MDMS: Mammography data Management System

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Abbreviated Abstract

Mammography is the primary method of detecting early stage breast cancer, the second most commonly diagnosed cancer for women and the leading cause of death among women aged 35-54 in the United States. In order to monitor the quality of mammography clinical services, NCI has established the Breast Cancer Surveillance Consortium (BCSC) initiatives. However, there are many issues associated with existing commercial mammography data reporting systems. This recognition has inspired this proposed effort to develop Breast Health Reporting & Tracking System (BHRTS), an advanced data collection, reporting, and tracking system for breast imaging (mammography, breast ultrasound, and breast MRI).

The Phase I project conducted an in-depth analysis about this problem domain to create the design of this software system. A preliminary prototype was also created to demonstrate the feasibility and to serve as a tool to solicit feedback from potential users. This Phase II project implemented a working software and database system prototype and conducted evaluations in mammography facilities.

BHRTS, the product of this Phase II project, is an electronic medical record (EMR) system with comprehensive functions for supporting paperless operations for mammography and breast ultrasound. It includes functions for patient registration, appointment scheduling, patient check-in, collecting medical history information from patients, exam interpretation and report generation, patient letter generation, exam follow-up, performance audit report, and data export for submission to mammography/cancer registries.

Many unique innovative features have been developed into this system. One example is its customizable multi-language patient history questionnaire module. This function allows patients to provide their relevant medical history to the technologists and radiologists in their native language while allowing the physicians to see collected data in English. This will greatly improve the patient-physician communications and healthcare outcome. With its innovative implementation design, this electronic form can be easily customized to fit the unique requirements of each facility.

This solution is expected to help mammography facilities to be compliant with Mammogaphy Quality standard Act (MQSA) regulation (with automatic generation of patient letters, follow-up management, and performance audit report), improve quality of services (by reducing errors, making reports instantly available, and improving patient communication) while reducing operation cost (by improving process efficiency and eliminating transcription) and liability (by reducing errors). This solution will also make it easier for mammography registries to collect standardized data for breast cancer research.

In this Phase II project, this system prototype has been tested in a series of 10 evaluation events by 64 participants: 9 radiologists, 11 mammography technologists, 6 radiology department office clerks, 31 English-speaking patients, 4 Chinese-English bilingual patients, and 3 Spanish-English bilingual patients. In general, we have received favorable

feedbacks from the participants and demonstrated that this system will fit with the operations in mammography facilities.

With the successful execution of this SBIR project, we are now ready to move on to the commercialization stage for this exciting product.

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Total Budget

$837,761

Research Objectives

Phase I Aims:

- Specify the requirements of the proposed system
- Develop system design
- Demonstrate the feasibility of the proposed solution with a concept prototype

Phase II Aims:

- Implement the beta version of the software system
- Evaluate system prototype in clinical setting

Theory/Hypothesis

A user-friendly electronic medical record system tailored to breast imaging can improve the quality of services (improve quality of medical records and operational process) at breast imaging facilities while helping them reduce the operational cost. When this system is based on standards, such as American College of Radiologists (ACR) Breast Imaging Reporting And Data System (BI-RADS), it will also make "standardized" data available for cancer research.

Experimental Design

We used an iterative development process to implement this large-scale software system incrementally. Therefore, we have conducted many testing events to ask potential users to try out different functions of the system prototype. At the end, we also conducted a comprehensive testing to evaluate multiple functions at the same time. In addition to this iterative implement-test approach, we also employed two different testing methods to ensure that the resulting system can fit different operational scenarios:

- Clinical testing: patients, technologists, and radiologists were asked to use the system with real patient medical information in real clinical settings. Patients receive no training prior to the usage of the system while other subjects did receive brief training (30 minutes to an hour). Unless the subjects asked for assistance, we do not interact with the subjects while they are using the system prototype. At the end of testing, each subject is asked to fill out an evaluation form about his/her experience of using the system prototype.
- Usability testing sessions conducted by professional usability consultant with paid participants in a usability lab. The subjects are asked to speak out what they were thinking while using the system. In addition, the usability consultant may interact with the subjects to ask the subjects to provide more information. Each subject is also asked to fill out an evaluation form at the end. Each session is one hour.

After every testing event, we analyzed the evaluation results and used them to improve the system design of next version of the prototype.

In order to protect the privacy of the subjects, no personal identifying information is written on the evaluation forms or entered into our prototype database. All information entered by the subjects was deleted from the system prototype's database permanently at the end of the each testing. Only system-recorded timestamp data were kept to compute the time a user spent on a task.

Final Sample Size & Study Demographics

Sixty four (64) subjects (potential users) participated in the testing:

- Nine (9) radiologists
- Eleven (11) mammography technologists
- Six (6) radiology office clerks
- Thirty-one (31) English-speaking patients (women who receive mammography exams)

- Four (4) bilingual patients who speak Chinese and English
- Three (3) bilingual patients who speak Spanish and English

Data Collection Methods

All together, we have conducted ten (10) testing events:

1. 9/25/06: usability testing with 4 radiologists and 2 technologists.
2. 10/24/06: clinical testing with one radiologist.
3. 11/3/06: clinical testing with one radiologist.
4. 11/13/06: clinical testing with one radiologist.
5. 11/17/06: clinical testing with one radiologist.
6. 4/26/07: clinical testing with two (2) technologists and nine (9) patients.
7. 7/12/07: clinical testing with two (2) technologists and nine (9) patients.
8. 8/28/07 to 8/29/07: usability testing with four (4) technologists, six (6) patients, and five (5) office clerks.
9. 1/24/08 to 1/25/08: clinical testing with one office clerk, nine (9) patients, two (2) technologists, and one radiologist.
10. 3/3/08: clinical testing with five (5) patients, one technologist, and one radiologist.

Each subject was asked to fill out an evaluation form (on paper, without personal identifying information) after completing testing of the system. Because different subject types (radiologists, technologists, office clerks, patients) were asked to perform different tasks, a different evaluation form was used for each subject type.

Whenever appropriate, collected data was then entered into Excel spreadsheet for analysis.

Additional verbal comments by the subjects during the usage of the system were also recorded on paper (without personal identifying information) by our team members.

Outcome Measures

The main questions our evaluation of this software prototype tries to answer are:

1. Is the software easy to use?
2. Does this software fit the operations in radiology facilities?
3. What do the users prefer?
4. Where/how can we improve in the system design?

For each type of subjects, we developed an evaluation form for them to fill out after they have tried out our software prototype. Four different types of questions are asked: yes/no, 4-point Likert scale, 5-point Likert scale, and open question.

The patients were asked to evaluate the system prototype by answering the following questions:

- clarity of the introduction/tutorial;
- easiness of reading the screen, completing the electronic questionnaire, using digital pen or finger, entering dates, making corrections, navigation;
- time spent on filling out the electronic questionnaire;

- computer usage experience;
- personal preferences;
- what they like or do not like about the prototype;
- suggestions for improvement.

The technologists were asked to evaluate the system prototype by answering the following questions:

- easiness of accessing patient's medical history information, entering data, correcting data;
- impact on operational flow;
- personal preferences;
- what they like or do not like about the prototype;
- suggestions for improvement.

The radiologists were asked to evaluate the system prototype by answering the following questions:

- easiness of accessing patient's medical history, entering data to generate draft reports, interactive diagram feature, report editing, overall usage;
- quality of system-generated draft report;
- time spent on creating a report;
- personal preferences;
- what they like or do not like about the prototype;
- suggestions for improvement.

The office clerks were asked to evaluate the system prototype by answering the following questions:

- easiness of entering patient information, making appointments, changing appointments
- time spent on making an appointment
- personal preferences;
- what they like or do not like about the prototype;
- suggestions for improvement.

Evaluation Methods

Clinical evaluation in mammography facilities:

- We contacted many mammography facilities in San Francisco Bay Area to solicit their participation in our project. As the result, we had 3 facilities participated.
- Administrator in each participating facility picked the test date(s) that best fit their schedule.
- Patients were selected randomly. If a patient agreed to participate, she would use the prototype to fill out the medical history questionnaire electronically. After completion, we asked the patient to fill out an evaluation form on paper. No personal identifying information was record.
- Technologists received brief 30-minute training on the date of testing. They would use the system prototype to enter/review/edit medical information for the patients who chose to participate. At the end of day, the technologists were asked to fill out an evaluation form on paper.

- Radiologists received a one to two hours training prior to the testing of the prototype. They would then use the prototype to generate mammogram and breast ultrasound exam reports. At the end of the day, the radiologists were asked to fill out an evaluation form on paper.

Usability testing in usability lab:

- All subjects in the usability testing in San Jose were recruited by the Chairman of the Radiology Department in Valley Medical Center.
- All subjects in the usability testing in Bethesda were recruited by a professional recruiting company.
- Some subjects were asked to spend 3 to 5 minutes to read brief introductory materials (printout of screens with explanation) in the beginning.
- The usability consultant asked the subjects to perform various actions using scripted scenarios. The subjects were asked to speak out their thought process while performing the tasks. The usability consultant may intervene and ask the subjects to elaborate more on certain issues.
- An observer records the conversations on paper.
- At the end of the testing session, the subjects were asked to fill out an evaluation form on paper.

Research Results

Patients' evaluation:

- The average time for completing electronic medical history form using this system was 4 minutes and 27 seconds.
- Using a 4-point Likert scale from very easy to very difficult, 28 rated the prototype as very easy and 9 rated the prototype as easy. This indicates that this system is suitable for patients.
- Using a 4-point Likert scale from very clear to very unclear in response to the question about understanding how medial history questionnaire is used in cares to the patient, 16 responded very clear, 13 responded clear, 3 responded not clear. This indicates that there is a need to improve patient's understanding about how their information is used in mammography services.
- Comparing electronic form with paper form. 34 prefer electronic form (this system), only 3 prefer paper form. This indicates that expected resistance from patients would be minimal.
- Some patients have concern about privacy issue in electronic system.

Technologists' evaluation:

- Using a 4-point Likert scale from very easy to very difficult, 6 rated the prototype as very easy and 5 rated the prototype as easy. This indicates that this system is suitable for technologists.
- Comparing electronic form with paper form, 8 prefer electronic form (this system), only 2 prefer paper form. This indicates that expected resistance from technologists would be minimal.
- While all agreed testing with only some patients has not negative impact on follow, some had concern that using this system in clinics for all patients might have negative impact to the operational flow.
- All emphasized the need to be able to customize the form to fit the needs of the facilities.

Radiologists' evaluation:

- Using a 5-point Likert scale from very easy to very difficult, 1 rated the prototype as very easy and 5 rated the prototype as easy.
- Using a 5-point Likert scale from very good to very bad, 1 rated the system-generated report as very good, 2 rated good, 2 rated OK, 1 rated bad. This indicates that we should keep improving in this function.
- Comparing this system with dictation, most would prefer to use this system for simple cases (majority of the exams) and use dictation for complicated cases. This indicates that incorporating speech recognition technology into this system might be the best solution.

Office Clerks' evaluation:

Using a 4-point Likert scale from very easy to very difficult, 2 rated the prototype as very easy and 3 rated the prototype as easy. This indicates that this system is suitable for technologists.

Barriers & Solutions

The biggest problem we had was to find mammography facilities to participate in our "preliminary" clinical testing. In order to make sure that the resulting system would be useful clinically, we have to conduct these "preliminary" testing before we have a final product that is ready to deploy in clinics. However, most facilities are not willing to do so because they do not see a clear immediate benefit. Furthermore, a facility may agree to participate, and then decided to withdraw a few months later. It happened twice in this project. As a result, we spent many valuable hours trying to find and convince facilities to participation. In addition to reaching out through our social/professional network, we also used the mammography facility listing from the FDA web site to obtain phone numbers and addresses of "local" facilities in San Francisco Bay Area. We contacted many of them to introduce our project to them to ask them to participate. Eventually, we had three (3) facilities that participated in the testing of our system prototype.

Product(s) Developed from This Research

Breast Health Reporting & Tracking System