast cancer screening with our current technology?

What are the biggest challenges within our current breast cancer screening method?

Several large, tertiary care centers, including UNC Hospitals, have transitioned completely from plain film to digital mammograms for breast cancer screening. What are your feelings about digital mammography?

Do you think it's reasonable for digital mammography to become the new standard screening method for breast cancer, nationwide? Is it the right time?

How do you think we should measure the successes and shortcomings of new methods of breast cancer screening, especially digital mammography, in the future?

Appendix 4: Interview Respondents and Positions

Respondent	Position	Interview Date	Interview Location	Interview Length
Matthew Moore	Senior Policy Analyst at Susan G. Komen Foundation	3/24/08	Phone call to Dallas, TX	20 minutes
Cherie Kuzmiak, MD	Director of Breast Imaging at UNC Hospitals	3/24/08	Phone call to Chapel Hill, NC	33 minutes
Jo Anne Earp, ScD	Medical Sociology, Breast Cancer Screening Patterns Expert, Patient Advocate	3/28/08	Chapel Hill, NC	45 minutes
Carl Ravin, MD	Chair, Department of Radiology, Duke University Medical Center	3/31/08	Durham, NC	25 minutes
Jay Baker, MD	Director of Breast Imaging, Duke University Medical Center	4/1/08	Durham, NC	45 minutes
Marlene Rifkin	Senior Vice President, Women's and Children's Hospitals and Cancer Services, UNC Hospitals	4/4/08	Chapel Hill, NC	35 minutes
Michael DeGennaro	Administrative Director of UNC Radiology Department	4/4/08	Chapel Hill, NC	35 minutes
Daniel Schultz, MD	Director of FDA Center for Devices and Radiological Health	4/10/08	Phone Call to Washington, DC	23 minutes
Mills Antley, Jr, MD	Blue Ridge Radiology, General Radiologist	4/10/08	Phone Call to Morganton, NC	10 minutes
Etta Pisano, MD	PI, DMIST	4/14/08	Chapel Hill, NC	30 minutes
Eugenie Komivies, MD	Vice President/Senior Medical Director of BCBS NC	4/14/08	Chapel Hill, NC	30 minutes
Jackie Wynn, RN	Director of Medical and Reimbursement Policy of BCBS NC	4/14/08	Chapel Hill, NC	30 minutes

*I conducted all interviews in person except for those with the FDA Director, the Director of breast imaging at UNC, the senior policy analyst from the Susan G. Komen Foundation, and Dr. Mills Antley, whom I interviewed by telephone.

Appendix 5: Top 25 Circulating Newspapers

Rated by A.C. Nielsen in Spring 2007

- 1 USA Today
- 2 The Wall Street Journal
- 3 New York Times
- 4 LA Times
- 5 New York Post
- 6 New York Daily News
- 7 Washington Post
- 8 Chicago Tribune
- 9 Houston Chronicle
- 10 Arizona Republic
- 11 Dallas Morning News
- 12 Newsday (Long Island)
- 13 San Francisco Chronicle
- 14 Boston Globe
- 15 Star-Ledger of Newark
- 16 Atlanta Journal Constitution
- 17 Philadelphia Inquirer
- 18 Star Tribune of Minneapolis
- 19 Cleveland Plain Dealer
- 20 Detroit Free Press
- 21 St. Petersburg Times
- 23 San Diego Union-Tribune
- 24 Orange County Register
- 25 Sacramento Bee

*I reviewed all available articles published after 1990, but several newspaper electronic archives were not accessible from this early date. Thus, I reviewed *The Cleveland Plain Dealer* from 1991, *The Star-Ledger of Newark* from 1996, *The Arizona Republic* from 1999, *The NY Daily News* from 2000, *The N.Y. Post* from 1999, *The L.A. Times* from 1996, and *The N.Y. Times* from 1995.

