# PROPOSAL FOR A MAMMOGRAPHY REMINDER SYSTEM DEMONSTRATION PROJECT IN MASSACHUSETTS

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> Note: this project is now underway, and thus is considerably more developed than is described in this proposal



#### The Susan G. Komen Breast Cancer Foundation

**Project Summary:** <u>Background</u>: Failure to return promptly to annual breast cancer screening examinations is a common occurrence with very negative health consequences. Indeed, we have found that while most women begin screening close to their 40<sup>th</sup> birthdays, as recommended, one-in-four women never return for an additional screening mammogram. Among the women who do return, screening intervals of 2, 3, 4 and more years are common. One-quarter of women who make appointments for screening mammograms forget to attend them. Computer simulation studies have indicated that this underutilization of screening probably increases the breast cancer death rate by 50%. Much of the failure to use screening to its fullest can be ascribed to the absence of effective reminder tools. While the staff of many screening centers make heroic efforts to call women to remind them of their u pcoming appointments, such efforts are both costly and inefficient; screening centers usually make their reminder calls during the day when they are open, but most women are usually away from home at the that time. Few screening centers have individuals who speak Spanish, Chinese, and other languages in widespread use. Systems for identifying women who have not made appointments for screening mammograms do not exist. Nor are there tools for notifying women who have missed appointments, so that they can be rescheduled. **Objective:** To solve these problems, we have developed an integrated breast cancer tracking/reminder system, which sends computer generated telephone reminder messages to women to make, and then keep, appointments for screening mammograms. The reminder messages may be sent in the language desired by each woman, and at the time requested by each woman. For women who have not made appointments, the system sends messages to make such appointments, and the system informs those women who have forgotten to attend their appointments to reschedule. The system contains a Web-calendar, which screening centers can use to schedule their practices; for those centers that use the Web-calendar, the system can assign screening appointments automatically. Appointment data can be entered from each screening center through simple Web-forms, which means that screening centers need no special software, telephony equipment, or telephone lines: all that is required is access to the Internet. This system, in prototype form, is now fully functional. Hypothesis: We hypothesize that the reminder system will increase the utilization of breast cancer screening. Specific Aims: Aim #1: We propose to adapt our prototype mammography reminder system for use in all screening centers in the greater Boston (617 area code) region. Aim #2: We propose to test the impact of mammography reminder system by making it available to the women who attend screening in the greater Boston (617 area code) region. Aim #3: We propose to analyze the impact of the reminder system on the utilization of breast cancer screening after it is in use among the women who attend screening in the greater Boston (617 area code) region. Aim #4: We propose to adapt our mammography reminder system for use in Massachusetts as a whole. Aim #5: We propose to adapt the reminder system for subsequent addition of reminder and tracking tools for other aspects of preventative medicine, including reminders for colorectal cancer screening, influenza immunizations, diabetes control, tracking tools for women with symptoms of breast cancer, etc. Study Design: We propose to carry out the demonstration project of this reminder system in the greater Boston Area, as defined by women served by mammography screening centers in the 617 area code, and then to adapt the system for use in Massachusetts as a whole. The greater Boston area where the system will initially be deployed and tested region contains ~1 million people, of whom ~220,000 are women who are eligible for screening. The region contains 12 cities and is culturally, ethnically, economically, and linguistically diverse. Furthermore, approximately 10% of the women in this region receive their screening at the Massachusetts General Hospital, where a detailed record of screening use since 1985 is available, and this provides an opportunity to compare the impact of the system against previous usage. Since the reminders sent by the system are initiated by the entry of data on the attendance or failure to attend screening examinations the system itself will provide information on its impact on screening use across the 617 area code as a whole. Relevance to the Susan G. Komen Breast Cancer Foundation's mission. The integrated breast cancer tracking/reminder system that we have developed is the only one of its type, and offers the potential to lead to considerable reductions in the breast cancer death rate. Testing the effect of the reminder system has important implications for the nation as a whole, since it is technically capable of being widely utilized and should also be adaptable to the task of increasing screening for other cancers (colon, skin, cervical, etc). Furthermore, since mammography has become the most common point of interaction with the medical care system for women over age 40, the mammography reminder provides a point of contact from which information on other preventative health interventions can be provided. The system also provides a framework, upon which can be built reminder and tracking tools for other aspects of preventative medicine, such as for influenza immunizations, diabetes control, tracking tools for women with symptoms of breast cancer, etc. Finally, the mammography reminder can provide a point of contact from which the Susan G. Komen Breast Cancer Foundation can raise community awareness about its efforts to control cancer and to initiate requests for support.

5005 LBJ Freeway • Suite 250 • Dallas TX • 75244 • 972.855.1600 To eradicate breast cancer as a life threatening disease by advancing research, education, screening and treatment.

# **TABLE OF CONTENTS**

Collaborators:	p 1
Abstract	p 3
Specific aims	p 4
Background	p 4
Preliminary studies	p 6
Research design and methods	p 17
Timeline	p 21
Budget	p 27
Biographical sketches	p 28
References	p 56

## A. Specific Aims:

Specific Aim #1: We propose to adapt our prototype mammography reminder system for use in all screening centers in the greater Boston (617 area code) region.

Specific Aim #2: We propose to test the impact of mammography reminder system by making it available to the women who attend screening in the greater Boston (617 area code) region.

Specific Aim #3: We propose to analyze the impact of the reminder system on the utilization of breast cancer screening after it is in use among the women who attend screening in the greater Boston (617 area code) region.

Specific Aim #4: We propose to adapt our mammography reminder system for use in Massachusetts as a whole.

Specific Aim #5: We propose to adapt the reminder system for subsequent addition of reminder and tracking tools for other aspects of preventative medicine, including reminders for colorectal cancer screening, influenza immunizations, diabetes control, tracking tools for women with symptoms of breast cancer, etc.

# **B. Background and Significance:**<sup>1-21</sup>

Underutilization of breast cancer screening

While many studies have show that breast cancer screening saves lives<sup>22-28</sup>, many other studies have found breast cancer screening is underutilizated. For example, we have found that while most women begin breast cancer screening close to their 40<sup>th</sup> birthday, as recommended, prompt return after that is the exception<sup>20,15,29</sup>. One in four women never return for an annual screening examination. Among those women who do return, prompt return is rare; many women go 2, 3,or more years until they return for their exams. Computer simulation analysis suggest that this underuse of screening probably results in a 50% greater breast cancer death rate than can be expected from regular use of screening<sup>15</sup>.

### An important cause of screening underutilization: Forgetting

Even after appointments are made, considerable numbers of patients fail to attend breast cancer screening. For example, McCoy et al<sup>30</sup> found that 40% of appointments for a screening mammogram in the population they studied were no-shows, while Margolis et al<sup>31</sup> found that 23% of the appointments in their study population were missed.

Many psychological, sociological, and economic factors contribute to the failure to attend breast cancer screening exams<sup>32-40</sup>, but the main reason is forgetting<sup>41,42</sup>. Aids that can help patients remember their appointments offer the potential for increasing screening use. Indeed, this is the central goal of the reminder system we have developed.

#### A tool for improving screening utilization: Computer-generated reminders

Why do so many women fail to return promptly for their annual breast cancer screening exams? The simple answer is that women are seldom provided with effective reminders to help them remember to make and keep mammography appointments. In one recent survey in Wisconsin, 60% of women over 40 could recall having received a dental reminder over the last year, and 70% a reminder for a veterinary appointment, but only 9% could recall having received a reminder for a mammogram<sup>43</sup>.

If forgetting is an important mechanism behind much of the failure to make and keep mammography appointments, then might simple reminding improve the use of screening? More than a hundred studies have shown that postal and telephone reminders enhance the likelihood of attendance at mammography exams<sup>44-56</sup>. Indeed, aggressive use of all types of reminders is common in dentistry, where the rate of no-shows is typically less than 10%<sup>57-61</sup>. Reminders are an unglamorous, neglected, expensive, time-consuming, and tedious aspect of cancer screening, and are frequently ineffective. Most screening centers make their calls during the day, while many women are not home until the evening, especially women who are employed. At the MGH Avon Comprehensive Breast Cancer Center, reminder messages are not made on Sundays and the rate of no-shows is twice as high on Mondays as on other days of the

week (L. Santos, personal communication). Screening centers also seldom have individuals who can deliver messages in Spanish or Chinese. At the MGH, two clerks spend 3 to 6 hours each day making reminder calls, and yet there remains a 10-30% no-show rate. There is no special system for identifying women who have missed appointments, or women who have not made appointments, so that they can be reminded to make appointments.

However, there is an effective and economical solution to the problem of reminders: computer telephony. The technology of computer telephony has become remarkably sophisticated in the last few years, with the development of powerful new computer languages (such as SALT and VXML), voice recognition tools, and text-to-speech synthesizers. The standard in the industry is Amtrak's talking computer, "Julie" (800-872-7245); interested readers are encouraged to call it to get some idea of the remarkable ease and power of current technology. Computer generated reminders have been found to greatly increase immunization compliance<sup>62</sup>, and have also been widely used in general medical practices<sup>63-66</sup>.

US Census data have revealed that 98% of US families, and 95% of US families below the poverty level, have telephones. Telephone reminders have repeatedly been found to be more effective than mailed reminders<sup>44-56</sup>. While the general perception of computer-generated messages is negative, mostly due to their association with tawdry telemarketing schemes, when used in a medical context, patients like such communications<sup>67</sup>, not the least because they can ask the same question repeatedly without the possibility of embarrassment.

Key to successful computer speech is the use of the optimal text, voice, personality, accent, emotion, and other features. The leader in the analysis of computer voice, and our collaborator on this work, is Dr. Clifford Nass of Stanford University. Dr Nass has spent the past decade systematically charactering these components of computer speech<sup>68,69</sup>, and he will be working with us to identify, and test, the optimal reminder messages for screening mammography.

Despite this potential of computer telephony to reduce delay in appearance at screening, there had yet to be a system designed for the specific requirements of mammographic screening centers. For this reason, we have developed just such a system, as we will outline in the Preliminary Studies section below.

#### Screening use, race, ethnicity, language, and socioeconomic status

It has long been appreciated that minority women, as indicated by race, language, ethnicity, or socioeconomic status, have lower levels of cancer screening<sup>70</sup>. Among such women, breast cancers have also been found to present at more advanced stages, with higher levels of cancer death<sup>71-77</sup>. Thus, the potential to reduce cancer death by increasing screening use remains even greater for underserved women than for the population as a whole<sup>78-82</sup>.

Our studies of the women who utilize screening at the MGH revealed that underutilization of mammographic screening also occurs among traditionally underserved groups of women, as defined by race, ethnicity, language, insurance status, and socioeconomic status<sup>16,20</sup>. For example, we found a direct relationship between income and screening use. Thus, only 8% of the women with a residence in Chelsea, a community with a median family income \$30,161 utilized five screening mammograms over the five year period examined, while 23% of the women with a residence in Arlington, a community with a median family income \$63,621, achieved this level of screening use<sup>15</sup>. Low levels of screening use was also found among women who did not have health insurance, or who did not have a primary care physician, or who did not speak English. We also found lower rates of return for women from traditionally-underserved lower-socio-economic, racial and ethnic groups, women without insurance, and women who did not speak English, as well as women below age 50, women over age 65, women attending their first mammogram, and women who had not previously returned promptly for screening<sup>15,20</sup>. However, none of the sub-populations of women sorted by age, race, ethnicity, zip code, income, previous screening use, language, insurance status, or medical history were found to utilize prompt annual screening over extended periods of time<sup>15,20</sup>. Thus the problem of underutilization of

breast cancer screening occurs throughout our population, although it is more extreme among traditionally underserved women.

Women of lower socioeconomic status are more likely to be working during the day, and thus less likely to home when the reminder calls are made by clerks in screening centers. They are also more likely to speak a foreign language, and thus are less likely to be helped by reminders in English. These barriers mean that traditionally underserved women are less likely to get appropriate reminders. Indeed, one of the goals of the reminder system we have created it is to be able to deliver reminders to women in the language that they prefer, and at the time that they prefer. The demonstration project we outline here provides a way to test whether this system will help to improve screening use among traditionally underserved women.

# If the US can't have a national cancer screening program, perhaps it can have a national cancer screening reminder program

While organized breast cancer screening is the norm in the UK, Europe, Australia, Canada, and other parts of the developed world, there is no centralized system for screening in the USA, and this greatly degrades our capacity to reduce breast cancer death through the optimal use of screening. However, if the US can't have a national cancer screening program, perhaps it can have a national cancer screening reminder program<sup>83</sup>. Perhaps a national reminder system, based around a system of the type we propose to test here, would provide a way to gain the advantages of a national screening program, that is, a centralized source from which one could track patients, assess screening performance, measure population-wide screening use, and send invitations to screening. The system we propose to test here offers a way to learn whether such a centralized reminder system might be possible.

#### **C. Preliminary Studies.**

Research on the health impact of various breast cancer screening intervals.

For the past decade, we have been interested in the question of how mammography can be scheduled so as to achieve its maximal life-sparing potential.<sup>1-21</sup> When we began this work, there was no obvious way to determine whether it was better to carry out screening on an annual basis, as is recommended in the United States, or every three years, as is the practice in the United Kingdom, or indeed at some other screening interval<sup>11</sup>. To answer this question, we developed a computer simulation model of the growth, spread, and detection of breast cancer, which could derive estimates of the likely breast cancer survival rates that would be expected from various patterns of screening use<sup>4,8,9</sup>. We further collected data on the impact of screening on the sizes at which cancers come to medical attention<sup>1,3,5,6,7,9,15,16</sup>, and the likely survival outcomes of these cancers, which could test the results of the To make our simulation model as realistic as possible, we developed new simulation analysis<sup>5,6</sup>. mathematical methods<sup>13</sup> and collected patient data<sup>1-21</sup>, which could measure the distribution of the sizes at which cancer becomes detectable by screening mammography<sup>3</sup>, the sizes at which these cancers come to medical attention in the absence of screening<sup>1,3</sup>, the rate of tumor growth<sup>2</sup>, and the relationship between tumor size and breast cancer lethality<sup>5,6</sup>. These studies revealed that prompt annual screening should be expected to yield a considerably greater reduction in breast cancer death than screening with longer intervals (FIGURES 1 and 2, TABLE). Indeed, the results of these studies suggested that women who attend screening every other year who are found to have breast carcinoma can expect to have approximately a 50% greater risk of death than the women who attend promptly once a year. On a lifetime basis, women who follow the national recommendation of prompt annual screening from age 40 can expect to achieve a 66% reduction in their risk of breast carcinoma death (in comparison to women who do not use screening) while women who follow the UK recommendation of screening every three years from age 50 to age 70 can expect to achieve only a 12% reduction in the risk of death (TABLE). The simulation results also suggest that women who follow the recommendation of prompt annual screening from age 40 can expect to achieve almost a 90% chance of breast carcinoma survival, which represents and enormous reduction in the current level of lethality of this disease.

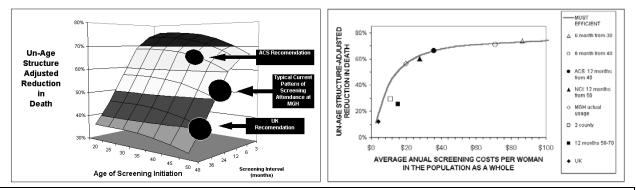


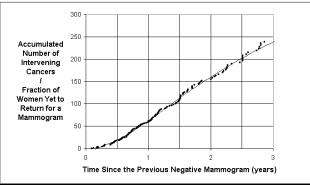
FIGURE 1 Three-Dimensional display of the effect of various screening interval, begun at various ages, on the expected un-age adjusted population-wide reductions in breast cancer death, as determined by computer simulation analysis<sup>9</sup>.

Curve of the reduction in breast cancer death versus the annual screening costs, for the *efficient* possible screening strategies calculated by the equimarginal method, as well as a number of other screening strategies either currently in use or under consideration.<sup>9</sup>

								Reduction	Survivors	Average	Program Screening Costs
		SCREENING INTERVAL (MONTHS)						in Br Ca		Screening Costs	(screening dollars
								death		(in dollars	per woman per year
								(un-age-		per cancer free	averaged over the
	age	age age age age age age age		structure-		years of life saved)	whole USA population				
	20	30	40	50	60	70	80	adjusted)		(USA population)	of women over age 20)
UK	none	none	none	36	36	none	none	12%	68.9%	\$1,353	\$4
MGH-actual	none	none	none	17	17	17	17	56%	84.6%	\$1,707	\$14
ACS	none	none	12	12	12	12	12	66%	88.1%	\$2,978	\$30
12 months 40-70	none	none	12	12	12	12	none	33%	76.4%	\$3,489	\$24
NCI	none	none	none	12	12	12	12	60%	85.9%	\$2,225	\$19
12 months 50-70	none	none	none	12	12	none	none	25%	73.7%	\$2,473	\$13
2 COUNTY	none	none	24	33	33	33	none	29%	75.0%	\$1,916	\$11
6 month from 40	none	none	6	6	6	6	6	71%	89.8%	\$5,415	\$59
6 month from 30	none	6	6	6	6	6	6	74%	90.7%	\$8,948	\$82

**<u>TABLE</u>** The effect of various life-long screening strategies, as determined by computer simulation analysis.<sup>9</sup>

The conclusion of the simulation analysis, that annual screening examinations provide a considerably greater reduction in the risk of breast cancer death than longer screening intervals, was supported by other studies that we carried out on the time course of the appearance of larger, palpable invasive breast cancer among women who had screening mammograms at the MGH. We found that the occurrence of these tumors is relatively rare in the 12 month after a negative mammogram, but from that point in time onwards they appear at a regular rate (FIGURE 3). Indeed, we have found that almost all of the larger palpable cancers seen among women who had used screening at the MGH occur in women who have not returned promptly for annual examinations, and that this greatly increased the sizes at which cancers in the population as a whole came to medical attention<sup>1,2,6</sup>



#### FIGURE 3

Accumulation of the non-mammographically detected cancers found in women with a previous negative mammogram. By dividing the number of these tumors by the fraction of women yet to be screened, the rate of appearance of these tumors was visualized. Note that for approximately the first 9 months after the negative mammogram, the rate of accumulation appears to be reduced, but that after this point in time these tumors appear at a regular rate<sup>2</sup>.

Research on the actual utilization of breast cancer screening.

Our studies, outlined above, on the likely health consequences of various screening intervals, suggest the evident superiority of prompt annual screening. We next examined the question of how frequently women actually utilize screening. To answer this question, we analyzed the pattern of screening use and its consequences at the MGH Avon Comprehensive Breast Center. From these studies, we found that:

- **Prompt attendance at mammographic screening is uncommon**<sup>1,7,11,15,19-21.</sup> While most women begin screening close to age 40 as recommended<sup>20</sup> (60% of the women at the MGH attend their first mammogram by their 41<sup>st</sup> birthday, 90% by age 50), prompt return after that is rare<sup>7</sup>. For example, only 6% of the women with a mammogram in 1992 utilized all 10 mammograms possible over the next ten years, while the mean number of mammograms utilized was 5.06 (51% of the national recommendation). Similar values have been found in other populations of women<sup>84,85</sup>.
- Screening use is especially low among traditionally underserved Asian, Hispanic, and African-American women, as well as among women of low income, women without insurance, women who do not have a primary care physician, and women who do not speak English<sup>15,20</sup>.
- While some groups do better than others, none of the sub-populations of women sorted by age, race, ethnicity, income, previous screening use, language, insurance status, or medical history reliably attend annual screening exams over extended periods of time<sup>15</sup>.

Our research has also revealed that this *failure to use screening to its fullest extent has a number of decidedly negative impacts*:

- *First,* our research by computer simulation analysis has indicated that *the current low level of screening utilization should result in a 50% increase in breast cancer death*<sup>5,6,7,8,9-12,15</sup>.
- Second, our research has indicated that underserved women are likely to bear a disproportionate lethal burden due to their low level of screening<sup>15,20</sup>. Thus, while our simulation studies indicate that the current low level of screening utilization should result in a 50% increase in breast cancer death in the populations as a whole<sup>5,6,7,8,9-12,15</sup>, the degree of underutilization found for women who are Hispanic, or who do not speak English, or who do not have health insurance, or women from the poorest communities served by the MGH can be expected to result in ~ 100% increase in breast cancer death<sup>15</sup>. In simple terms, had the women in the MGH population attended screening promptly, they would have lowered their chance of dying of breast cancer by a third. Attendance at screening once every five years or less was the practice for about 1-in-5 of the women in the MGH population as a whole, and about 1-in-3 women from the poorest communities served by the MGH, and the simulation results suggest the these women can expect a much higher breast cancer death rate of 25%<sup>15</sup>. Had these underserved women been able to attend screening promptly, they would have cut their chance of dying of breast cancer in half.
- Third, we have found that the cancers in a considerable number of women became evident as larger, and thus more dangerous, palpable masses because they had not had a screening mammogram within the previous year. We also found that while the appearance of larger palpable tumors is reduced in the year after a negative mammogram, they begin to accumulate at a regular rate from about one year onward<sup>2</sup> (FIGURE 3). These non-mammographically detected cancers were larger and, thus, potentially more lethal, than the screen detected cancers, and most of these cancers would probably have been detected at screening had return been more prompt<sup>2,6</sup>.
- *Fourth*, our research has shown that *underutilization of screening results in a population-wide increase in the size, and thus lethality, at which invasive breast cancers come to medical attention*<sup>1,3,5,6,7,12,15,19</sup>. Similar findings have been reported by Mandelson et al<sup>86</sup>, and by Hunt et al<sup>87</sup>.
- *Fifth,* our research has found that *failure to attend screening promptly results in a paradoxical increase in the incidence of false positive mammograms.* False positive mammograms present a problem of long standing concern<sup>88-91</sup>. We have found that women who attend screening regularly actually have a lower rate of such negative events over the long-term than women who attend intermittently<sup>21</sup>. Apparently intermittent screening deprives the radiologist of recent mammograms, which can rule out the necessity of a biopsy<sup>21,92</sup>.

#### Our integrated reminder system for breast cancer screening

Our research, as outlined above, makes clear that prompt return to annual screening examinations is important for achieving the maximal life-sparing potential of screening mammography, but that very few women actually follow such a pattern of screening use. Furthermore, there are a variety of reasons to believe that much of this failure to use screening at its maximal effective level can be ascribed to the absence of effective reminders. While computer telephony offers the potential for providing such reminders, there have been no computer telephony reminder systems designed specifically for mammography practices. For this reason, we developed just such a reminder system, which provides computer-generated telephone reminder messages for women to make, and then attend, mammography screening appointments. The system is built around a SQL Server database, and uses ASP and ASP.net forms, which can be used by screening centers to enter requests for reminders to be sent to their patients. The system is on a server outside of an individual hospital, and thus can be accessed through the web from anywhere. This makes it possible to follow a woman wherever she seeks medical care. It is fully secure and HIPAA compliant. As the system uses web-forms, accessible from common browsers, it requires no special software to be installed on the screening center's computers. Furthermore, as the computer-generated telephone reminder messages originate from our server, no special telephony equipment or dedicated telephone lines are required by the screening center. All that is needed is access to the Internet.

A clerk at any screening center that has been given a password can log on to the system through a conventional log-on form.

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NO	Today - View appointments booked today at Test Hospital 3.	
{ \	Appointments By Patient - View all mammogram appointments for a specified patient at Test Hospital 3.	
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511	Make a test phone call - Test the automated telephony part of the system.	
	Reminder Script - View a webbased version of the reminder phone call and make suggestions.	
NG	Change Parrword - Change the parrword you use to log in and out of the system.	
200	Logost - Log out of the system	

The most commonly used function is the calendar form, which gives the clerk a tool for entering upcoming appointments as they are made. Indeed, the calendar system itself provides a convenient service to the screening center, which we have created to provide an extra motivation for use of the system. When scheduling an appointment, the clerk needs only to click on the day of the month:

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The calendar displays which times are free, and the clerk can the click on the desired time of the day. (The calendar is configurable to the specific hours and scheduling units of each practice).

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In the next step the clerk assigns the patient to that free time slot. If the patient is already in the system, a single click by the clerk retrieves the patient's relevant data: all that is required is the patient's social security number or first/last name.

Mammography Reminder System - Appointment details - Microsoft Internet Explorer	<u>~</u> 🖄
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	A
Friday, May 27, 2005 11:00:00 AM	
Identify patient by Social Security Number	
If the patient is not a new patient, please enter their social security number to retrieve the rest of their personal information.	
Social Security Number: 123456789	
Get Patient Information via Social Security Number Location: Test Hospital 3. Room 2	
Identify patient by last name Scheduled on: Scheduled by:	
If you do not know the social security number, enter the patient's last name Call Completed: and first inclui.	
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Last Name: Get Patient Information via Last Name	
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Return to the Calendar Return to the Main System Page	
	Thursday, May 05, 2005
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If the patient is not in the system, a web-form provides a convenient way to add the data. Note that the form allows the opportunity for the clerk to enter the language that the patient wishes to receive the message in, and the time of day desired. The patient may also opt out of the message, if desired.

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1	Friday, May 27, 3	2005 11:00:00 AM	1
	Update a Patient's Information		
	Peticent Name: Liss Simpson SN: 12345799 Birthday: September w 16 w 1902 Telephone Number(6177241364 Atternate Phone(6177241364 c-Hait; Simpson@spingfeld clus Language: Portuguese Primary Care Physician: Westbeimer, Ruth w Submit, Reset	Lecation: Test Hospial 3, Boom 3 Scheduled on: 352/2005 8:56:33 PH Scheduled by: guest Cell Requested: Cell Completed: Cell Status: Never Called	
<b>A</b>	Return to t	Day View he calendar ain System Page	
			D Internet

The system has been designed to send the telephone message in a language chosen by the patient, and at the time she wishes. The script has now been recorded in English; we are presently in the process of recording the script in other languages: Spanish, Haitian Creole, Chinese (Mandarin and Cantonese), Portuguese, Laotian, French, and Vietnamese. (Additional languages will be added as requested by the patients).

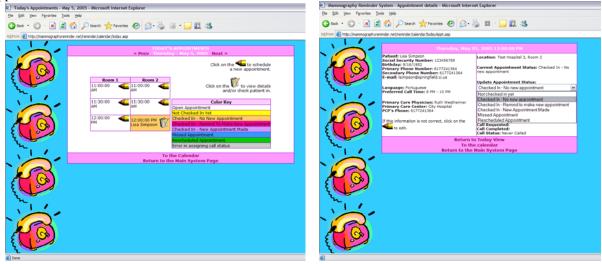
A few days before each patient's appointment, the system sends the telephone reminder. (See below for a script; a trial version of our computer telephone reminder can be heard at 866-514-0393.) To ensure confidentiality the telephone message requires the patient to enter her day and month of birth.

# <u>Script For Computer-Generated Telephone Reminder Message</u> (MGH Avon Comprehensive Breast Center)

The Massachusetts General Hospital is calling with a medical appointment reminder for Ms [first name] [last name]. If this is your name, please press "1" now. Otherwise, press "2". Nothing pressed - wait 3 seconds: This is an automated message from the Massachusetts General Hospital calling with a medical appointment reminder for Ms. [first name] [last name]. To confirm the time and day of your upcoming appointment, you may call 617-726-0985 from 9 AM to 5 PM. Thank you. Goodbye. 2 (or other key) pressed: This is a private medical appointment reminder. Please tell Ms. [first name] [last name] that the Massachusetts General Hospital called. If Ms. [first name] [last name] wishes to confirm the date and time of her upcoming appointment, she may call 617-726-0985 from 9 AM to 5 PM. To repeat this telephone number, please press "1" now. If 1 is pressed: [Repeat italicized part of paragraph above] If any other key is pressed or 3 seconds passes: Goodbye. [hang-up] 1 pressed: I am calling to provide you with a medical appointment reminder. To insure your confidentiality, so that only you may receive this reminder, please enter the month and day of your birthday, in numbers, followed by the pound sign. For example, if your birthday is February 14th, please press zero two one four followed by the pound key. Incorrect birthday (first time): I'm sorry, but that's not correct. [Repeat italicized part of paragraph above]. Incorrect birthday (second time): This is a private medical appointment reminder. Please tell Ms. [first name] [last name] that the Massachusetts General Hospital called. If Ms. [first name] [last name] wishes to confirm the date and time of her upcoming appointment, she may call 617-726-0985 from 9 AM to 5 PM. To repeat this telephone number, please press "1" now. If 1 is pressed: [Repeat italicized part of paragraph above] If any other key is pressed or 3 seconds passes: Goodbye. [hangup] **Correct birthday entered:** Thank you. Please remember that you have an appointment for your annual mammogram on [day of week] [month] [day] at [hour] [minute] [AM/PM]. If you have any questions, feel free to call the center at 617-726-0985 between 9 AM and 5 PM. If you'd like to receive another telephone reminder the day before the appointment, please press 1 now, otherwise, press 2. {If 1, any key other than 2, or nothing is pressed, set "repeat reminder" to true. If 2 is pressed, set "repeat reminder" to false. Then continue.} To hear the date and time of your appointment again, please press 1. If you need directions to the center or instructions as to how to prepare for the mammogram, please press 3 now. To hear this message again, please press 4. To conclude and hang up, please press 5. 1 pressed: [Repeat italicized part of paragraph above (minus "another reminder" part).] **3 pressed:** The MGH Breast Imaging Division is located on the Second Floor of the Wang Building at the Massachusetts General Hospital, Blossom Street, Boston, Massachusetts. Please arrive 10 minutes early to the Avon Center and do not apply any deodorants, lotions, or powders to your skin that day. [Repeat "menu" section of the previous paragraph (starts "To hear ...")] 4 pressed: [Repeat the "menu" section of the previous paragraph (second italicized part that starts "To hear the date and time of your appointment...")] 5, other, or no key pressed: Goodbye. [hangup]

Each day, the receptionist at the screening center can go to a "TODAY CALENDAR". As each patient comes in for screening, the "TODAY CALENDAR" web-form can be used to indicate whether the patient wishes to receive future messages, whether future messages can be left on an answering machine, as well as whether she wishes to modify information on the language and best time for future messages. Should the patient wish to schedule next year's exam, a simple click opens another web-form that can be used to schedule that appointment and to initiate the reminder for the next year's screening visit. If the patient chooses not to schedule an appointment for next year's screening examinations, the system will send another computer generated telephone reminder message ~6 months later with a script

that encourages the patients to make the appointment. The "TODAY CALENDAR" web-form also provides a place where the clerk can indicate which patients have not shown up for their scheduled exams, and the patients will be called by another computer generated reminder message informing them of their missed appointments, and encouraging them to call the screening center to reschedule their appointments.



Data on the outcome of telephone calls made by the system the previous day to each patient will be available to the clerk at the screening center (that web-form is now under construction). Information to be made available includes whether the call was answered, and if so, whether it was answered by the woman or by someone else. If the message was left on the women's answering machine, that information is also provided. The form will show whether multiple attempts were made to place the call, whether the line was busy or unanswered, and the times of each attempt.

# II. Communication/Tracking tools for women with breast symptoms and for women initiating screening:

The second part of our system provides web-forms for primary care physicians to enter requests for women to schedule their first screening exams, as well as to track patients with breast symptoms. The forms for this system are shown on the next page. The primary goal for this component of the system is to provide web-based tools, which will minimize delay in the treatment of breast cancer. A second goal is to provide a simple tool that primary care physicians can use to make referrals for women who are initiating screening.

The system has been designed to help the primary care physician keep track of patients who have had breast symptoms. Barton et al<sup>93</sup> in their analysis of a US HMO found that 23% of women over age 40 will present with a breast complaint over a 10-year period, while studies in the UK have found that the average GP will see 15 to 35 patients with breast symptoms each year<sup>94,95,96</sup>. Tracking these patients presents a formidable challenge to medical professionals, especially in the current fragmented nature of the US medical care system, where patients may move from physician to physician, with the possibility of loss of exchange of information. One of the indications of the frequency of such delay is that delay in the treatment of breast cancer is the most frequently filed, and second most expensive (after neurologically impaired newborns) malpractice category<sup>97,98</sup>. Surveys of health practice have also found that there are a significant number of women for whom there is a considerable degree of delay from the time of first symptoms and the time of treatment<sup>99</sup>: from the time from the first symptom until the time of presentation to the physician ("patient delay")<sup>100-102</sup>; from the time from the first presentation to appearance at the hospital ("GP delay"); and from the time of entry into the medical system until the time of treatment ("hospital delay")<sup>101-105</sup>. Delay has been ascribed to practical, administrative and economic

considerations, as well as to the failure of the patients to act in a timely fashion to utilize the resources made available to them<sup>100,104,106,107</sup>. Much of this delay appears to result not from diagnostic error on the part of the physician, or of procrastination on the part of the patient, but rather from a system that is failing both the physician and the patient by not providing adequate communication and tracking. Indeed, while the features of the cases that have been extracted by the Physicians Insurers Association of America study<sup>97</sup> are complex and heterogeneous, the overriding impression is of patients who have simply "fallen though the cracks".

The system we have created is designed to make it possible for multiple physicians to track, and share data, on individual patients, regardless of where they go for treatment. We have designed the system to be available over the web to any physician's office. As the system uses web-forms, accessible from common browsers, it requires no special software to be installed on the physician's computers. All that is necessary is access to the Internet.

The physician, or an assistant to the physician, can log on to the system through a conventional log-on form. Once logged on, the system redirects to a form on which it is possible for the primary care physician to either check on the status of the physician's patients, or to enter data on a new patient.

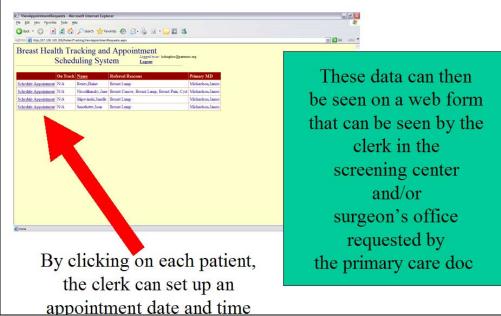
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Breast Health Tracking and Appointment Scheduling System	Î
Veccome Dr. James Michaelson Organier zeginer die Name halte vergeband für redning Orek der name dijver polent. Sahere	
Stre	e Internet

A patient data entry form allows the physician to request an appointment for a first screening mammogram for an asymptomatic woman, or a surgical visit or imaging visit for diagnostic imaging for a woman with a symptom. The form can also be used to simply register a patient with a breast symptom, so that her progress can be tracked.

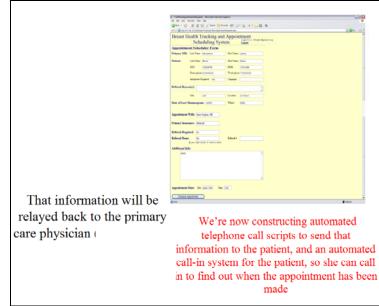
A Primary Care Physician or Screening Center Can use Our System to Conveniently Request an Appointment for a First Screening Mammogram for Asymptomatic Women, or a Surgical Visit or Imaging Visit or to Simply Register a Patient with a Breast Symptom	If the Physician Requested a Mammogram or Referral to a Surgeon, the Web Forms Transmits all the Necessary Information
E) Patient Tracking System - Hiscourt Explorer	0
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Patient Entry Form	10 (vini 00 vini <u>n</u>
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Would you like to request an appointment for a surgical exam? O'Yes O'No	
Would you like to request an appointment for a breast imaging? O'Yo O'No	
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Web-forms for receiving information on referral requests are available to any screening center, breast center, or surgeon's office. Again, the system uses web-forms, accessible from common browsers. Thus, no special software needs to be installed on the computers of the screening center, breast center, or surgeon's office.

The clerk at the screening center, breast center, or surgeon's office only needs to log on and the system redirects to a web-form, which displays whether there are any requests for referrals.



Once the appointment is scheduled, the web-form shown below has a place where the clerk can enter data on the day, time, and place of the appointment. Once entered, that information is relayed back to the primary care physician (by email), and it will also appear on the web-form that the primary care physician uses to track all of the patients with a breast symptom (form shown on next page). If the screening center, breast center, or surgeon's office requests it, a computer-generated telephone call will also be send to the patient informing her that the appointment has been scheduled, and an automated callin system for the patient is under construction, so she can call in to find out when the appointment has been made.



Once the visit to the screening center, breast center, or surgeon's office is completed, the results of the visit are reported back to the primary care physician and other medical professionals involved in the patient's care through an additional set of web-forms. Sending such communications by paper and email is, of course, normal practice, and it is simple for the secretary preparing these letters to also paste them into our web-form.

Thus, the system provides a useful tool by which the primary the care physician, and indeed all health professionals caring for patients, can track the patient's status. Because the server is outside any individual hospital, and available to all healthcare professional, communication is ensured no matter where the patient travels to for her care.

All of the information collected by the system resides in the database. By referring to the single form summarizing all data on all of the patients in a primary care practice, the physician can see whether the patients are on track, as judged by the standard of the RMF algorithm. When a patient falls behind, all medical personnel involved in treatment of this patient will be sent an email. The goal here is to provide all concerned with a simple Web-tool that makes it easy to track patients, so as to prevent delay in the treatment of breast cancer.

Physician Can See Whether the Patient is on Track by the RMF Algorithm d Appointment Logged in at: im-michaelson@earthink.net Home Logget								
Back								
	On Track	<u>Name</u>	Initial Symptoms	Appointment Requested	Appointment Date	Initial Entry Date		
<u>Details</u>		3	Breast Pain	Yes	L	5/1/2005 9:06:28 AM		
<u>Details</u>	! Please Follow Up	Benes,Elaine	Nipple Discharge	Yes		4/13/2005 6:01:11 PM		
<u>Details</u>	OK	Flabogian, jenell	Palpable Mass,	Yes	4/17/2005 4:46:00 PM	4/5/2005 10:55:50 PM		
<u>Details</u>	OK	Framingotette,Ellen	Nipple Discharge, Breast Pain, Palpable Mass	No	1	4/8/2005 10:33:14 PM		
<u>Details</u>	OK	Namonica,Nelli	Breast Pain,	Yes	4/17/2005 4:44:00 PM	4/5/2005 10:57:27 PM		
<u>Details</u>	! Please Follow Up	Nicodiliansky, Jane	Abnormal Mammogram	Yes	[	4/13/2005 10:14:50 PM		
<u>Details</u>	OK	Schmellino, jeanette	None, Abnormal Mammogram	Yes	5/1/2005 12:00:00 PM	4/8/2005 10:31:26 PM		
<u>Details</u>	OK	Slabojionizzmalid, Grileeeiani	Nipple Discharge,	Yes	OK	4/5/2005 11:02:35 PM		
<u>Details</u>	OK	Sliboviztian, jENNEL	Breast Pain	Yes	4/27/2005 2:00:00 PM	4/13/2005 6:19:52 PM		
<u>Details</u>	OK	Slipovinski, Janelle	Nipple Discharge	Yes	0	4/16/2005 2:17:09 PM		
<u>Details</u>	OK	Smithdfrejs,Jame	Abnormal Mammogram	Yes	1	4/11/2005 10:11:55 AM		
Details	OK	Trugbar,Saleem		Yes	0	4/9/2005 1:51:16 PM		
	OK	Zilgin,Lori	Abnormal Mammogram.	Yes	4/17/2005 4:48:00 PM	4/5/2005 10:53:07 PM		

## **D.** Research Design and Methods.

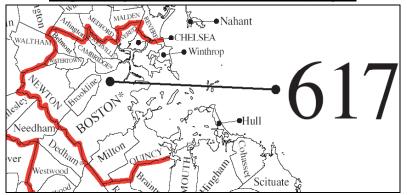
#### Features of the population to be served.

We propose to carry out the demonstration project of this reminder system in the greater Boston Area, as defined by women served by mammography screening centers in the 617 area code, and then to adapt the system for use in Massachusetts as a whole. The features of the population of the greater Boston (617 area code) region, by city, can be seen in the TABLE and map below. This area contains approximately 1 million people and approximately 220,000 women who are of age 40 and older are thus eligible for screening mammography. Approximately 30,000 of the women in this region (~14%) receive their screening at the Massachusetts General Hospital, where a detailed record of screening use since 1985 is available<sup>7,15,20</sup>. Furthermore, for this population of patients, the features of screening use<sup>7,20</sup>, the occurrence of false positives<sup>21</sup>, and the nature of the cancer detected among women who use screening<sup>2,3,6,7,16</sup>, has been exhaustively studied by our group, and this provides a wealth of detail against which the outcome of screening after the introduction of the reminder system can be compared. The region contains 12 cities and is culturally, ethnically, economically, and linguistically diverse<sup>15,20</sup>.

While the reminder system will be offered to screening centers in the greater Boston (617 area code) region, the reminder messages will be sent to all women who utilize screening at these screening centers, regardless of the woman's location or area code. Thus, the patient population and the geographical population will be largely overlapping but not identical.

	(or area coucy region	
City	Population	% of Massachusetts Population
Boston	589,141	9.3%
Winthrop	18,303	0.3%
Chelsea	34,106	0.5%
Brookline	57,107	0.9%
Newton	84,323	1.3%
Milton	26,062	0.4%
Quincy	89,059	1.4%
Somerville	76,296	1.2%
Everett	37,540	0.6%
Belmont	24,194	0.4%
Watertown	32,915	0.5%
Cambridge	101,587	1.6%
TOTAL POPULATION	1,106,267	18.4%
Estimated number of woman age 40+	221,253	
Estimated number of calls/year (2 per woman)	442,506	
Estimated Cost/year (2 calls per, at \$0.05/call)	\$22,125	

#### Map of the greater Boston (617 area code) region



Mammography facilities in the greater Boston (617 area code) region					
Facility	Phone Number	City	Zip Code	Phone Number	Harvard Affiliation
BETH ISRAEL DEACONESS MEDICAL CENTER	330 BROOKLINE AVENUE	BOSTON	02215	617-667-7160	Yes
BOSTON'S MAMMOGRAPHY VAN	44 BINNEY STREET	BOSTON	02115	617-632-1974	Yes
BRIGHAM & WOMEN'S AMBULATORY	850 BOYLSTON STREET/ST 60	CHESTNUT HILL	02467	617-732-9801	Yes
BRIGHAM & WOMEN'S HOSPITAL	75 FRANCIS STREET	BOSTON	02115	617-732-8525	Yes
CAMBRIDGE HEALTH ALLIANCE	1493 CAMBRIDGE STREET	CAMBRIDGE	02139	617-665-1312	Yes
DANA FARBER CANCER INSTITUTE	44 BINNEY STREET	BOSTON	02115	617-632-3215	Yes
FAULKNER HOSPITAL-SAGOFF CENTER	1153 CENTRE STREET	BOSTON	02130	617-983-7090	Yes
HARVARD MEDICAL FACULTY, PHYSICIANS D.B.A. BETH ISRAEL RADIOLOGY	25 BOYLSTON STREET, STL	CHESTNUT HILL	02467	617-754-0300	Yes
HARVARD MEDICAL PHYSICIANS GROUP DBA B.I. RADIOLOGY	1101 BEACON STREET, 3 WEST	BROOKLINE	02146	617-731-5250	Yes
HARVARD UNIVERSITY HEALTH SERVICES	75 MOUNT AUBURN ST.,	CAMBRIDGE	02138	617-496-0699	Yes
HARVARD VANGUARD MEDICAL ASSOCIATES	291 INDEPENDENCE DRIVE	WEST ROXBURY	02467	617-541-6395	Yes
HARVARD VANGUARD MEDICAL ASSOCIATES	40 HOLLAND STREET	SOMERVILLE	02144	617-629-6110	Yes
HARVARD VANGUARD MEDICAL ASSOCIATES -KENMORE CENTER	133 BROOKLINE AVENUE	BOSTON	02215	617-421-8990	Yes
HARVARD VANGUARD MEDICAL ASSOCIATES -QUINCY	1250 HANCOCK STREET	QUINCY	02169	617-774-0710	Yes
MGH AVON COMPREHENSIVE BREAST CENTER	15 PARKMAN STREET, ST240	BOSTON	02114	617-726-5005	Yes
MT. AUBURN HOSPITAL	330 MT. AUBURN STREET	CAMBRIDGE	02138	617-499-5070	Yes
NEWTON-WELLESLEY HOSPITAL	2014 WASHINGTON STREET	NEWTON	02162	617-243-6065	
1180 BEACON IMAGING, LLC	1180 BEACON STREET	BROOKLINE	02446	617-232-1486	No
BIOCARE DIAGNOSTICS	300 CONGRESS STREET	QUINCY	02169	617-770-9300	No
BOSTON IMAGING ASSOCIATES	ONE BROOKLINE PL, ST105	BROOKLINE	02146	617-754-6500	No
BOSTON MEDICAL CENTER DOCTOR'S OFFICE BUILDING	720 HARRISON AV, ST703	BOSTON	02118	617-638-8139	No
BOSTON MEDICAL CENTER.	850 HARRISON AV	BOSTON	02118	617-414-4854	No
CODMAN SQUARE HEALTH CENTER	637 WASHINGTON STREET	DORCHESTER	02124	617-825-9660	No
DORCHESTER HOUSE MULTI-SERVICE CENTER	1353 DORCHESTER AVENUE	DORCHESTER	02122	617-288-3230	No
EAST BOSTON NEIGHBORHOOD HEALTH CENTER	10 GOVE STREET	EAST BOSTON	02128	617-569-5800	No
LEMUEL SHATTUCK HOSPITAL	170 MORTON STREET	JAMAICA PLAIN	02130	617-971-3366	No
MEDICAL CARE CENTER NORTH	1000 BROADWAY	CHELSEA	02150	617-660-6302	No
MILTON HOSPITAL	92 HIGHLAND STREET	MILTON	02186	617-696-4600	No
MIT HEALTH SERVICE CENTER NEW ENGLAND MEDICAL CENTER HOSPITAL	25 CARLETON STREET	CAMBRIDGE	02139	617-253-4481	No No
DEPT OF RADIOLOGY	750 WASHINGTON ST	BOSTON	02111	617-636-0040	
QUINCY MEDICAL CENTER	114 WHITWELL STREET	QUINCY	02169	617-376-4135	No
SCHATZKI ASSOCIATES, INC.	725 CONCORD AVENUE	CAMBRIDGE	02138	617-876-8630	No
SCHATZKI ASSOCIATES, INC.	521 MOUNT AUBURN STREET	WATERTOWN	02172	617-924-5210	No
SOMERVILLE HOSPITAL RAD DEPT.	230 HIGHLAND AVENUE	SOMERVILLE	02143	617-591-4150	No
SOUTH BOSTON COMMUNITY HEALTH CENTER	409 WEST BROADWAY,	SOUTH BOSTON	02127	617-269-7500	No
SOUTH COVE COMMUNITY HEALTH CENTER	885 WASHINGTON STREET	BOSTON	02111	617-521-6864	No
ST. ELIZABETH'S MEDICAL CENTER OF BOSTON	736 CAMBRIDGE STREET	BOSTON	02135	617-789-2762	No
THE CARNEY HOSPITAL. INC.	2100 DORCHESTER AVENUE	DORCHESTER	02124	617-296-4000	No
UPHAM'S CORNER HEALTH CENTER	415 COLUMBIA ROAD	DORCHESTER	02125	617-287-8000	No
WHIDDEN MEMORIAL HOSPITAL	103 GARLAND STREET	EVERETT	02149	617-389-6270	No
WOMEN'S HEALTH CENTER	96 GARLAND STREET	EVERETT	02149	617-381-7196	No

Specific Aim #1: We propose to adapt our prototype mammography reminder system for use in all screening centers in the greater Boston (617 area code) region.

We propose to test our mammography reminder system by providing reminder messages to all women who attend screening at centers in the Greater Boston (617 area code) region. To accomplish this task, the prototype system outlined above, while now fully functional, will require a number of modifications before it will run efficiently in such a large population.

1.1 Features of the reminder system to be deployed:

The system to be deployed will generally follow the prototype system, as described in the Preliminary Studies section above. Indeed, it will use the web-forms shown in the images in the Preliminary Studies Section above, together with a number of enhancements that are now under development:

- <u>Reminder Messages</u>: The system will send computer generated telephone reminder messages for upcoming scheduled mammography appointments, in the language desired by each woman (see below), and at the time requested by each woman:
  - One reminder will be sent ten days before the scheduled examination.
  - A second reminder will be sent the day before the examination.
- Answering Machines: Should the system make three unsuccessful attempts to deliver a telephone message, the system will leave a non-specific message on the answering machine indicating that the patient has an upcoming medical appointment. This message will contain no specific information on the nature or time of the appointment, but will leave a generic message for the individual that she has an upcoming medical appointment, together with the telephone number of the screening center that the patient can call to receive additional information.
- <u>Email Reminder Messages</u>: The system will also send computer generated email reminder messages for upcoming appointments, for those women who have requested them (see below).
- Messages For Women Who Have Not Yet Made Appointments: For those women who come in for a screening mammogram, but did not then schedule an appointment for the next year's mammogram, the system will send, in six months time, a computer generated telephone reminder message to call the screening center to schedule a mammography appointment. For those screening centers that have chosen to use our web-calendar to schedule all of their appointments, this message will identify a range of appointments, and allow the woman to schedule automatically. The scheduled appointment will then appear on the web-calendar. Appointment-making scripts will be written in a variety of languages.
- <u>Messages Informing Women of Missed Appointments</u>: For those women who have forgotten to attend their appointments, the system will launch a computer generated telephone reminder message informing them that they have forgotten to attend the appointment, and encouraging them to call the screening center to schedule a mammography appointment. For those screening centers that have chosen to use our web-calendar to schedule all of their appointments, this message will identify a range of available appointments times, and allow the woman to schedule automatically. The scheduled appointment will then appear on the web-calendar. Missed-appointment scripts, and accompanying appointment-making scripts, will be written in a variety of languages.
- Additional Web-forms Now Under Development, that will Provide Screening Centers Greater <u>Control of the Reminder Process</u>: In addition to the Web-forms presently in the prototype system (as shown in the images in the Preliminary Studies section above) we are continuing to add additional functionality and new web-forms, which can be used by the screening centers and patients to enter information:
  - <u>Electronic Entry of Appointment Data</u>: As we have described in the Preliminary Results section above, the clerks at the screening centers can enter information on who has scheduled an upcoming appointment by filling out web-forms. We are developing uploading tools, which can be used by screening centers to enter appointment data in bulk, when it is available in electronic form (see below).
  - Options Provided to Women for Customizing Their Reminder Messages: At the time when each woman comes in for her screening appointment, she and the clerk at the screening

center are able to review the language of the reminder and the time of day it is to be sent. Women will also be able to opt out of the reminder process if they desire. Women will also be offered the opportunity to provide email addresses for emailed reminders.

- <u>Check-In Web-Forms:</u> Typically, women check in at the reception desk of the screening center. We will produce a check-in form that screening centers can provide directly to the patient to automate the check-in process. On this form, each woman can carry out all of the update information noted above: she can review the language of the reminder and the time of day it is to be sent, opt out of the reminder process if she wishes, provide an email address for emailed reminders, update telephone numbers, etc.
- <u>Computer Generated Written Reminders that Can Be Sent in Coordination with the</u> <u>Telephone Reminders</u>: The system will produce computer generated written reminder messages for upcoming appointments, which the screening center can download, printout, and mail.
- <u>Web-Forms for Apprising Screening Centers of the Success of the Reminder Messages:</u> We will provide web-forms that the clerks in each screening center can view to see which women were reached by telephone on the previous day.
- Enhancements to the Web-calendars Provided to Each Screening Center: The web-calendar will soon be upgraded to a more versatile form (<u>http://www.quickwebsoft.com/</u>).
- <u>Provision of Web-Forms That Can be Used by Screening Centers to Customize the Range of Reminder Messages They Wish to Send Out:</u> We will make it possible for each screening center to choose the range of reminders they desire to send to their patients. For example, screening centers that prefer only to send reminders for upcoming screening appointments, and not send messages for missed appointments, may do so. Screening centers will also be able to choose the timing of the messages (default: 10 days and 1 day before), whether they require birthday confirmation of patient identity, etc. Each center will be able to provide a text message giving directions to the center, and providing specific preparation instructions. Each center will be able to request a caller ID reflecting the center.
- <u>Primary Care Physician Appointment Mammography Request Forms</u>: This form will be available to primary care physicians and their offices for requesting screening mammograms for patients. For those screening centers that have chosen to use the webcalendar, appointments can be scheduled automatically (screening centers will able to select the range of PCP's from whom they will accept such appointments).
- Telephone Scripts:
  - <u>Script language</u>: The recorded portions of the scripts will be recorded in Spanish, Portuguese, Cantonese, Russian, and Haitian Creole. The choice of these languages is derived from an informal survey of our colleagues, and by a review of the most common languages among the women in the MGH breast cancer tumor registry. We will add to the web-form a place for women to answer the questions "would you have preferred to receive your message in a language not listed here?" and "If so, which language?". From the results of this information, as well as from requests made by the screening centers, we will add additional languages as we proceed.
  - <u>Wrong number scripts</u>: We will record an additional script for "wrong" phone numbers, offering the person who receives such a wrong phone call to indicate whether the identity of the person to whom the message is addressed is known to the recipient of the call, and if so, whether the intended recipient of the reminder has moved, and whether the new phone number is known. The script will allow the recipient to enter the new phone number.

• <u>Script development</u>: The current reminder script was developed as a collaborative effort with Dr Daniel Kopans, Mr Richard Moore, and their colleagues at the MGH. We will continue to work with our collaborators in the refinement of the script.

We will also be working with Dr Clifford Nass of Stanford University on the development of the optimal text, voice, and other aspects of the reminder message. Dr. Nass has spent the past decade systematically charactering these components of computer speech<sup>68,69</sup>, and is acknowledged to be the recognized leader in the field. We will address such questions as: What is the optimal nature of the text (for example: is "hello, I am calling with a medical reminder message from the Massachusetts General Hospital" more effective than "hello, this is the Massachusetts General Hospital calling with a medical reminder message")? Should the voice in the message be male or female, extroverted or introverted, etc? What is the optimal speed for the reminder message? What is the optimal accent? We will assess which of these major and minor variants of the message results in the highest rates of return to screening.

<u>Patient Survey Scripts</u>: A small random sample of the women receiving reminders will get a message at the end of the script saying "this reminder was provided by the Susan G. Komen Breast Cancer Foundation, as a service to the Boston Community; we would be very interested in getting your feedback on the content of this message, so that we could improve upon it, if you have a few minutes to answer a survey". The survey script will collect information on whether the women liked the reminder, and what suggestions they might have for improving it.

#### 1.2 System hardware and software:

While the system is now fully functional, as a prototype, several modifications are needed before it can be used on the scale required to serve the greater Boston (617 area code) region:

#### 1. Server and Database Security

Regulations specifying security requirements for patient data, as mandated by HIPAA, have been published by the Department of Health and Human Services<sup>108</sup>, which must be implemented by April 21 2006. We are currently in the process of implementing these security and auditing features on the server and the database.

#### 2. User Interaction

Use of the system by a screening center requires a password, and utilization will be audited. Issuing of passwords will be carried out by the research assistant whose task will be to liaison with the screening centers.

#### 3. System reliability

Reliability of the system will be insured by the purchasing of a second server, which will be hosted at a separate location. This server will be used to maintain a backup copy of the database, as well as a fully functional backup system. We will also use this server as the tool for making modifications to the system. In the event of equipment failure at the primary server, this secondary server will be able to take over operation of the system.

#### 4. <u>Text-to-speech synthesizer</u>

We are currently using the Lucent Technology text-to-speech synthesizer to pronounce each patient's name, the name of the screening center, and the day and time of the appointment. However, in the last few years there have been remarkable improvements in computer speech synthesis. In our judgment, the best such text-to-speech engine is the ScannSoft RealSpeak Telecom 4.0, which converts text into remarkably realistic human sounding synthesized speech. This engine also generates speech in more than 20 languages, with more than 30 voices in a variety of accents and speaking styles. Initially, we will implement this text-to-speach engine in those parts of the telephone script where it is now required: in the pronunciation of the patient's name, and the time and day of the appointment. However, we will also experiment with using the text-to-speech engine to create completely synthesized messages.

Specific Aim #2: We propose to test the impact of mammography reminder system by making it available to the women who attend screening in the greater Boston (617 area code) region

We propose to introduce the system in phases, so that unanticipated defects can be identified and repaired before the system is fully deployed. Our approach will be to offer the system to screening centers and not to require participation, even with those colleagues with whom we are collaborating; whether the centers decide to use the system, and whether they continue to use it once they have tried it out, will be the first tests of the system's practicality.

#### TIMELINE

The system will be offered:

• 1<sup>st</sup>, to the Mass General Hospital Avon Foundation Comprehensive Breast Center, at the 6-month time point.

Initial deployment at the Massachusetts General Hospital Avon Comprehensive Cancer Center will be carried out as a collaborative effort with Dr Daniel Kopans and Mr. Richard Moore. Indeed, the design of the reminder script we have deployed in our prototype system was constructed in collaboration with these scientists, and the analysis of screening at this institution after the introduction of the reminder system will be a continuation of our ongoing collaborative effort to understand the patterns of screening and its health consequences.

• 2<sup>nd</sup>, to the Brigham and Women's Hospital Screening Center by the 9 month time point.

Deployment at the Brigham and Women's Hospital Screening Center will be carried out as a collaborative effort with Dr Robyn Birdwell, Director of Breast Imaging.

3<sup>rd</sup>, to all Harvard Hospitals, by the 12 month time point.

The reminder system will be offered to these institutions, which are affiliated with Harvard Medical School:

Beth Israel Deaconess Medical Center; Boston's Mammography Van; Cambridge Health Alliance; Dana Farber Cancer Institute; Faulkner Hospital-Sagoff Center; Harvard Medical Faculty, Physicians D.B.A. Beth Israel Radiology; Harvard Medical Physicians Group DBA B.I. Radiology; Harvard University Health Services; Harvard Vanguard Medical Associates; Harvard Vanguard Medical Associates; Harvard Vanguard Medical Associates-Kenmore Center; Harvard Vanguard Medical Associates-Quincy; Mt. Auburn Hospital; Newton-Wellesley Hospital

Deployment at the Screening Centers of the other Harvard Affiliate Hospitals will be carried out as a collaborative effort with Dr Janet Baum, Director of Breast Imaging, Beth Israel Deaconess Medical Center, Dr. Alan Semine, Director of Breast Imaging, Newton Wellesley Hospital, and David S. Rosenthal, M.D, Director and CEO of Harvard University Health Services (HUHS) and Medical Director of Dana-Farber Cancer Institute Leonard P. Zakim Center for Integrated Therapies.

• 4<sup>th</sup>, to all Boston Hospitals and screening centers within the 617 area code by the 18 month time point.

These institutions include:

1180 Beacon Imaging, Llc; Biocare Diagnostics; Boston Imaging Associates; Boston Medical Center, Codman Square Health Center; Dorchester House Multi-Service Center; East Boston Neighborhood Health Center; Lemuel Shattuck Hospital; Medical Care Center North; Milton Hospital; Milton Health Service Center; New England Medical Center Hospital; Quincy Medical Center; Schatzki Associates, Inc; Schatzki Associates, Inc; Somerville Hospital Radiology Dept; South Boston Community Health Center; South Cove Community Health Center; St. Elizabeth's Medical Center Of Boston; The Carney Hospital. Inc; Upham's Corner Health Center; Whidden Memorial Hospital; Women's Health Center

Deployment at the other Screening Centers located in the 617 area code region will be carried out as a collaborative effort with Drs. Marc Homer, Director of Breast Imaging, Tufts New England Medical Center, Jeffrey Mendel, MD, Chair of Radiology, Caritas St. Elizabeth's Medical Center, & Tufts University School of Medicine, Deborah ter Meulen MD, Section Head, Breast Imaging, Boston Medical Center, and Priscilla Slanetz MD, Director of Breast Imaging, Caritas St. Elizabeth's Medical Center.

We are requesting funding for one research assistant, who will liaison with the screening centers. This research assistant will contact the centers, visit them, elicit suggestions for improving the system, and determine how the system is being adopted. The database in the system itself will be assembling data on how the system is being used at each screening center, particularly the frequency and nature of the interaction between the center and the system that are mediated by the web-forms. Each clerk will be given a separate log-on name and password, so that data on usage by individual clerks use can also be examined.

# Specific Aim #3: We propose to analyze the impact of the reminder system on the utilization of breast cancer screening.

The impact of the reminder system on screening behavior will be analyzed.

#### 3.1. De-Identification of system data.

To insure patient confidentiality, the operational system database data will be converted into de-identified data, such that each patient name, telephone number, address, etc, will be converted into a non-recoverable code. The program that we will write to carry out this de-identification process will extract generic information for each patient (such as whether each name was Hispanic or Asian, the census tract of each patient, etc), but will eliminate all potential to identify individual women.

#### 3.2. We will analyze the impact of the reminder on the use of mammographic screening.

The primary goal will be to characterize the overall pattern of screening use and rates of attendance after the introduction of the reminder message. The likely health impact of the resulting pattern of screening usage will be assessed by our computer simulation model of breast cancer screening, which can convert data on the pattern of usage into an expectation of the population-wide risk of breast carcinoma death<sup>8,9,10,11,12,19</sup>.

The system will be collecting data on the actual phone calls, i.e.: which reminder calls are unanswered, which reminder messages are left on answering machines or answered by individuals other than the recipient and, for those calls that are answered, how many times the call had to be initiated before it was answered, whether the recipient listened to the whole call, whether the recipient requested directions, etc. Those women who have opted out of the reminder process entirely are also known. Questions to be addressed will include: How does the pattern of usage vary among women differing by whether or not they received their reminder call? By whether or not they requested a reminder call? By whether the reminder was received by the woman herself, left on the answering machine, or with another individual?

Since the system requires a great deal of information, including patient name, date of birth, address, primary care physician, insurance, language, time-of-day preference, phone type (cell vs. line), email use, etc, this will afford the opportunity to determine the correlates of screening usage. (Note that these data will be de-identified before analysis, as indicated in the previous section). Questions to be addressed will include: How does the pattern of usage vary among women differing by ethnicity? By Town, Zip Code, and census tract (together with corresponding US Census income data)? By language? By age? By the time of day that the receipt of the telephone message was requested? By whether the woman uses a cell phone or line phone? By whether the woman requested an email reminder?

The data will also afford a unique opportunity to assess mammography usage on a geographic basis. Virtually all previous studies have had to rely upon either survey data, or data from specific screening centers, and both provide an incomplete image of actual screening usage. We will be able to determine mammographic screening usage in the whole 617 area code. It will be possible to determine the absolute fraction of women who do not use screening by comparison with census data, which can tell us the number of eligible women in each town, Zip Code, and Census Tract who are of eligible age.

As time progresses, it will be possible to determine the long-term pattern of screening use. For example, we have found that while there is a correlation between a woman's previous screening use and

her subsequent use, the correlation is not particularly strong, suggesting a considerable degree of the failure to return to screening may be ascribed to systematic failure rather than to individual patient characteristics. It might be hypothesized that in the context where effective reminders are made, the individual patterns of screening use will become more evident.

The reminder system also affords the opportunity to gain insight into the appointment making process, and we will use the results of our studies to analyze this aspect of screening use. For example, we will measure the impact of missed appointments on screening use. Do women who have missed appointment reschedule them? If they reschedule, how much does this contribute to the delay in the return to screening? Is rescheduling more common if the screening center uses the web-calendar and allows for automatic telephone appointment making? Are women who make their appointments a year in advance more likely to return on time to screening than women who make their appointment closer to the actual appointment time? How does the pattern of screening use vary by the day of the week, by the time of the year, by the weather, by the time of day the appointment is scheduled, etc?

# 3.3. We will analyze the impact of the reminder system by comparing the pattern of return to screening before and after introduction of the system at the MGH.

It is possible to compare the impact of the reminder system on screening usage among the women who use screening at the MGH Avon Comprehensive Breast Cancer Center, because a detailed record of screening use since 1985 is available, and because this usage has been exhaustively analyzed by our group<sup>1-3,6-11,15,16,20,21</sup>. These studies will be a continuation of our analysis of the pattern of screening use, and its performance, at the MGH (Protocol #2004-P-001562/2: latest IRB approval 6/05), and will use data from the MGH screening database.

<u>Return to Screening</u>: We will characterize screening use in terms of the cumulative distribution of the times to return for those women who return (The "return curve"), and estimate the likely survival impact of these patterns of screening use by the use of our computer simulation model of breast cancer growth, spread, and detection<sup>6,8,9,10,11,15</sup>. In addition to examining the pattern of screening usage before and after the introduction of the reminder system among women in the population as a whole, we will also examine its impact upon specific subpopulations of women, as defined by race, ethnicity (Hispanic, Asian, etc), language use, insurance status, Zip Code (as correlated with median income and other socioeconomic factors provided by the US Census), previous screening use, and body type.

<u>Missed Appointments</u>: At the present time, a sheet with all of the patients to be called for an appointment scheduled the next day is printed out daily at the MGH. The clerks write on this sheet who has been reached, and those patients who attended their appointments the next day are noted. We are presently collecting these sheets, so as to be able to compare the rates of non-attendance before and after the introduction of the reminder system. In addition to measuring the overall rate of no-shows before and after the introduction of the reminder system, we will also examine the reminder system's impact upon specific subpopulations of women, as defined by race, ethnicity (Hispanic, Asian, etc), language use, insurance status, Zip Code (as correlated with median income and other socioeconomic factors provided by the US Census), census tract (as correlated with median income and other socioeconomic factors provided by the US Census), previous screening use, and body type.

<u>Impact on the size-distribution of cancers found</u>: The impact on the reminder system at the MGH will be assessed not only in terms of the patterns of screening usage but also in terms of the types and sizes of the cancers detected<sup>1,2,3</sup>. From such tumor size data, it is possible to estimate directly the likely survival outcome among the women found to have invasive breast carcinoma<sup>5</sup>.

Specific Aim #4: We propose to adapt our mammography reminder system for use in Massachusetts as a whole.

Once the system has been shown to be effective in the in the greater Boston (617 area code) region, we shall adapt the system for use throughout Massachusetts, and apply for funding for the continuation of the reminder service on this basis. Statewide implementation will allow full integration of our system with the efforts of Women's Health Network of the Massachusetts Department of Public Health, and this aspect of implementation will be carried out as a collaborative effort with Mary Lou Woodford, Director of the Women's Health Network, Massachusetts Department of Public Health. Statewide implementation will also allow a unique opportunity to measure the utilization of screening on a large-scale geographic basis.

Specific Aim #5: We propose to adapt the reminder system for subsequent addition of reminder and tracking tools for other aspects of preventative medicine, including reminders for colorectal cancer screening, influenza immunizations, diabetes control, tracking tools for women with symptoms of breast cancer, etc.

Of course, promptness in attendance at mammographic screening examinations is but one example of a large class of preventative health interventions, which are underutilized because of deficiencies in reminders and tracking tools, and the system we shall develop can provide the backbone for many additional reminders for preventative interventions. While beyond the scope of the proposal outlined here, the system will be designed for the potential of incorporating such reminders at a later date, should there be a request for such additions. However, we shall build the system with the potential to add these interventions next:

### 1. Colorectal Cancer Screening

Underutilization of colon cancer screening is even greater an occurrence than underutilization of breast cancer screening. For example, in 2001, only 23% of surveyed adults over the age of 50 had received fecal occult blood testing in the previous year, and only 43% had received lower endoscopy in the previous 10 years<sup>109</sup>. Even after appointments are made, considerable numbers of patients fail to attend colon cancer screening. In the UK Flexible Sigmoidoscopy Screening Trial<sup>110</sup>, 29% of the individuals scheduled for screening failed to attend their screening examination. Turner et al<sup>111</sup> using the University of Pennsylvania Health System's ambulatory scheduling and billing system found that 38% of patients who had made an appointment for a flexible sigmoidoscopy or colonoscopy failed to attend their exams. However, Turner et al<sup>111</sup> found that of the 38% of patients who failed to attend, 61% subsequently rescheduled and, of these, 64% (39% of those who missed their first appointment) kept that second appointment. Clearly, many patients who forget to attend are not inalterably resistant to such screening. Turner et al<sup>111</sup> also found that patients who tend to forget to attend an appointment for a flexible sigmoidoscopy or colonoscopy also tend to forget to attend more general medical appointments. Aids that can help patients remember their appointments offer the potential for increasing screening use. Finding ways to make it easier for primary care physicians to schedule these initial screening examinations, and for individuals in the population as a whole to make these appointments themselves, would also be most desirable. There is no reason why our system could not be adapted to provide simple web-forms, which can aid in the process of recruiting patients for colorectal cancer screening, and reminder messages to help prepare patients and remind them of their upcoming colorectal cancer screening appointments.

# 2. Influenza Vaccination

In the last year for which we have complete data (2003), there were approximately 114,000 hospitalizations and 36,000 deaths ascribable to influenza, including 93 deaths in children.<sup>112</sup> Only one of these 93 children had received adequate vaccination. Vaccination rates in 2003 were 17% for age 0-18, 37% for age 18-49 and 65% for age 50+, revealing the enormous gap in the delivery of this cheap and effective tool for reducing death and disease. It should be straightforward to make outgoing telephone reminder messages to individually inform members of the Massachusetts population of when and where vaccine is available. The names and telephone numbers of Massachusetts residents can be purchased in bulk in the form of telephone directory assistance databases.

#### 3. Diabetes Control

Simple reminder systems for diabetes patients to check their Hemoglobin A1C have an enormous potential for reducing death and morbidity associated with this disease<sup>113</sup>. Again, there is no reason why simple interactive telephone reminders could not be added to our system to help physicians and patients to control diabetes.

#### 4. Tracking Tools For Women With Symptoms Of Breast Cancer

Our prototype system contains forms that physicians and mammographers can use to register patients with symptoms suggestive of breast cancer, so as to minimize delay in the treatment of this disease. While beyond the scope of this proposal, there is no reason why they could no be added to the system for use in Massachusetts, should there be interest.

### 5. End of Life Care: Pain Management

Management of pain at the end of life presents an enormous challenge, with an equally enormous potential for ameliorating suffering. Cantor et al<sup>114</sup> have shown that a simple interactive voice response system, using conventional computer speech and telephony, such as the system we have developed, can greatly aid physicians in managing such pain, and in reducing the pain in terminally ill cancer patients. There is no reason why such a functionally could not also be added to our system, should it be of value to physicians and patients in Massachusetts.

# 6. <u>The synergistic power of computer telephony</u>

Each of these interventions can work together to strengthen their impact. For example, there is no reason why each mammography reminder cannot end with a message asking "Is there any additional information I can provide you with to help preserve the health of you and your family?" and then link to appropriate information about colorectal cancer screening, or a clinic nearby, or tobacco control, or immunization, or, indeed, information any of a number of important health issues.

# 7. Other reminding and tracking tools

This list points out just a few possibilities by which computer speech can provide tools to help keep people healthy, and we believe that the potential applications will present themselves as our work proceeds. The key, however, to exploiting the potential of this very new and very powerful technology resides in the development of the appropriate infrastructure and expertise that will be made possible as a consequence of the study we have proposed here.

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