

***Grant Final Report***

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**Using Electronic Data to Improve Care of Patients with  
Known or Suspected Cancer**

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# Structured Abstract

**Purpose:** The goal of this project was to test the use of health information technology (HIT) to identify patients with delays in diagnosis of certain cancers and facilitate their movement through the health care system.

**Scope:** Delays in cancer diagnosis continue to occur despite improved availability of diagnostic information through advanced EHRs. We built upon our previous and ongoing work in innovative data mining techniques to identify patients likely to have delays in cancer diagnosis, and we facilitated their care processes using electronic communication and surveillance.

**Methods:** First, we developed and tested the use of new triggers to identify patients with delays and conducted chart reviews to determine trigger performance. Then, we recruited providers on a voluntary basis and randomized them to intervention or control. Providers in the intervention group received electronic communications and surveillance if potential delays on their patients were identified by triggers.

**Results:** Triggers were successfully developed and achieved positive predictive values (PPVs) greater than 50%. Using a randomized controlled trial design, we applied the trigger to all patients cared for by study providers for 15 months and were able to improve time to follow-up of prostate and colorectal cancer.

**Key Words:** electronic health records; health information technology; HIT; triggers; diagnostic error; diagnostic delays; medical informatics; primary care; cancer

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# Final Report

## Purpose

The goal of this proposal was to test the use of HIT to identify patients with cancer related diagnostic delays and to facilitate their movement through the health care system. Patients with known or suspected cancer have complex health care needs that are served by several different facets of ambulatory care. Their diagnosis involves multiple sites of care and coordination among several disciplines, a process sometimes characterized by process breakdowns.[1-7] The survival benefit conferred by early diagnosis of many types of cancer (e.g., colon, breast, lung)[8,9] can be unnecessarily lost due to delays in patient movement among settings of care.[5] Our preliminary work showed that diagnostic process breakdowns may originate in several ambulatory care settings (e.g., primary care practitioner offices and specialty services such as gastroenterology and radiology)[5,10,11] and in navigation[12] of patients among these systems of care. Given that cancer patients in general are older and have a high comorbidity burden,[13] it is critical to improve the coordination of their management.[14] Preventing process breakdowns makes care patient-centered and efficient and improves health outcomes.[1,15-18]

Health IT has the potential to facilitate communication and coordination of care between several disciplines and settings that constitute ambulatory care. In cancer care, the concept of patient navigation has been proposed to minimize barriers in the movement of patients through the complex cancer care system and thereby help ensure timely diagnosis.[19] However, key questions remain on how to identify patients likely to experience diagnostic delays among tens of thousands of patients seen at a healthcare facility. This project sought to address the challenge in detecting these patients.

Our specific aims were:

**Aim 1: To identify patients with cancer-related diagnostic delays using “trigger”-based data mining of an electronic health records (EHR) repository.**

More specifically, our objective was to design and evaluate EHR-based triggers to identify diagnostic delays related to lack of follow-up of key alarm features of prostate and colorectal cancer diagnosis.[20] Successful development of such triggers could help create a future back-up system to prospectively detect patients at risk of prolonged delays in cancer diagnosis.

**Aim 2: To determine the effectiveness of an IT-based intervention (consisting of data mining using triggers tested in Aim 1 followed by targeted electronic communication and surveillance techniques) to facilitate cancer diagnosis as compared with usual care.**

In other words, the goal was to evaluate whether a trigger-based intervention was effective at reducing delays in diagnostic evaluation for cancer.

## **Inclusion of AHRQ Priority Populations:**

Our study recruited providers from two diverse health systems: the Houston Michael E. DeBakey VA Medical Center, a mixed rural/urban system that cares for an elderly population with heavy chronic disease burden, and Scott and White clinic, which is representative of most other primary care settings in the United States. Patients from both systems are ethnically and socioeconomically diverse and from both rural and urban areas. The sites' patient case mix addresses AHRQ's priority populations, though for this study, we recruited providers and did not enroll patients, instead completing retrospective chart reviews on them. We did not collect patient demographic information.

## **Scope**

### **Background**

Identifying and preventing delays in cancer diagnosis have proved challenging.[21,22] Such delays are common and lead to poor outcomes and increased malpractice litigation,[2,5,23-26] and many arise when abnormal cancer screening results or other “red flags” are missed by providers.[5,24,27-36] These missed opportunities can result in delays in diagnosis and reduce the chances of early, potentially curative therapy.[37] Thus far, detection of diagnostic delays across the fragmented ambulatory care setting is inefficient, and tracking patients with suspected cancer via existing tools is cost-prohibitive.

### **Context**

Comprehensive EHRs that contain data across the longitudinal continuum of care and facilitate data mining[38] make detection of diagnostic delays possible. However, use of the simple search tools currently embedded within EHR reports (e.g., “find all patients with a positive fecal occult blood test (FOBT)”) generates large numbers of false positive results, resulting in information overload among providers who are already overloaded by the amount of data they receive through the EHR each day. [39-41] Thus, novel methods are needed to create a back-up system to detect delays efficiently. The use of “triggers” [42-46] to identify specific patterns within clinical data (e.g., lack of follow up action after an abnormal test results) allows a selective set of records to be targeted for confirmatory review. Triggers are defined as a specific set of clues used to flag records of patients at higher risk of harm so that they can be reviewed for possible safety events.[47] Thus far, they have been used primarily to retrospectively identify errors of commission, such as those related to adverse drug events and nosocomial infections.[48-54] Although we have applied triggers to detect diagnostic errors,[55] their use in the outpatient setting remains limited.

## Participants

Aim 1 involved only retrospective chart review. In Aim 2, full time primary care providers (PCPs; defined as physicians, physician assistants, and nurse practitioners in outpatient internal medicine or family medicine working >36 hours per week) were invited to participate in the randomized controlled trial.

## Settings

We conducted our research in two settings: an urban Veterans Affairs facility and a large primary care network. These settings include internal medicine and family medicine; academic and nonacademic practices; and significant racial, gender, ethnic, age, urban/rural, and socioeconomic diversity.

## Incidence/Prevalence

In a study of ambulatory diagnostic malpractice claims, missed and delayed cancer diagnoses constituted the majority of claims (59%).<sup>[2]</sup> Delays in lung cancer have been identified in numerous studies on care breakdowns.<sup>[5,56-59]</sup> Studies of colon cancer diagnosis, including our own,<sup>[11]</sup> also support the scope of the problem. For example, in a retrospective study of 100 patients presenting with colorectal cancer during a year, 34 had a delay in diagnosis, about half of which could be attributed to physicians.<sup>[60]</sup> There is recent data to support delays in prostate cancer diagnosis.<sup>[31]</sup>

Despite an abundance of literature on cancer-related delays, few studies address the direct outcomes of delays, and results are inconsistent. Thus, no clear definitions exist about what time period constitutes an unacceptable delay. Regardless, reducing delays to improve time to diagnosis constitutes an important facet of health care quality.<sup>[16]</sup>

## Methods

### Study Design

In Aim 1, we iteratively developed electronic triggers to detect delays in diagnosis in prostate, colorectal, and lung cancer using information from literature reviews, expert opinion, and clinical logic. We then validated the triggers using manual chart reviews as the gold standard to determine the positive predictive value (PPV) of each trigger.

In Aim 2, we performed a cluster-randomized controlled trial to test an intervention consisting of applying the triggers to the data repositories at the two study sites and communicating findings to the patient's treating provider. A study physician assistant conducted chart reviews on records identified by the trigger to confirm and analyze the presence of diagnostic breakdowns. The study staff then used electronic communication to communicate these delays to the patient's treating provider and used electronic tracking to monitor these

patients. To test the effectiveness of the intervention, we compared the amount of time to follow-up action in the intervention and control cohorts.

## Data Sources/Collection

We used EHR data repositories from two large geographically disparate health care systems. Each institution possessed a data warehouse (data repository) where trigger queries were conducted. After running the triggers, data was collected via manual chart reviews of each institution's EHR on standardized data collection forms. Provider demographic information was obtained through online surveys.

## Intervention (Aim 2 only)

Our intervention arm consisted of two related steps: The first step included biweekly application of the trigger to the data repository of each health care system by a locally housed program analyst. We applied the trigger to the records of all patients under the care of an intervention provider. The trigger identified records of patients who were at a higher risk of delays in their care. We then confirmed, through medical record review, whether the patient truly experience a delay in diagnostic evaluation. The second step included electronic communication and surveillance that facilitated the care of patients experiencing delays. A trained chart reviewer conducted chart reviews on trigger-positive patients to confirm they were at risk for care delays, and this was followed by an electronic and/or verbal communication to the provider. The intervention was compared to usual care at both sites.

Because many patients follow up with their providers at least twice a year, a final review was performed at seven months after the red flag date to incorporate additional actions that were taken on these visits. For the final review, we applied triggers retrospectively to the control group records to allow for comparable analysis.

## Measures

In Aim 1, we measured trigger performance by calculating PPV, defined as the number of triggers-flagged records with delayed care over the total number of triggers flagged. We also measured reasons for lack of follow-up, and cancer outcomes.

In Aim 2, as a primary outcome, we measured time to documented follow-up action in response to the red flag. Secondary outcomes included the subsequent diagnosis of nonmalignant neoplasia, pre-cancerous lesions, cancer, or death.

To estimate the amount of time required to perform such reviews, we also reported the amount of time required to review charts.

## Limitations

**Aim 1.** This project occurred at only two sites, both of which were integrated health systems and used a comprehensive EHR. Thus, our results might not necessarily be generalized to other sites. Next, we were unable to report sensitivity and specificity of the triggers due to the vast number records requiring review to identify a single false negative, and thus, our results are

affected by the low prevalence of missed follow-up given the large number of patients who receive diagnostic testing, as well as the paucity of adverse events that occur even when care is delayed. Third, the study was not designed to identify the root cause of the delayed care or missed diagnosis. For example, reviewers noted many cases where delays in follow-up were beyond the control of primary care providers, such as difficulty obtaining timely appointments with specialists or patients failing to show up to scheduled appointments. However, trigger information could still facilitate delivery of timely health care. Additionally, evaluation of follow-up was based on chart reviews and may not fully reflect the care delivered or provider's rationale.

**Aim 2.** This project was not designed to test whether it led to improved clinical outcomes. However, prior research has suggested that reducing unnecessary delays likely improves outcomes,[56,61,62] which in turn might also lead to reduced malpractice claims.[2] Second, reviews relied on documentation in the EHR, and thus, might not reflect the actual care delivered or provider's rationale for failing to take action. However, prior studies have identified little deviation between documented care and actual care delivered.[10]

## Results

### Principal Findings

**Aim 1.** Four trigger algorithms were successfully designed to identify patients at high risk for delayed prostate cancer and CRC diagnosis and were developed after iterative review of 214 records (88 prostate cancer and 126 CRC). Each of the triggers achieved positive predictive values (PPVs) of 58.3-70.2%.

**Aim 2.** The trigger-based intervention was successfully implemented and continued for a 15-month period. Compared to the control group, patients cared for by providers in the intervention group experienced shorter time to follow-up care for the prostate and colorectal cancer triggers, while no difference was seen in the lung cancer triggers.

### Outcomes

**Aim 1.** Trigger algorithms were successfully developed for prostate cancer and colorectal cancer and were able to exclude most "clinical exclusion" criteria, such as known diagnosis of prostate cancer, prostatitis, terminal illness, or recent prostate biopsy.

After applying the PSA trigger to the records of 292,587 patients who visited their respective facilities between January 1 and December 31, 2009, 426 were identified by the trigger as high risk for delayed diagnosis, of which 299 (PPV of 70.2%; 95%CI, 65.7%-74.3%) truly lacked expected follow-up

The final FOBT and IDA related triggers were applied to 291,773 patients seen at both sites between March 1, 2009 and February 28, 2010, while the hematochezia trigger was applied to 202,553 records at one site due to difficulties encountered running the trigger at one site. A total

of 1138 records identified as high risk for missed follow-up. Based on 258 record reviews, reviewers identified 52 (PPV of 66.7%; 95%CI, 55.6%-76.2%) records from the FOBT trigger, 81 (67.5%; 95%CI, 58.7%-75.2%) from the IDA trigger, and 35 (58.3%; 95%CI, 45.7%- 70.0%) from the hematochezia trigger as lacking follow up.

**Aim 2.** We recruited 72 PCPs for the study applied the trigger to all patients cared for by study providers for 15 months from April 20, 2011 to July 19, 2012. The trigger identified a total of 675 patients at high risk for delayed diagnosis. All three triggers achieved a positive predictive value (PPV) of 0.52.

At the final chart review performed seven months after the red flag, 247 of the 351 patients (70.4%) in the intervention group with delayed diagnostic evaluation were subsequently found to have received follow-up action. In the control group, only 189 of the 326 patients (58.0%) with delayed diagnosis subsequently received follow-up action. Time to follow-up was significantly shorter for the intervention group in both the prostate and colorectal cancer-based triggers. Only 21 records with delayed follow up were identified for lung cancer, and no difference in the time to follow-up between intervention and control groups was observed.

## Discussion

**Aim 1.** We developed, applied, and evaluated four electronic triggers to search large electronic health record repositories for patients at high risk for delayed diagnosis of prostate and colorectal cancer. Because there are no current methods to harness electronic data to identify these types of delays, our trigger-based methods are more efficient than non-selective chart reviews. Thus, these triggers could potentially allow appropriate action to be taken earlier in the disease progression continuum.

**Aim 2.** In a randomized controlled trial, we tested an intervention that used the EHR to identify patients at risk for delays in cancer diagnosis and communicated this information to their providers. We found that the intervention improved timeliness of patient follow-up as compared to usual care. Similar EHR-based interventions could be applied to other conditions where delays in diagnosis and/or follow-up are common in order to reduce patient harm related to diagnostic delays. Despite the success of the intervention, further work is necessary to understand whether alternate methods of communication of trigger results will improve subsequent follow up and better support provider's practice.

## Conclusions

**Aim 1.** We successfully developed electronic triggers to identify patients at high risk for delayed diagnosis for prostate and colorectal cancer. Triggers had reasonable predictive values and could be useful for others trying to develop measurement systems to detect delays in diagnostic care. This study serves as a basis for future research to evaluate the effect of prospective application of triggers on patient outcomes.

**Aim 2.** An EHR-based intervention to identify patients with delayed diagnostic work-up for cancer has the potential to improve patient follow-up. Implementing the intervention required reasonable amounts resources for reviews that make it practical for implementation even at large



sites.

## Significance

Diagnostic delays in ambulatory care are an important problem, and this study advances knowledge about methods to detect delays and prevent them from making clinical impact. No such methods currently exist, and the use of IT for such purposes has been limited. Our methods put into place novel monitoring and surveillance tools that can significantly reduce delays in ambulatory cancer care (and perhaps in other chronic conditions after testing).

## Implications

The information gained by carrying out this study will lay groundwork for future work to enhance the safety of the diagnostic process in ambulatory care. There are overwhelming benefits from reducing diagnostic delays in terms of preventing excess morbidity and mortality and reducing associated costs.

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patients with colorectal and breast cancer but not lung or thyroid cancer. *Ann Surg Oncol* 2013, 20: 2468-2476.

## List of Publications and Products

Murphy DR, Laxmisan A, Reis B, Thomas E, Singh H. Using electronic triggers to identify patients at risk for diagnostic delays in prostate cancer [abstract]. Society of General Internal Medicine 2011 Annual Conference; 2011 May; Phoenix, Arizona.

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