CMDS: A Data System for a Multi-institutional Mammography Registry

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Abstract

Background: Radiologists subject are to numerous regulations, including those set forth by Mammography Quality Standards Act (MQSA) and the Breast Density and Mammography Reporting Act (BDMRA). Compliance with these regulations can be extremely challenging, particularly for communitybased and rural practices with limited budgets to the adoption of commercial support Mammography Information System (MIS) mammography-supported Electronic Medical Record (EMR) system that can assist regulatory requirements for patient follow-up and reporting. Since its inception in 1994, the Carolina Mammography Registry (CMR) has captured prospective data on ~650,000 female patients and >2.4 million visits to more than 40 radiology practices located in 39 counties in North Carolina. One of the goals of the CMR is to assist participating radiology practices with regulatory requirements. The Carolina Mammography Data System (CMDS) captures CMR data from eight practices without access to a commercial MIS or mammography-supported EMR system.

Objective: To describe our experience in the research, development, and evaluation of a major update to CMDS, promoting it to a modern medical informatics platform.

Methods: We engaged in an extensive requirements gathering phase, followed by an

iterative testing, evaluation, and modification period after development of a protocol CMDS

solution. A second round of iterative testing, evaluation, and modification followed "live" deployment of CMDS v1.0. After applying fixes, CMDS v1.1 was deployed and remains in use. The system undergoes continuous evaluation and modification in response to user feedback.

Results: We designed the CMDS to: (1) assist participating CMR radiology practices in meeting the reporting requirements of MQSA and BDMRA through automated generation of letters reports; (2) provide a data repository participating radiology practices and a data collection tool for researchers interested population-level research on breast imaging and clinical outcomes; and (3) improve patient care by facilitating the tracking and follow-up of patients and promoting innovative outcomes-based research. Conclusion: The CMDS was custom-made to support the CMR, but it can be adapted for a variety of uses in radiology practice. We are currently modifying the system to support a Lung Cancer Screening Registry.

Keywords: mammography; breast imaging; radiology; information systems; registries; legislation; mandatory reporting; MQSA; BDMRA

I. Introduction

Mammography is one of the most common imaging procedures conducted by radiologists. Indeed, while clinical guidelines on mammography remain a topic of great debate [1], the procedure remains the primary means of early detection of breast cancer and reduction of associated risk of morbidity and mortality [2].

As with most healthcare professionals, radiologists are facing increasing federal regulations regarding the use of mammography [3,4]; these include regulations set forth by the Mammography Quality Standards Act (MQSA) and the Breast Density and Mammography Reporting Act (BDMRA). Compliance with these regulations can be extremely challenging, given the amount of patient follow-up and reporting that is required. For community-based and rural radiology practices without access to a Mammography Information System (MIS), a mammography-supported Electronic Medical Record (EMR) system, or another advanced Healthcare Information Technology, compliance with federal regulations can present a significant administrative and financial burden [5].

The Carolina Mammography Registry (CMR) was founded at our institution in 1994 and currently comprises data on ~650,000 female patients and >2.4 million visits to more than 40 radiology practices located in 39 counties in North Carolina. One of the goals of the CMR is to facilitate compliance with MQSA and BDMRA. The Carolina Mammography Data System (CMDS) was developed to support participation in the CMR among practices without access to a MIS or mammography-supported EMR system.

This paper describes our experience with research, development, implementation, and evaluation of the CMDS. Our specific aims were to: (1) transition historical CMDS data from an Access-based data system to a new SQL-based data system; (2) update the CMDS to enable easy modification and continual alignment with clinical best practices and regulatory requirements; and (3) assist in compliance with MQSA and BDMRA.

II. Methods

Assessment of Existing Systems

Prior to development of the custom CMDS, the CMR technical and clinical/research teams engaged in a multi-month requirement gathering and evaluation period, which took place from May 2013 through November 2013 and involved in-person working sessions, phone calls, and email exchanges. The legacy CMR data system was implemented using an Access database. However, over time, as the CMR grew and as technologies evolved, the CMR team identified several factors that prompted the decision to consider a new custom system, including: (1) inadequacy of Access to handle a growing number of data fields (Access sets a maximum of 255 fields); (2) incompatibility of the old system with newer versions of Windows; (3) need for multiple users to be able to access the system at any given time (Access supports only one user at a time); and (4) requirement for an enterprise-level system to assist in compliance with federal mandates as outlined in MQSA and BDMRA.

A variety of commercial MIS are available [6]. These include: MagView (MagView, http://www.magview.com/home), which was originally developed for the American College of Radiology; Opal-wRIS (Viztek,

http://viztek.net/products/products_opal-wris/);
PenView (PenRad,

http://www.penrad.com/products_penview.html); RadNet® Mammography Management (Cerner Corporation, https://store.cerner.com/items/2265); Siemens Mammography Systems (Siemens Medical Solutions USA, Inc.,

http://usa.healthcare.siemens.com/mammography); and the MRS Suite of Systems (MRS, http://www.mrsys.com/about). In addition, commercial EMR systems often include MIS capabilities as an add-on feature. The CMR technical and clinical/research teams evaluated existing options but concluded that none of them were sufficiently modifiable to meet the specific needs of the CMR, including the inclusion of project-specific data elements. The commercial systems also were too expensive for use in community-based and rural radiology clinics. Thus,

a decision was made to replace the legacy Accessbased data system with a custom-made, SQL-based system: the CMDS.

Development of New System

The CMR technical and clinical/research team members worked closely with one another to design the new data system, map variables from the old system to the new system, and migrate data and operations. System development began November 2013. The underlying design of the new system was intended to be largely generic in order to promote reuse of design features and software code for related projects (e.g., a Lung Cancer Screening Project that is funded by the National The Microsoft .NET Cancer Institute). framework was chosen as it supports the Windows 7+ platforms in place at the participating radiology practices.

The SQL database was developed after extensive modification of the Access database, in terms of both layout and organization (variables and schema). Database variables, as defined in the old schema, were manually mapped one-to-one to variables used in the new schema. More than two hundred new variables were added to the new schema in order to improve the granularity of the data system and better reflect current clinical practice and the variables in the CMR data collection form.

Templates for follow-up letters and reports were modified as part of the mapping and updating processes and also are continuously evaluated and modified to align with evolving federal regulations and radiology practice needs. Finally, a new User Interface (UI) was created to reflect the new variables, data collection form, and templates.

Implementation of New System

Rollout of a protocol CMDS took place during August 2014 and September 2014. An iterative testing process accompanied rollout of the protocol solution (see below). Fixes were added to the system, and "live" rollout of CMDS v1.0 began in January 2015. Data migration of historical data from the Access-based system to the new SQL-based system took place practice-by-practice, either

remotely or by manual, on-site copy after deployment of CMDS v1.0. A second round of iterative testing and fixes took place after deployment of CMDS v1.0, and "live" rollout of CMDS v1.1 began in August 2015. CMDS v1.1 remains in use today. Ongoing feedback from participating radiology practices allows for continual refinement of the system as modifications and fixes are compiled for future versions.

Most of the historical data were successfully migrated to the new system. Of 616 variables in the old schema, 108 (17.5%) were not mapped to the new schema because of broken foreign keys or upon request of the CMR clinical/research team (i.e., they were deemed outdated or otherwise irrelevant due to the addition of new variables). Approximately 99% of the historical data were captured in the new system. The CMR team maintains an archived copy of the complete historical data set for each participating radiology practice.

Testing and Evaluation of New System

After the protocol CMDS solution was developed and deployed, CMR technical and clinical/research team members engaged in a multi-month iterative testing and evaluation period. Testing evaluation were conductedbvthe clinical/research team through the use of virtual machines equipped with Windows 7 and populated with extensive dummy data. The CMR technical team modified the system in response to the feedback thev received from the CMR clinical/research team. A second iterative testing and evaluation period followed deployment of CMDS v1.0, during which time participating radiology practices were asked to pilot test CMDS v1.0 alongside the existing Access system by entering a subset of patient records into CMDS v1.0 and providing feedback to the CMR technical team regarding features in need of modification. The CMR technical team modified the system accordingly before deployment of CMDS v1.1.

The testing period was implemented to ensure the clinical utility and completeness of the data collection form, letter templates, report templates, and system UI, as well as the accuracy of the data

collection process and the overall functionality of the new system.

III. Results

Technical Functionality of the CMDS Overview of Process and Database Schema

Figure 1 provides an overview of the CMR data capture and storage process; Appendix A provides a partial schema of the CMDS, showing patientrelevant tables. Currently, eight radiology practices use the CMDS. The system is designed such that each radiology practice maintains an on-site SQL database. Users interact with the system via an intranet-based CMDS UI running on Windows 7+ (Appendix B). Data obtained during patient visits include risk factors, reason for and type of imaging performed, radiology findings and interpretation, recommendations for follow-up, and pathology The data are manually results (if performed). entered into the CMDS through one of two methods: direct data entry or data entry from a standardized, bilingual (English/Spanish) collection form (Appendix C).

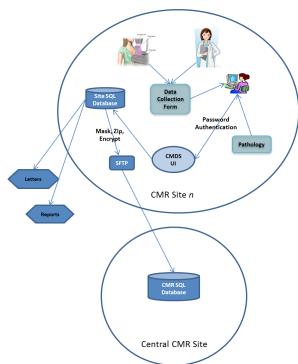


Figure 1. An overview of the CMR and CMDS system.

Data from patients who agree to participate in the CMR for research are exported from the local CMDS SQL database to the central CMR SQL database located at and maintained by the Office of Information Systems in the School of Medicine at our institution (Figure 1). Data transfer occurs on a biannual or annual basis. Each radiology practice conducts a query of the local SQL server, and the data are captured and encoded by site and patient medical record number (MRN). The data are then masked, zipped, and auto-encrypted and transferred by SFTP to the CMR team for import into the central CMR SQL database.

Security Features

Stringent security measures include the use of dummy data for testing at the central CMR site, password protection for entry into the CMDS UI at participating radiology practices and access to the central CMR database, masking of identifiers before encryption, and the use of GPG4win for encryption. In addition, a single delegate at each radiology practice has access to the encryption key but not the decryption key; only the central CMR administrator has access to both the encryption and decryption keys and hence, access to fully identified data for research purposes.

Technical Fixes Post Deployment

The CMDS has been in continuous development since deployment. The majority of fixes occurred after deployment of the protocol CMDS, with little ongoing need for fixes since "live" deployment of CMDS v1.1. Most fixes have been minor and in response to requests of the radiology practices or the CMR clinical/research team. For example, a common software issue has been the incorrect spelling of a clinical term or a user request to change the spelling of a term to the preferred (or updated) clinical or research usage. Other software issues have been more impactful, yet easy to fix. For instance, the initial system design did not take into account the fact that women can have normal radiology findings for one breast and abnormal findings for the other breast. Before the fix was applied to delineate separate fields for the left and right breast, two separate follow-up letters were generated, one indicating that the radiology findings were normal, and the other indicating that the findings were abnormal. Additionally, several radiology practices requested additional documentation on the dates when letters were printed and mailed to each patient. Specifically, the initial system would track only the print date of the most recent letter of a specific type for an individual patient; previous print dates for the same type of letter were overwritten by the system. To address this, changes were made to portions of the database structure related to letters, such that the system now tracks the print date of each letter by type of letter and by patient. The system also now has the capability to generate a list of all printed letters stamped by date for each patient, for a subgroup of patients, or for a type of letter within a specified timeframe. Another software issue involved changes in patient mailing address. Initially, when a patient had a change in mailing address, radiology practices were able to update the address in the system, but they were unable to print a second copy of a letter, such as the "Visit Reminder" letter, to mail to the new address. In this case, the software fix was to incorporate a feature to allow sites to manually print second copies of letters for individual patients.

Rather substantial changes were made to the layout and configuration of the UI, although these were mostly stylistic and involved the rearrangement of menus on various screen displays. Several dropdown menus also were expanded to increase the granularity of the data that are captured.

IV. Application of the System Regulatory Compliance

One of the primary applications of the CMDS is to meet the patient follow-up and regulatory reporting requirements set forth by MQSA and BDMRA. The CMDS accomplishes this largely through the automated generation of patient follow-up letters and regulatory reports. Twenty-two letter templates have been created and are classified into 3 categories: follow-up/appointment reminders; mammography and pathology reports; and non-mammography imaging reports (i.e. ultrasound, MRI, CT). The letters include follow-

up reminders for upcoming appointments, regulation-compliant reports of mammography and other imaging findings, and clinical recommendations (e.g., consultation with your physician regarding breast cancer risk screening, screening options/frequency).

Thirty-nine report templates have been created and are classified into 5 categories: audit reports; tracking reports; patient lists; mammography and pathology reports; and other reports. The reports include required auditing reports (e.g., MQSA tracking requirements), lists of all patients who received appointment reminder letters, reports of all patients who received specific mammography results (e.g., positive, outstanding [positive but not yet followed-up], negative, indeterminate, etc.), and reports of all patients who had biopsies performed by pathology.

Of note, the letter and report templates can be tailored to meet the needs and desires of a given radiology practice. This is accomplished via the CMDS UI, without the need for additional software programming by the central CMR administrator.

Research

In addition to providing automated letters and reports, another primary application of the CMDS is to facilitate research. This is accomplished primarily through an export functionality that allows an auto-generated "dump" of patient, radiology, and pathology data from each radiology practice's local SQL database. The data are sent to the CMR team and loaded into the central CMR SQL server for processing and long-term storage. The data are used for population-level research on breast imaging and clinical outcomes. The CMDS supports the CMR and several other federally funded research projects, including a new project funded by the National Cancer Institute that aims to adapt the CMDS to support a Lung Cancer Screening Registry.

V. Discussion

Principal Findings

The CMDS: (1) assists participating CMR radiology practices in meeting the reporting requirements of MQSA and BDMRA through the

automated generation of follow-up letters and reports; (2) provides a data repository for radiology practices and a data collection tool for researchers interested in population-level research on breast imaging and clinical outcomes; and (3) improves patient care by facilitating the tracking and follow-up of patients and by promoting innovative outcomes-based research.

We note a few interesting features of the CMDS system. First, the majority of participating CMR radiology practices are small practices located in primarily rural counties in North Carolina. These radiology practices generally do not have access to an MIS or mammography-supported EMR system, which is typical for rural areas of the United States [5,7]. As such, our CMDS system incorporates a combination of paper data collection, manual data abstraction from radiology and pathology reports, and manual data entry via the intranet-based CMDS UI. The data collection standardized, bilingual, and requires minimal effort to complete, with one page of patient-reported data and one page of radiologist-reported data. The CMDS UI likewise requires minimal effort or training in data entry.

While the United States government has advocated for universal adoption of EMR systems by healthcare providers, offering incentives such as the "Meaningful Use" program enacted as part of the Health Information Technology for Economic and Clinical Health Act, providers have been slow to adopt EMR systems, in part because of costs, real or perceived reductions in provider productivity, and lack of incentives for sharing patient data [8]. This is especially true in rural areas, despite the additional incentives provided by the Regional Extension Center program [7]. Moreover, even among institutions that have an EMR system in place, EMR data are rarely incorporated into radiology workflows or Radiology Information Systems [9], which was the situation for the majority of our participating CMR radiology clinics. Thus, the custom CMDS provides a streamlined solution to assist with the patient follow-up and reporting requirements of MQSA and BDMRA among radiology practices without access

to an MIS or mammography-supported EMR system.

Security features of the CMDS also are vital to its success. These security features include password protection for authentication and access and GPG4Win encryption of data at participating radiology practices. For data capture and storage within the central CMR database, a manual method was chosen, in which participating radiology practices capture and encode the data by site and patient MRN stamps, mask all identifiers before encryption, zip and auto-encrypt the data, and transfer the data via SFTP to the central site. The encryption key is maintained by a single delegate at each site and by the central CMR administrator, but only the central administrator holds the decryption key, which opens access to fully identified data for research purposes. In combination, these features help to ensure that identified patient data stored in the CMDS are secure at all stages of the data collection, entry, and export process.

Limitations

The CMDS was developed specifically for the CMR and to assist participating radiology practices with compliance with MQSA and **BDMRA** requirements. A limitation is that the system requires continuous updating to meet evolving federal regulations. However, the system was designed $_{
m with}$ $_{
m this}$ inmind, and administrative tasks are streamlined and require little programming by the central CMR administrator. Another limitation generalizability of the system. While the general approach and system design of the system can be modified for other applications and for other institutions, modification requires a certain level of technical and clinical expertise.

Conclusions

The CMR was founded in 1994 and supported initially by an Access-based data system. The new, custom, SQL-based CMDS v1.1 contains numerous features and capabilities that were not present in the earlier data system, including a user-friendly UI, an unlimited number of data fields, compatibility with the latest versions of Windows,

and multi-user operability. Importantly, the CMDS provides an enterprise-level system that assists participating CMR radiology practices with compliance with the regulatory requirements set forth in MQSA and BDMRA. The CMDS also serves as a data repository for participating radiology practices and a data collection tool for researchers interested in population-level research on breast imaging and clinical outcomes. The system currently supports several federally funded research projects in addition to the CMR. Finally, the CMDS improves patient care by facilitating the tracking and follow-up of patients and by fostering innovative clinical research.

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About the Authors

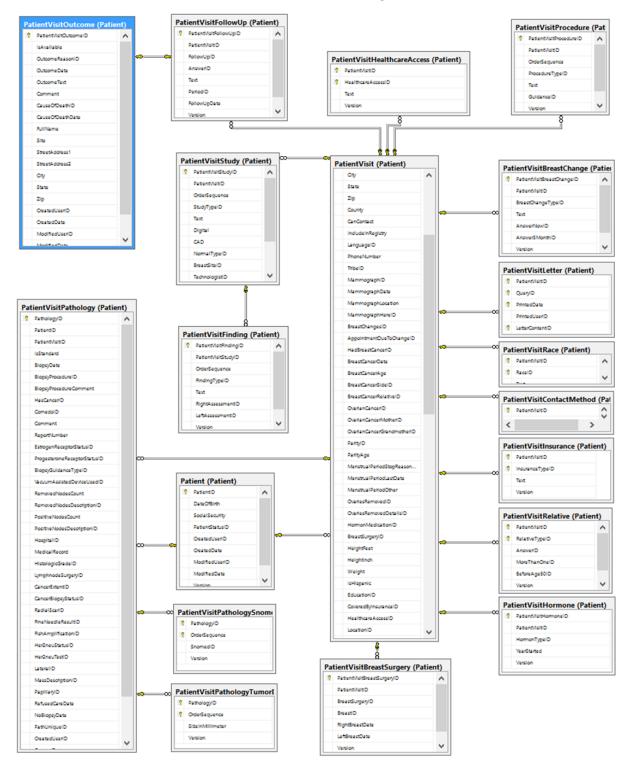
Oleg Kapeljushnik is a Software Developer at RENCI and led the development of the CMDS. Charles Schmitt formerly served as Chief Technology Officer and Director of Informatics at RENCI and now serves as Director of Data Science at the National Institute of Environmental Health Sciences. Kapeljushnik designed, implemented, and tested the CMDS under the scientific direction of Schmitt. Louise Henderson is an Associate Professor within the Department of Radiology at UNC and Director of the CMR. Henderson provided the conceptual vision for the CMDS. Anne Greenwood-Hickman formerly served as Data Manager for the CMR.

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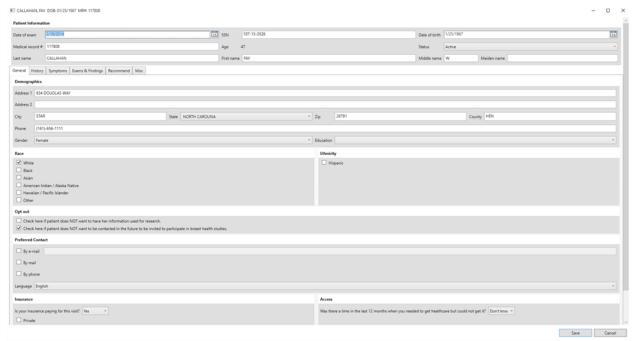
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Appendix A: Partial schema of the CMDS, showing patient-relevant tables.

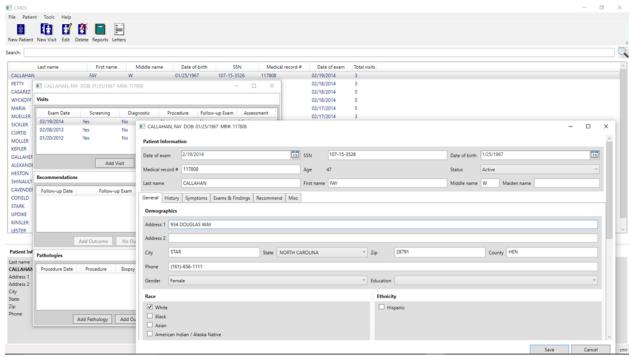


Appendix B: Screenshots of the CMDS UI.

Α.



В.



Appendix C: Data collection form used to capture patient and radiology data for manual entry into the CMDS.

A. Page 1: Patient form.

< <pre><<pre><<pre><<pre><<pre></pre></pre></pre></pre></pre>	Study date		_ Chart/	MR#			
Name (first, ml, last) 88N (last 4 digits) xxx-xx- Date of birth	OF OM	Practice Name>> fammography Regis ssociated follow up lease read the attach Check here if you Registry. Check here if you research.	stry. Informa care may be ched docum i do <u>not</u> wan	tion from to included ent for more t to be incl	his visit and in the Regis e information uded in the	stry.	
Have you ever had a mammogram? No O Yes → If yes, in what month/year? → If yes, where?		Are you currently taking any of the following medications? O Not taking any O Don't know Not taking any Year started					
Have you noticed any changes in your breacts No ○ Yes → if yes, please indicate type of ci Present today Pas ROM Left ROM Breach breach	hanges: Birth it 3 months Raic	none therapy i control loxifen loxifene natase inhibitors	O O O	¥000000		ar100	
Lump (new/unusual) O O Nipple discharge O O Pain O O Other O O	0 11.	Have you had any or treatments?	No breast s	urgery or b	reatment	Date	
3. Did you make this appointment because of the changes? O No O Yes 4. Have you had breast cancer? O No O Yes	Cys Con Sury Lum	needle asp t aspiration e blopsy plcal blopsy pectomy	000000	mmlyyyy	000000	nimm	
→ if yes, in what year? or at what a → if yes, which breast(s)? ○ Right ○ Le 6. Has a blood relative ever had breast cancer? ○ No ○ Yes → if yes, please indicate who: 0001	ft O Both Rad Che Rec Impl Red	tectomy lation therapy motherapy onstruction ants uction	00000	\equiv	000000		
Mother	0 13.1	How tall are you? _ How much do you Are you of Hispani O No O Yes	weigh?	p	ounds		
Have you or a blood relative ever had ovarian (Select all that apply) No history of ovarian cancer Yes, I have had ovarian cancer Yes, my mother joister/daughter has had ovarian to Yes, my grandmother/aun	oanoer? 16. I	What is your race? D Black D White D American Indian/ D Other	O Hawa O Asian	llan/Pacifi		_	
Have you ever given birth? No ○ Yes → If yes, age when first child was born		18. Highest level of education you completed. O Some high school O Some college /technical school O High school / GED O College graduate or more					
8. Have your menstrual periods stopped perman O No -> Date last period began O Not sure, periods are less frequent O Yes, they stopped naturally O Yes, they stopped due to birth control O Yes, but have them now from taking hormones O Yes, other reason 9. Have your ovaries been removed? O No O Yes, one O Yes, both O Don't kno	17.	is insurance paying No No Yes → O Private O BCCCI Was there any time needed to get heal O No O Yes → if yes, rea Select all that apply	e O Medic P O Medic e in the past th oare but isson: O Far y) res	are aid 0 0 12 month could not nily, schoo ponsibility st or insura	ns when yo get it? I, or work	u	
Rev 08/2014				vel or trans er		_	

${\bf B.}$ Page 2: Radiology form.

< <pre><<pre><<pre><<pre>study d.</pre></pre></pre></pre>	ate Chart/MR#					
Technologist code	8. Does the patient have implants?					
Radiologist code	O No O Right O Left O Both					
Referring physician	9. Are you aware of any palpable masses in the breasts?					
Address	O No O Right O Left O Both					
City State Zip						
Phone ()	Soreening mammogram findings. O Check if no findings (BI-RADS 1)					
1. Which breast(s) are being imaged? ○ Both ○ Right ○ Left	Right Bi-RADS Left Bi-RADS					
2. What is the reason for this visit?	11. Other imaging findings. (Which exam?					
O Asymptomatic (screening)	O Check if no findings (BI-RADS 1)					
Symptomatic, problem solving, diagnostic work-up Continued work-up following abnormal mammo or US	Right BI-RADS 0 2 3 4 5 6 0 2 3 4 5 6					
O Short-term follow-up (mostly 6 month follow-up)						
Short-term follow-up (mostly 6 month follow-up) Post-cancer follow-up	0 0 0 0 0 0 Mass 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0					
O Biopsy	O O O O O Arch distortion O O O O O					
O Other	O O O O O Calcifications O O O O O					
	0 0 0 0 0 0 Cysts 0 0 0 0 0					
3. What soreening studies were performed at this visit?	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0					
O No screening studies						
Yes Digital CAD	12. Other Imaging findings. (Which exam?					
Screening 2-view mammogram ○ → ○ ○	O Check if no findings (BI-RADS 1)					
Tomography ○ → ○	Right BI-RADS Left BI-RADS					
Ultrasound O → O	0 2 3 4 5 6 0 2 3 4 5 6					
MRI ○ → ○	0 0 0 0 0 0 Mass 0 0 0 0 0 0					
	O O O O O O Asymmetry O O O O O					
Other ○ → ○	0 0 0 0 0 0 Arch distortion 0 0 0 0 0 0					
What <u>diagnostic</u> studies were performed at this visit? No diagnostic studies Yes <u>Digital CAD</u>	O O O O O O Calcifications O O O O O O O O O O O O O O O O O O O					
Diagnostic mammogram ○ → ○ ○ ○ Tomography ○ → ○	13. Complete workup assessment.					
Tomography ○ → ○	0 1 2 3 4 5 6					
Ultrasound ○ → ○	Right 0 0 0 0 0 0 0 0 0 Left 0 0 0 0 0 0 0 0					
MRI 0 + 0	Left 0 0 0 0 0 0 0					
CT						
Other	14. Next mammogram.					
5. What procedures were performed at this visit?	O 1 year scmidlag O Age 40					
O No procedures	O 2 years O Return to screening schedule O 6 months (short term) O Not applicable					
Quidance (e.g., US, stereo, Yes mammo, MRI, CT, palpation)	O Other (months)					
Ductogram ○ →	16. Recommended follow up.					
Fine needle aspiration ○ →	R L Imm 6-mths 3-mths Other					
Cyst aspiration ○ →	Additional views ○ ○ → ○ ○ ○ ○					
Core blopsy O >	Ultrasound 0 0 + 0 0 0					
	Core biopsy					
Other ○ →	Open blopsy					
	FNA OO OO OO					
8. Are there prior comparison films/images?	MRI 000 0 0 0					
O No films/Images O Walting for films/Images O N/A	Surgical consult O O → O O O					
○ Yes → If yes, are there changes?	Clinical follow O O → O O O O					
O No changes O Breast density <u>decreased</u>	Nuclear med					
O New finding O Breast density Increased						
O Old finding changed	18. Clinical abnormality? O No O Yes					
7. What is the parenchymal density classification?						
	17. Double read? O No					
O Extremely dense O Scattered fibrodensities O Heterogeneously dense O Entirely fat	17. Double read? ○ No ○ Yes → If yes, date 2 nd reader R assessment L assessment					