Project Title: Factors that Enhance Diagnostic Imaging Safety in the Ambulatory Setting

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Project Dates: 08/01/2016 – 05/31/2021
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Acknowledgment of Agency Support:
This project was supported by the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (HHS) as part of an award totaling $1,685,492 with 0% financed with non-governmental sources. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by AHRQ, HHS, or the U.S. Government.
Grant Number: 1R01HS024722

Abstract

Purpose: Assess the incidence of and types and contributing factors related to diagnostic failures, specifically delayed or missed performance of ambulatory imaging follow-up.
Scope: Aims were to (1) measure incidence of safety events related to diagnostic imaging from reports submitted to an electronic safety reporting system (ESRS) and (2) assess impact of sociotechnical factors on suboptimal ambulatory diagnostic exam follow-up care for lung nodules and BI-RADS 3 breast findings.
Methods: This study was conducted at ambulatory healthcare facilities associated with a large academic hospital. Five information sources were evaluated, including an ESRS. We collected data 2015-2016 to quantify the incidence of potential safety events and their sociotechnical contributors per the Systems Engineering Initiative for Patient Safety framework. Subsequently, we assessed breast imaging exams in patients with an assessment of BI-RADS 3 and CT scans in patients with lung nodules and determined factors associated with optimal follow-up.
Results: All five data sources captured events that potentially lead to patient harm; incidences ranged from 0.5% to 62.1%. Younger age, Hispanic ethnicity, divorced status, and lack of insurance were associated with suboptimal breast imaging follow-up. Care setting was associated with suboptimal pulmonary nodule follow-up completion; exams performed in the Emergency Department had significantly decreased odds of follow-up (OR=0.15).

Keywords: diagnostic failure, diagnostic imaging, patient safety, delayed diagnosis

I. Purpose

The use of diagnostic imaging has increased significantly in the past two decades. In a 15-year study of six large integrated health systems, an estimated 1.18 imaging tests per patient per year were performed, amounting to an estimated 400 million imaging tests performed in the United States each year at an annual cost of approximately $100 billion.[1] Three quarters of these tests are performed in the ambulatory setting.[2] Although diagnostic imaging is predominantly noninvasive, it carries potential patient safety risks.[3-8] In addition, diagnostic errors are magnified when diagnostic imaging is utilized inappropriately and/or when there is no system to monitor diagnostic follow-up.[8,9]

Optimal diagnostic follow-up is critical in order to address the Institute of Medicine's mandate for healthcare professionals to improve the diagnostic testing process, errors in which may lead to missed or delayed diagnoses.[10] Cancer is one of the leading missed diagnoses in diagnostic litigation cases. Lung cancer is the leading cause of cancer deaths in the United States and the most common abnormalities suspicious for lung cancer on CT scan include pulmonary nodules.[11] Standardized follow-up of these nodules impacts early cancer detection, which provides the best chance for survival in patients with lung cancer.[11] Breast cancer is the second leading cause of cancer deaths in women, second only to lung cancer.[12]

We proposed a project to be conducted in a large academic healthcare organization with 183 practices, including 16 primary care ambulatory practices caring for 160,000 patients. A broad exploration of the incidence of and contributing factors to diagnostic failure across diagnostic imaging was undertaken using safety reports in the organization's Electronic Safety Reporting System (ESRS). An additional "deep dive" on the incidence of and types and causes of factors related to failures related to delayed or missed performance of ambulatory imaging follow-up was conducted for incidental pulmonary nodule and BI-RADS 3 findings. Our research approach utilized the Systems Engineering Initiative for Patient Safety 2.0 framework (SEIPS 2.0) to identify contributing factors to diagnostic failures in our ambulatory setting.[13] The two specific aims included:

Aim 1: Measure the incidence of reported safety events that are related to diagnostic imaging from safety reports submitted in the ESRS, identify those that relate to diagnostic imaging failure, and assess the point of failure in the diagnostic imaging chain: patient-physician interaction, test ordering, protocol selection, imaging procedure, and result interpretation/communication.

Aim 2: Report the incidence of suboptimal follow-up and comprehensively assess factors that affect suboptimal diagnostic exam follow-up care in the ambulatory setting for two clinically significant imaging findings with follow-up requirements:
a. Incidental pulmonary nodules; and
b. BI-RADS category 3 breast findings.

II. Scope

Background - Systems Factors

System factors that affect patient safety in diagnostic imaging include workflow and communication processes to ensure that patient care tasks are communicated efficiently and appropriately;[14] hardware and software infrastructure necessary to support clinical applications (e.g., Picture Archiving and Communication System);[15] and the human/computer interface that interferes with or adds additional burden to care providers (e.g., having to perform multiple mouse clicks and page through several computer screens before being able to order a test).[16] In addition, both internal organizational (e.g., institutional policies) and external factors (e.g., national guidelines and rules) provide additional constraints on providing patient care.

The SEIPS 2.0 Model provides a framework for understanding various structures, processes, and outcomes for diagnostic follow-up testing.[13] This model focuses on sociotechnical system design as well as person-centeredness – with design improvements in systems and processes leading to improved outcomes.

Context

We assessed the incidence of reported safety events that are related to diagnostic imaging from safety reports submitted in the ESRS, as stated in Aim 1. In order to more accurately elucidate errors related to diagnostic imaging, we also assessed several other information sources. In total, five information sources were evaluated: the ESRS, the alert notification for critical result (ANCR) system, a Picture Archiving and Communication System (PACS)-based quality assurance (QA) tool, an imaging peer-review system, and an imaging Computerized Physician Order Entry (CPOE) and scheduling system. Using data from these sources, we quantified the incidence of potential safety events (**See List of Publications A**).

To address Aim 2, we measured the incidence of patients receiving suboptimal follow-up among all patients who have recommended follow-up testing (**See List of Publications B**). Incidence rates were reported as the proportion of patients who received suboptimal follow-up out of all patients who had recommended follow-up testing for incidental pulmonary (lung) nodules and BI-RADS level 3 breast findings. Suboptimal follow-up was defined as follow-up examinations that were recommended but were missed or delayed, unless the following exceptions applied:

1. The PCP decided and documented that follow-up was no longer necessary.
2. The patient died.
3. The patient moved to another location/practice.
4. The patient refused recommended follow-up care.

This incidence rate more accurately reflects the rate of failure based on all patients who require follow-up. We then assessed factors related to delayed or missed performance of diagnostic exam follow-up for lung nodules and BI-RADS-3 breast findings, using data about factors in the diagnostic imaging chain captured in our safety net initiative for follow-up monitoring.

Study Setting and Participants

The study site, Brigham and Women's Hospital (BWH), consists of a 777-bed university-affiliated tertiary care hospital with 44,000 inpatient admissions, 950,000 ambulatory visits, and 54,000 emergency department (ED) visits annually. The institution's outpatient network spans 183 practices, with 16 primary care ambulatory practices caring for 160,000 patients. Study sites included all BWH-affiliated ambulatory healthcare facilities that utilize radiologic imaging at BWH. These sites all utilize an enterprise-wide, fully integrated CPOE system that integrates imaging order entry for all levels of patient care. The system handles all imaging orders from off-site ambulatory facilities, inpatient care, and associated ED. The study population included all patients over 17 years of age for whom one or more ambulatory diagnostic imaging tests are performed during the study period. Within the study site, all of the ordering clinicians and radiologists were also participants.

Health Information Technology Enhancement

We implemented a follow-up system (**See List of Publications C**), which was incorporated into the critical alert notification system. Originally referred to as Radiology Result Alert and Development of Automated Resolution (RADAR)[17-19] and eventually renamed Addressing Radiologist Recommendations Collaboratively (ARRC), the system provides a process to notify ordering providers, attending physicians, and primary care providers regarding recommended follow-up management for diagnostic imaging findings. More importantly, it also enables collaborative planning between care providers. This enabled us to assess suboptimal diagnostic exam follow-up care in the ambulatory setting for the two clinically significant findings with follow-up requirements - incidental lung nodules and BI-RADS 3 findings.

In addition, we implemented a natural language processing (NLP) tool (**See List of Publications D**) to assist in identifying cohorts of patients for analysis, especially for those who did not use ARRC. We trained and developed the NLP tool using a machine learning algorithm to assess follow-up recommendations in radiology reports.[20,21]

Incidence and Prevalence

For Aim 1, we measured the incidence rate of diagnostic failure due to diagnostic imaging as a proportion of all reported safety events in ESRS. A previous estimate of radiology-related safety events reported outcomes related to patient diagnosis in 12% of cases.[22] Incidence identified in this study is reported below in Results.

For Aim 2, we measured the incidence of suboptimal follow-up for pulmonary nodules and BI-RADS category 3 breast imaging findings. In our study assessing patients with pulmonary nodules pre-ARRC, the incidence of suboptimal follow-up for pulmonary nodules was 39/110 (35.5%). Post-ARRC, the incidence of suboptimal follow-up was 17/108 (15.7%), which was decreased significantly (p=0.001). In another study wherein we assessed other factors that were associated with suboptimal follow-up in patients with pulmonary nodules, the incidence of suboptimal follow-up (without ARRC) was 35.7% (82/230). In assessing suboptimal follow-up for patients with BI-RADS category 3 breast imaging findings, we calculated an incidence of 386 of 1,511 patients (26%).

III. Methods

A. Assessing Information Sources (including ESRS) that can Further Elucidate Diagnostic Imaging Errors

Study Design

We assessed potential safety events related to diagnostic imaging identified from five information sources: ESRS, an imaging interpretation radiology peer review program, a PACS-based QA system, an imaging CPOE and scheduling system, and an ANCR system. The ESRS is institution-wide, although we limited the study to safety events reported in ESRS that concern diagnostic imaging. All the other information sources are radiology-specific and integrated into the radiology information system.

Data Sources

Each information source was categorized into diagnostic imaging chain steps that were impacted by events reported in the information source, and what sociotechnical factors contributed to these events per the SEIPS framework. The structural component of SEIPS 2.0 is the Work System, which includes a combination of sociotechnical factors – Person, Tasks, Tools and Technology, Organization and Environment. Finally, events were classified into whether they could cause potential harm. The study period for four information sources (ESRS, radiology peer review program, PACS-based QA system, and ANCR) was January 1, 2015, through December 31, 2015; data from the imaging CPOE and scheduling system were limited to January 1, 2016, through October 21, 2016, due to technical limitations in obtaining CPOE data for 2015.

Measures

The primary outcome measure was the incidence of safety events, calculated as the proportion of "potential harm" events to the total number of events recorded. Incidence was calculated separately for each information source (excluding the PACS-based QA forms). As secondary outcome measures, we included the number of imaging chain steps elucidated in each information source, and the number of relevant sociotechnical factors responsible for events in each information source. We enumerated contributory factors, classified into SEIPS sociotechnical categories.

B. Factors Associated with Suboptimal Follow-up (Breast Findings and Pulmonary Nodules)

BI-RADS 3 Breast Findings:

Study Design and Data Sources

We conducted a 12-month study (January 1, 2016, – December 31, 2016) to evaluate follow-up imaging. All radiology reports corresponding to eligible breast imaging during the study period were retrieved from the imaging data repository populated by Epic (Epic Systems Corporation, Madison, WI). The Institutional Research Data Warehouse was used to extract (1) patient-specific features, including age, race, marital status, previous breast cancer and other concurrent malignancies, as well as insurance coverage, and (2) provider-related features, including referring provider site (i.e., urban academic medical center, community teaching hospital, cancer institute, or outpatient facilities), and referring provider specialty (e.g., medicine, surgery, obstetrics). Referring provider site was coded as "other" for referring providers with no listed affiliations. In addition, diagnostic exams performed at outside facilities and documented in physician notes were noted.

Other information extracted from the imaging data repository included presence of follow-up breast imaging within 1 year from the index report date, performed on the same breast. Modality was classified into mammography (with or without ultrasound) and ultrasound alone. The Institutional Cancer Registry was used to identify patients diagnosed with breast cancer at the study institution. BI-RADS 3 assessment and breast density were retrieved using a natural language processing application that has been previously validated.

Measures

The unit of analysis included unique patients who had eligible breast imaging exams with BI-RADS 3 findings. The primary outcome measure - rate of *optimal follow-up* - was calculated as all patients with follow-up breast imaging 3 to 9 months from the index exam out of all patients with BI-RADS 3 findings in an index exam within the study period. Patients with follow-up performed after 9 months and those with no-follow-up up to 1 year from the index exam were counted as not having optimal follow-up (i.e., suboptimal follow-up). Patients with breast imaging within 3 months from the index case were excluded from analysis, because these examinations may have been performed for other reasons, given that they are earlier than recommended for BI-RADS 3 findings. A secondary outcome - malignancy rate - was recorded for the study cohort as all patients diagnosed with breast cancer as of December 31, 2017. Time to malignancy detection was recorded, including the mean time for all patients in the study cohort as well as the mean time for those with optimal follow-up and those without (i.e., suboptimal follow-up).

Univariate analysis was performed on all patient-related and provider-related factors collected, using the chi-squared statistic for categorical variables and logistic regression for continuous variables. Multivariable logistic regression was used to assess optimal follow-up by modeling patient- and provider-related factors. T-test was used to assess time to malignancy detection. We used the presence of optimal follow-up as the outcome variable for our model.

Pulmonary Nodules:

Study Design and Data Sources

This institutional review board–approved, retrospective cohort study was conducted from January 1, 2016, to December 31, 2016, to evaluate pulmonary nodules in adult patients completing a chest, abdomen/pelvis, or spine CT scan during the study period. Radiology reports for patients in the sampling frame were extracted from a data repository populated by the electronic health record (EHR) (Epic Systems Corporation, Madison, WI). To determine whether a radiology report contained a pulmonary nodule, a previously validated NLP tool was used, as described earlier under Health Information Technology Enhancement. We randomly selected 362 reports from the eligible study population. All 362 reports were manually and independently reviewed by two research fellows individually with a 30% overlap to verify the presence of pulmonary nodules and check for concurrent malignancy, imaging nodule features (nodule size, number of nodules [single or multiple], location [upper lobe, laterality], morphologic features [calcification, spiculation], and density [solid, part-solid, ground-glass]), and presence of follow-up recommendations in the report. Discrepancies were resolved by consensus. Of 362 reports, 230 were assessed to require follow-up by experts. Subsequently, the need for follow-up in the remaining reports was reviewed by a radiology fellow after discussions with the thoracic radiologists. The need for follow-up was determined based on Fleischner Society recommendations.[23]

The warehouse was also used to extract (1) patient-specific features, including sex, age, race, and concurrent malignancies, and (2) organization-related features, including having an in-network primary care physician, imaging examination type (e.g., chest CT), ordering care setting (inpatient, outpatient, or ED), and whether the provider used ANCR to report the presence of pulmonary nodules. Other information extracted included pathology reports and chest CT reports within 1 year from the index report date, including reports from other institutions recorded in our EHR, and lung malignancy reported to the cancer registry up to 3 years from the report date.

Measures

Two primary outcome measures were (1) rate of follow-up completion, defined as either a lung biopsy or repeat chest CT performed within 1 year from the date of the index imaging when a pulmonary nodule was identified, and (2) rate of follow-up completion limited to patients with pulmonary nodules assessed by experts to require follow-up. We also identified factors that were significantly associated with follow-up completion in the subset of patients assessed by experts to require follow-up.

Pulmonary Nodule Follow-up post-RADAR:

Study Design and Data Sources

Pulmonary nodules identified on chest imaging ordered by primary care providers (PCPs), performed between February 1, 2017, and March 31, 2019, and with at least 1 year of follow-up were evaluated after RADAR was implemented on March 1, 2018, consisting of (1) a novel, electronic communication tool enabling radiologist-generated alerts with time frame and modality for incidental pulmonary nodule follow-up recommendations and (2) a safety net team for centralized care coordination to ensure that communication loops were closed.

Measures

The primary outcome measure was timely follow-up of the pulmonary nodule, defined as execution of collaborative follow-up care plans in the recommended time frame (within ± 30 days). In the preintervention cohort, not all radiology reports had specific follow-up recommendations with time frame or modality explicitly stated. If an explicit time frame was not stated, then follow-up was defined as imaging completion within 1 year of the exam date. We defined late follow-up as completion of the follow-up imaging study within 6 months of the recommended time frame. For preintervention alerts in which an explicit time frame was not stated, late was defined as imaging completion within 18 months of the original exam date.

C. Other Factors Contributing to Diagnostic Errors

Study Design and Data Sources

We demonstrated clinically necessary diagnostic imaging orders that remain unscheduled represents an important risk factor for diagnostic delays in medicine. In a human factors analysis of various information sources to inform diagnostic process errors, the EHR and CPOE system were demonstrated to contain unscheduled orders for diagnostic imaging examinations that were potential safety events.[24] These events included unscheduled orders that were clinically necessary for acute, episodic, or follow-up care, clinically unnecessary duplicate orders, and duplicate orders created during exam planning by radiologists (protocoling).

We identified radiology exam orders placed in the EHR (Epic v. 2014, Madison, WI) during a 10-month period between January and October 2016. We identified all radiology exam orders placed using the CPOE module of the EHR during the study period that had not been scheduled by December 1, 2016 (at least 1 month from the date the order was placed). We did not include expired orders, which can no longer be scheduled. We then identified all radiology exam orders that remained unscheduled for analysis. We identified orders for the following seven modalities, excluding nuclear medicine and interventional radiology, from the unscheduled radiology exam orders: Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Obstetric US, Bone Densitometry (DXA), Mammogram (MG), and Fluoroscopy (FL); these orders comprised the study cohort. From the study cohort of unscheduled radiology exam orders, 100 orders were randomly selected from each modality, and assigned to two individual reviewers for classification – a physician who is a radiology research fellow and a senior clinical radiology fellow. They classified the unscheduled orders into two major categories – clinically necessary and clinically unnecessary – based on review of the EHR to reflect the intent of the ordering provider.

Measures

The primary outcome measure was the prevalence of unscheduled radiology exam orders among all orders placed during the study period. In addition, the percentage of unscheduled radiology exam orders that were classified as clinically necessary and clinically unnecessary was assessed and compared by modality. Prevalence of unscheduled orders was calculated as a percentage.

Effects of COVID-19 on Diagnostic Examination Utilization

Study Design and Data Sources

While assessing diagnostic examination utilization, we noted significant decreases in diagnostic radiology utilization during the early stages of the coronavirus disease 2019 (COVID-19) pandemic. Because social determinants of health were identified as factors that influence diagnostic radiology examination utilization pre-pandemic, we assessed diagnostic radiology examination utilization and associated social determinants of health during early stages of reopening after a state-mandated shutdown of nonurgent services because of COVID-19.

Between March 9, 2020, and June 6, 2020, all nonurgent health care services in Massachusetts were deferred, per a statewide COVID-19 mandate. Therefore, the sampling frame for this assessment included all adult patients who completed a diagnostic radiology examination between January 1, 2020, and March 8, 2020, or between June 7, 2020, and July 15, 2020 (post-COVID-19 shutdown).

All radiology reports and imaging examinations for patients in the sampling time frames were identified and retrieved from the institutional research data repository populated by the electronic health record (Epic Systems Corporation, Madison, WI). Corresponding patient features were extracted from the repository, including age, sex, race, ethnicity, marital status, health insurance, and zip code. Last, we extracted the patient care setting (inpatient, outpatient, or ED) and imaging modality (CT scan, dual energy x-ray absorptiometry, mammography, MRI, ultrasound, and x-ray). Zip codes were used to identify patients coming from priority populations in our community, areas with persistent racial and ethnic inequities in healthcare.[25,26] The priority populations in our community were identified previously by a hospital-sponsored community health needs assessment based on disproportionate burden of poverty, housing instability, and other social determinants of health, along with citywide health equity studies.

Measures

The primary outcome measure was the mean number of diagnostic radiology examinations per day post-COVID-19 shutdown and the proportion of post-COVID-19 shutdown examinations compared with pre-COVID-19 shutdown. We also assessed factors that may be associated with completing a diagnostic radiology examination post-COVID-19 shutdown, including social determinants of health (e.g., race, ethnicity, health insurance, coming from priority population), care setting, and imaging modality.

IV. Results

A. Assessing Information Sources (including ESRS) that Can Further Elucidate Diagnostic Imaging Errors

Principal Findings and Outcomes

Of 11,570 safety reports submitted in the ESRS, 854 (7%) were related to diagnostic imaging.[27] Among these safety reports, there was 22.2% incidence of potential harm. However, all five data sources captured events that potentially lead to patient harm (Table 1); the incidence of potential safety events ranged from 0.5% to 62.1% across the data sources.[24]

Table 1: Number and incidence of safety events by information source

Source	Total number of safety events reported in study period	Number of events reviewed	Number of potential patient harm events	Incidence of potential harm events
ESRS	11,570	854*	190	22.2%
Radiology peer review program	12,320	12,320	67	0.5%
PACS-based QA form	695	695	40	5.8%

Source	Total number of safety events reported in study period	Number of events reviewed	Number of potential patient harm events	Incidence of potential harm events
Imaging ordering CPOE system	33,546	630[**]	391	62.1%
ANCR	8,536	8536	194	2.3%

[*]Diagnostic imaging events only.
[**]Randomly selected for manual review.

Each of the information sources contributed to elucidating diagnostic process errors in various steps of the diagnostic imaging chain (Table 2).[24] In the ESRS, errors were assessed to occur at all points of the diagnostic chain, including patient-physician interaction, test ordering, protocol selection, imaging procedure, and result interpretation/communication. Although the most common step was imaging procedure (54% of reports), potential harm occurred more in result communication (odds ratio: 2.36; *P*=.05). Person factors most commonly contributed to safety reports (71%).[27]

Table 2: Classification of Data Sources by Imaging Chain Steps and Socio-Technical Factors Elucidated

Source	**# of Steps**	**Imaging Chain Steps**	**# of Socio-Technical Factors**	**Socio-Technical Factors**
ESRS	9	• Physician patient discussion • Provider discussion • Test ordering • Test scheduling • Test protocolling • Imaging procedure • Image interpretation • Reporting • Report communication	6	• Person • Task • Tools and Technology • Organization • Internal Environment • External Environment
Radiology Peer Review Program	1	Image interpretation	1	Person
PACS-based QA Form	1	Imaging procedure	3	• Person • Tools and Technology • Task
Imaging Ordering CPOE System	2	• Test ordering • Test scheduling	2	• Person • Tools and Technology
ANCR	1	Report communication	2	• Person • Tools and Technology

Subsequently, we assessed a system-based approach to event investigation and analysis, referred to as collaborative case reviews (CCRs), to measure impact of clinical specialty on strength of action items prescribed to address safety events.[28] Seventy-three CCRs in 2018 generated 260 action items from 10 specialties. Seventy percent (51/73) were adverse events identified through the ESRS.

The specialty most frequently associated with CCR was radiology (16/73, 22%). Most action items (204/260, 78%) were completed in 1 year; stronger action items were completed in 71 (27%) of 260.[28]

Discussion and Conclusions

We recognized that, although there appears to be a substantial percentage of potentially harmful events readily visible in the ESRS and CPOE, this data source does not take into account the magnitude of potential harm to patients and the variability in reporting. Thus, although the ESRS highlights potential harms resulting from ordering an imaging examination on the wrong side of the body, these are recognized and reported readily. On the other hand, errors in interpreting images by a physician, or failure in communicating critical results to another care provider, are potential errors that are more difficult to recognize and are likely to be less frequently reported. Thus, the percentage of potential harms vary in data sources, institutions, and settings – reflecting variability in percentage of reporting, recognition, and magnitude of impact; these therefore should be monitored more diligently in future studies.

Significance and Implications

There are multiple information sources that can inform diagnostic process errors related to diagnostic imaging. These sources provide insight into factors that impact patient safety. Some of these factors are related to task complexity and internal environment. These are modifiable factors that can be addressed in a systematic manner by healthcare institutions. More importantly, they can inform decisions to enhance diagnostic processes in general. Monitoring various information sources regularly should be performed more diligently by all healthcare institutions. In addition, active engagement in case reviews (i.e., CCR) can provide insights into addressing adverse events and promote patient safety and should therefore be encouraged.

B. Factors Associated with Suboptimal Follow-up (Breast Findings and Pulmonary Nodules)

Principal Findings and Outcomes

BI-RADS 3 Breast Findings: In 2016, 93,685 breast imaging exams were performed for 64,771 unique women. Of these, 5,229 exams (5.6%) were given a BI-RADS 3 assessment, 2,967 (4.6%) of which were from unique patients. Excluding those with index exams performed elsewhere, 1,721 imaging reports belonging to unique women were included. Of these 1,721 reports, 135 (8%) were excluded as they had another breast imaging examination performed less than 3 months from the index exam and another 75 were excluded because they were breast MRI, leaving 1,511 imaging reports belonging to unique women (2.4%) in the study cohort.1,125 of 1,511 women (74%) had optimal follow-up, with 26% having suboptimal or no follow-up.[29]

On multivariable analysis (Table 4), prior breast cancer and having a cancer institute as the referring provider site were significantly associated with more optimal follow-up. Younger patient age and divorced status were associated with less optimal breast imaging follow-up. Analysis considering race and ethnicity showed Asian women had more optimal follow-up, but Hispanic women had less optimal follow-up, compared to White women. Finally, lack of insurance coverage was associated with less optimal follow-up.[29]

Pulmonary Nodules: In 2016, 43,744 CT reports were extracted for the study period. Applying the NLP tool identified 6,283 patients with incidental pulmonary nodules and no known lung malignancy (14%). The rate of follow-up completion in our cohort was 187 of 362 (51.7%); 230 of 362 (63.5%) patients were assessed to require follow-up, and, of these, 148 had follow-up completion (64.3%). Of the remaining patients who were assessed to not require follow-up, 39 of 132 (29.5%, P<.00001) had follow-up completion.[30]

On multivariable analysis, the only significant factor associated with follow-up completion was care setting. Imaging ordered in the ED had decreased odds of follow-up (odds ratio: 0.15).[30]

Pulmonary Nodule Follow-up post-RADAR: When comparing on-time follow-up for pulmonary nodules in the preintervention vs. postintervention cohort, the rate increased from 71 of 110 (64.5%) to 91 of 108 (84.3%) following implementation of RADAR (P=.001).

The analytics feature of RADAR updated the list of patients without timely performance of collaborative care plans weekly, so each patient could be easily identified by the care coordination or safety net teams for outreach. When assessing pulmonary nodule follow-up as either on time or late, 87 of 110 (79.1%) pulmonary nodules were followed up prior to RADAR, compared to 102 of 108 (94.4%) followed up post-RADAR implementation (*P*=.0009). Only 2.8% of follow-up examinations were not completed post-RADAR implementation compared with 20.9% in the preintervention cohort.[18]

Table 3: Multivariable analysis of patient- and provider- related factors on optimal follow-up of BI-RADS 3 breast findings

Effect	Odds Ratio	95% Confidence Interval	
Age	1.011 *	1.000	1.021
Race			
White	Reference		
Asian	2.249 *	1.193	4.581
African-American	0.864	0.574	1.322
Hispanic	0.645 *	0.430	0.975
Other	1.022	0.637	1.684
Marital Status			
Married	Reference		
Divorced	0.527 *	0.331	0.849
Unknown	0.863	0.552	1.377
Single	0.916	0.680	1.239
Insurance Status			
Private	Reference		
Public	0.816	0.567	1.183
None	0.503 *	0.368	0.689
Provider Site			
Academic medical center	Reference		
Community teaching hospital	1.253	0.624	2.676
Cancer institute	4.925 *	1.698	15.696
Other	0.535	0.288	1.013
Outpatient facilities	1.442	0.952	2.217
Unaffiliated	2.159	0.956	4.889
Provider Specialty			
Medicine	Reference		
OB-GYN	0.998	0.677	1.484
Surgery	1.058	0.668	1.706
Unaffiliated	0.535	0.248	1.154
Cancer			
Prior breast cancer	1.685 *	1.022	2.779
Prior other cancer	0.754	0.546	1.041
Modality			
Mammography	Reference		
Ultrasound	0.550 *	0.400	0.758

* Statistically Significant

Other Factors Related to Suboptimal Follow-up: We identified multiple other factors that were associated with variability in follow-up recommendations, including (1) inter-radiologist variation in making follow-up recommendations within subspecialties[31] as well as between subspecialties (liver lesions seen by breast vs. abdominal radiologists),[32] (2) lack of physician agreement with recommendations within guidelines,[33] and (3) lack of completeness and concordance in documenting exam indications in order requisitions[34] as well as imaging findings in radiology reports.[35]

Discussion and Conclusions

Multiple factors are related to suboptimal diagnostic follow-up. In patients with BI-RADS 3 breast findings, prior breast cancer, older patient age, and married status were associated with optimal follow-up on univariate analysis and remained significant on multivariable analysis. Patients seen at a cancer institute and those who had insurance coverage also had more optimal follow-up. Previous studies have also noted more optimal follow-up in a group of women with prior history of breast cancer.[36] Marital status also appears to confer an advantage in having optimal follow-up. Perhaps, more attention should be focused on improving follow-up in unmarried women. In addition, the effect of social determinants on cancer prevention (e.g., younger Hispanic women, no insurance noted) is evident when examining disparities in mammography use.

For pulmonary nodules, a factor associated with follow-up completion was care setting. Imaging ordered in the ED had decreased odds of follow-up (odds ratio: 0.15). Incidental findings in ED imaging are often not communicated to the responsible provider, highlighting the need for improved handoff processes. Specific interventions, like a closed-loop communication tool to establish a follow-up care plan,[17] may be useful to further increase follow-up completion, especially in managing patients who span multiple care settings, and diminish potentially clinically unnecessary examinations.

Post-RADAR, another significant factor that increased the rate of on-time follow-up imaging is the RADAR system. By improving the processes of pulmonary nodule identification, communication, and follow-up, standard practices implemented through a radiology care coordination team provide a more reliable system for affecting diagnostic error in the ambulatory setting.

Significance and Implications

More active management of unresolved BI-RADS 3 using electronic audit tools, commonly available in breast imaging practices, could be utilized. Future studies should focus on follow-up disparities so that effective interventions may be designed and implemented.

Our study also demonstrates the value of a closed-loop system for abnormal test result follow-up, from pulmonary nodule identification to the point at which the patient receives a follow-up imaging study. Prior studies have leveraged technology for enhancing adherence to clinical guidelines. However, none have developed systems that can generate a collaborative care plan, assist with scheduling and patient outreach, or track follow-up completion---all essential features of our information technology–enabled QI initiative using RADAR.

C. Other Factors Related to Diagnostic Errors (Unscheduled Exams)

Principal Findings and Outcomes

Unscheduled Exams

In a study of orders placed in the first 10 months of 2016, 494,503 radiology exam orders were placed during the study period. After exclusions, 33,546 unscheduled orders were identified, representing 7% (33,546/494,503) of all radiology exam orders. Among 700 reviewed unscheduled orders, 87% of DXA examinations and 65% of mammograms were considered clinically necessary, primarily for follow-up management. Large numbers of radiology exam orders remain unscheduled in the EHR.[37] A substantial portion were clinically necessary, representing potential delays in executing documented provider care plans.

We subsequently designed and implemented a System for Coordinating Orders for Radiology Exams (SCORE), which aims to manage unscheduled orders for outpatient diagnostic imaging and assessed the impact of SCORE and other related factors (e.g., demographics) on rate of unscheduled orders.[38]

Pre-SCORE, 52,204/607,020 exam orders were unscheduled (8.6% of orders) compared to 20,900/475,000 exam orders (4.4% of orders) post-SCORE (χ^2, P<.00001), a 49% reduction in unscheduled orders.

Among 447 randomly selected orders, orders were addressed via cancellation (57%), expiration (21%), scheduling (1%), and performance (11%). SCORE may help reduce errors resulting from diagnostic delays due to unscheduled exam orders.

Effects of COVID-19 on Diagnostic Imaging Utilization
We demonstrated that a marked decrease in radiology examination utilization persisted in all care settings after COVID-19 shutdown (869 examinations per day pre-shutdown [39] versus 502 examinations per day post-shutdown [39]), with more significantly decreased odds ratios for having examinations in inpatient and outpatient settings versus in the ED. Inequities worsened, with patients from communities with high rates of poverty, unemployment, and chronic disease having significantly lower odds of undergoing radiology examinations after COVID-19 shutdown. Patients of Asian race and Hispanic ethnicity had significantly lower odds ratios for having examinations after COVID-19 shutdown compared with White and non-Hispanic patients, respectively.

Discussion and Conclusions
Identifying and performing clinically necessary unscheduled radiology exam orders may help reduce diagnostic errors related to diagnosis and treatment delays and enhance patient safety, and eliminating clinically unnecessary unscheduled orders will help avoid unneeded testing. A system to manage these unscheduled orders (i.e., SCORE) resulted in improved overall performance and reliability in resolution of unscheduled diagnostic exam orders, eliminating those that were not appropriate and expediting those that were clinically necessary.

Finally, another factor that impacted diagnostic imaging utilization was the COVID-19 pandemic. The COVID-19 pandemic exacerbated known pre-existing inequities in diagnostic radiology utilization. Resources should be allocated to address subgroups of patients who may be less likely to receive necessary diagnostic radiology examinations, such as patients of Asian race and Hispanic ethnicity, who had significantly lower odds ratios for having examinations post-COVID-19 shutdown, potentially leading to compromised patient safety and quality of care.

Significance and Implications
A system-based approach to unscheduled diagnostic imaging orders is necessary to complete the diagnostic process expeditiously. This may reduce errors resulting from delays in diagnostic management, thus promoting patient safety. Such approaches include systems to manage unscheduled diagnostic exam orders (i.e., SCORE) and those that include a care coordination system that incorporates analytics and risk estimation to identify persons at high risk for suboptimal follow-up, which could reduce follow-up disparities.

V. List of Publications and Products

A. Assessing Information Sources (including ESRS) that can Further Elucidate Diagnostic Imaging Errors

1. Cochon L, Lacson R, Wang A, Kapoor N, Ip IK, Desai S, Kachalia A, Dennerlein J, Benneyan J, Khorasani R. Assessing Information Sources to Elucidate Diagnostic Process Errors in Radiologic Imaging - A Human Factors Framework. J Am Med Inform Assoc. 2018 Nov 1;25(11):1507-1515. doi: 10.1093/jamia/ocy103. PMID: 30124890; PMCID: PMC7646913.
2. Lacson R, Cochon L, Ip I, Desai S, Kachalia A, Dennerlein J, Benneyan J, Khorasani R. Classifying Safety Events Related to Diagnostic Imaging from a Safety Reporting System using a Human Factors Framework. J Am Coll Radiol. 2019 Mar;16(3):282-288. doi: 10.1016/j.jacr.2018.10.015. PMID: 30528933; PMCID: PMC7537148.
3. Lacson R, Khorasani R, Fiumara K, Kapoor N, Curley P, Boland GW, Eappen S. Collaborative Case Review: A Systems-Based Approach to Patient Safety Event Investigation and Analysis. J Patient Saf. 2022 Mar 1;18(2):e522-e527. doi: 10.1097/PTS.0000000000000857. PMID: 35188937; PMCID: PMC8855947.

B. Incidence and Factors Associated with Suboptimal Follow-up (Breast Findings and Pulmonary Nodules)

4. Lacson R, Wang A, Cochon L, Giess C, Desai S, Eappen S, Khorasani R. Factors Associated With Optimal Follow-up in Women with BI-RADS 3 Breast Findings. J Am Coll Radiol. 2020 Apr;17(4):469-474. doi: 10.1016/j.jacr.2019.10.003. PMCID: PMC7509994.
5. DiPiro PJ, Alper DP, Giess CS, Glazer DI, Lee LK, Lacson R, Khorasani R. Comparing Breast and Abdominal Subspecialists' Follow-Up Recommendations for Incidental Liver Lesions on Breast MRI. J Am Coll Radiol. 2020 Jun;17(6):773-778. doi: 10.1016/j.jacr.2019.12.024. PMCID: PMC7549431.
6. Lacson R, Laroya R, Wang A, Kapoor N, Glazer D, Shinagare A, Ip I, Malhotra S, Hentel K, Khorasani R. Integrity of Clinical Information in Computerized Order Requisitions for Diagnostic Imaging. J Am Med Inform Assoc. 2018 Dec 1;25(12):1651-1656. doi: 10.1093/jamia/ocy133. PMID: 30517649; PMCID: PMC7647161.
7. Cochon L, Kapoor N, Carrodeguas E, Ip I, Lacson R, Boland G, Khorasani R. Variation in follow-up imaging recommendations in radiology reports: Patient, modality, and radiologist predictors. Radiology. 2019 Jun;291(3):700-707. doi: 10.1148/radiol.2019182826. PMID:31063082; PMCID: PMC7526331.
8. Kapoor N, Lacson R, Hammer M, Cochon L, DiPiro P, Boland GW, Khorasani R. Physician Agreement with Recommendations Contained in a National Guideline for the Management of Incidental Pulmonary Nodules: A Case Study. J Am Coll Radiol. 2020 Nove;17(11):1437-1442. doi: 10.1016/j.jacr.2020.07.020. PMID: 32783898; PMCID: PMC7655688.
9. Lacson R, Cochon L, Ching PR, Odigie E, Kapoor N, Gagne S, Hammer MM, Khorasani R. Integrity of clinical information in radiology reports documenting pulmonary nodules. J Am Med Inform Assoc. 2021 Jan 15;28(1):80-85. doi: 10.1093/jamia/ocaa209. PMID: 33094346; PMCID: PMC7810451.
10. Lacson R, Licaros A, Cochon L, Hammer M, Gagne S, Kapoor N, Khorasani R. Factors Associated With Follow-up Testing Completion in Patients With Incidental Pulmonary Nodules Assessed to Require Follow-up. J Am Coll Radiol. 2022 Mar;19(3):433-436. doi: 10.1016/j.jacr.2021.11.019. PMID: 35123957.
11. Addressing Radiologist Recommendations Collaboratively: Predictors of Follow-up Imaging Completion. (Submitted).

C. Health Information Technology Enhancement

12. Hammer MM, Kapoor N, Desai S, Sivashanker K, Lacson R, Demers JP, Khorasani R. Adoption of a closed-loop communication tool to establish and execute a collaborative follow up plan for incidental pulmonary nodules. AJR Am J Roentgenol. 2019 Feb 19:1-5. doi: 10.2214/AJR.18.20692. PMID: 30779667; PMCID: PMC7528936.
13. Emani S, Sequist TD, Lacson R, Khorasani R, Jajoo K, Holtz L, Desai S. Ambulatory Safety Nets to Reduce Missed and Delayed Diagnoses of Cancer. Jt Comm J Qual Patient Saf. 2019 Aug;45(8):552-557. doi: 10.1016/j.jcjq.2019.05.010. PMCID: PMC7545363.
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D. Natural Language Processing Tools

15. Carrodeguas E, Lacson R, Swanson W, Khorasani R. Use of Machine Learning to Identify Follow-Up Recommendations in Radiology Reports. J Am Coll Radiol. 2019 Mar;16(3):336-343. doi: 10.1016/j.jacr.2018.10.020. PMID: 30600162; PMCID: PMC7534384.
16. Lacson R, Eskian M, Licaros A, Kapoor N, Khorasani R. Machine Learning Model Drift: Predicting Diagnostic Imaging Follow-Up as a Case Study. J Am Coll Radiol. 2022 Aug 16;S1546-1440(22)00551-8. doi: 10.1016/j.jacr.2022.05.030. Online ahead of print.

E. Other Factors Contributing to Diagnostic Errors (Unscheduled Exams)

17. Lacson R, Healey MJ, Cochon LR, Laroya R, Hentel KD, Landman AB, Eappen S, Boland GW, Khorasani R. Unscheduled Radiologic Examination Orders in the Electronic Health Record: A Novel Resource for Targeting Ambulatory Diagnostic Errors in Radiology. J Am Coll Radiol. 2020 Jun;17(6):765-772. doi: 10.1016/j.jacr.2019.12.021. PMCID: PMC7509985.
18. Lacson R, Gujrathi I, Healey M, Fanning K, Morisset F, Hooton S, Landman A, Eappen S, Boland GW, Khorasani R. Closing the Loop on Unscheduled Diagnostic Imaging Orders: A Systems-Based Approach. J Am Coll Radiol. 2021 Jan;18(1 Pt A):60-67. doi: 10.1016/j.jacr.2020.09.031. PMID: 33031782.
19. Lacson R, Shi J, Kapoor N, Eappen S, Boland GW, Khorasani R. Exacerbation of Inequities in Use of Diagnostic Radiology during the Early Stages of Reopening after COVID-19. J Am Coll Radiol. 2021 May;18(5):696-703. doi: 10.1016/j.jacr.2020.12.009. PMID: 33482115; PMCID: PMC7834847.

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