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## Root Cause Analysis Reports Help Identify Common Factors In Delayed Diagnosis And Treatment Of Outpatients

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### Abstract

Delays in diagnosis and treatment are widely considered to be threats to outpatient safety. However, few studies have identified and described what factors contribute to delays that might result in patient harm in the outpatient setting. We analyzed 111 root cause analysis reports that investigated such delays and were submitted to the Veterans Affairs National Center for Patient Safety in the period 2005–12. The most common contributing factors noted in the reports included coordination problems resulting from inadequate follow-up planning, delayed scheduling for unspecified reasons, inadequate tracking of test results, and the absence of a system to track patients in need of short-term follow-up. Other contributing factors were team-level decision making problems resulting from miscommunication of urgency between providers and providers' lack of awareness of or knowledge about a patient's situation; and communication failures among providers, patients, and other health care team members. Our findings suggest that to support care goals in the Affordable Care Act and the National Quality Strategy, even relatively sophisticated electronic health record systems will require enhancements. At the same time, policy initiatives should support programs to implement, and perhaps reward the use of, more rigorous interprofessional teamwork principles to improve outpatient communication and coordination.

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The majority of medical care in the United States is delivered in the outpatient setting.<sup>1</sup> However, efforts to improve patient safety have primarily focused on the inpatient setting. A 2011 report from the American Medical Association highlighted how certain issues—such as missed and delayed diagnosis and breakdowns in communication—are widely considered to be threats to patient safety in outpatient settings but have received little empirical study. The report concludes that “we still know very little about patient safety in the ambulatory setting, and next to nothing about how to improve it.”<sup>2</sup>

Breakdowns and delays in diagnosis and treatment feature prominently in prior studies of errors in outpatient care.<sup>3–10</sup> The risk for harm in outpatient settings is substantial<sup>11,12</sup> but is likely to be underestimated because of underreporting and other measurement-related issues (for example, some errors may introduce serious risk but not cause injury).<sup>13</sup>

Moreover, the fragmented nature of ambulatory care leads to unique and complex risks as patients move across different settings of care.<sup>1</sup> Multiple health care providers, visits, and locations create opportunities for an array of possible breakdowns in the care process, making the study of ambulatory adverse events challenging.<sup>14-16</sup> Breakdowns in care processes might be attributable to a number of different patient, provider, and system-related issues<sup>17,18</sup> and can take place anywhere along the patient's path through the health care system over time—that is, across the longitudinal continuum of care.<sup>15,17</sup>

Few studies, however, have attempted to comprehensively identify and describe breakdowns that lead to ambulatory care delays, an essential step in understanding their origins and improving safety. Reducing harm from care delivery is a priority of the National Quality Strategy. This nationwide effort was established in 2011 by the Department of Health and Human Services in response to the Affordable Care Act and seeks to “align public and private payers with regard to quality and patient safety efforts” The rich stores of data collected by large, integrated health systems can provide insights into systemic and organizational failures that might result in delays along the longitudinal continuum of care. One such system is that of the Department of Veterans Affairs (VA), which has used integrated electronic health records at all of its facilities since 2000.<sup>19</sup> These electronic records allow easy access to data related to clinical problems, medications, orders, test results, procedures, and providers' progress notes for ambulatory and inpatient care.

Another advantage of working with information from the VA facilities is their comprehensive approach to conducting root cause analysis. The National Center for Patient Safety, which leads VA patient safety initiatives,<sup>20</sup> defines *root cause analysis* as “a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events or close calls.”<sup>21</sup> The safety center has used root cause analyses for more than a decade to identify causal and contributory factors associated with adverse events (those that resulted in harm to a patient) or with close calls (events that could have resulted in harm to a patient but did not because of chance or a timely intervention).<sup>20</sup>

The root cause analysis program was instituted to analyze and learn from adverse events and close calls occurring in the Department of VA health system. Approximately 1,500 deidentified reports are now submitted each year.<sup>20,22</sup> When an adverse event or close call is identified, a facility-based, multidisciplinary analysis team is charged with identifying the contributing factors involved and recommending interventions to eliminate or reduce the risk of recurrence.<sup>21</sup> The team conducts a detailed investigation, interviewing the people most familiar with the incident and focusing on problems in systems and processes instead of on faults or errors of individuals.<sup>21</sup>

The reporting format includes a narrative of the adverse event or close call, statements of the root cause and contributing factors, and action plans designed to mitigate or prevent similar occurrences in the future. The action plans are recommendations to the facility leadership; plans approved by the leadership are required to be implemented. All root cause analysis reports are subsequently submitted to the National Center for Patient Safety. Thus, unlike voluntary error reports that may shed little light on contributing factors, root cause analyses are a rich source of information about system-level risks, determined through a labor-intensive process of information gathering and analysis.

Various methodologies have been used to identify and analyze adverse events and close calls (for example, chart reviews, surveys or interviews, and incident reports).<sup>17,18</sup> To our knowledge, however, data from root cause analyses has never before been used to gain insights into diagnostic and treatment delays in ambulatory care. Our objective was to

review root cause analysis reports related to delays in ambulatory care so as to describe process breakdowns and contributory factors associated with such delays. We also sought to identify actions that might help prevent delays at VA outpatient facilities and, possibly, in other ambulatory settings.

## Study Data And Methods

### Design

We performed a retrospective descriptive analysis of a subset of deidentified root cause analysis reports that were submitted to the National Center for Patient Safety in 2005–12. Analysts at the center use an internal taxonomy to categorize all incoming reports, from where we chose the subset involving delays in diagnosis and treatment in the outpatient setting. Any such delay associated with an encounter in an outpatient clinic was considered to have occurred in the outpatient setting, as long as the visit did not lead to a hospitalization.

Two authors of this article (Beth King and Aartee Ignaczak) independently analyzed each report in detail, using an adaptation of a framework of ambulatory care processes previously used to study diagnostic breakdowns.<sup>15,17,23</sup> The adapted framework included the following four dimensions: the provider-patient encounter, in which problems might occur with history gathering and other exchanges at the time of the patient visit; performance and interpretation of diagnostic tests, where problems include delays in tests and incorrectly performing them or interpreting their results; follow-up and tracking of patients, which includes problems with timely follow-up of test results or appointments; and referral and consultation processes, where delays might occur from lack of actions related to referrals. To provide clinical input, another author (either Douglas Paull or Laura Hoeksema, both of whom are physicians) always joined the review team, with Paull and Hoeksema each reviewing about half of the reports. The team members then discussed their responses to achieve consensus. Additional details of the sampling and data collection processes are provided in the online Appendix.<sup>24</sup>

The team reviewed each report to identify contributory factors related to process breakdowns. Contributory factors were coded using a comprehensive list derived from the patient safety literature.<sup>4,17,18</sup> They included poor coordination of care between health care providers, such as issues with follow-up and transitions of care; failures of team cognition, or cognition that emerges from interaction among the individual members of a team;<sup>25</sup> poor communication among providers, patients, and other health care team members; administrative issues, including staffing problems, and difficulties in obtaining a specific service or equipment (such as access to scanners and fax machines); and patient-related behaviors, such as failing to keep a scheduled appointment. The team also reviewed the reported action plan categories, which included standardized descriptions of actions being implemented to reduce or eliminate recurrence of incidents. Additional methodological details are provided in the Appendix.<sup>24</sup>

Although the focus of root cause analyses on systems precludes isolating an individual's role in an adverse event or close call, the reviewers noted the type of health care personnel identified in each report (regardless of the personnel's contributing role in the incident). This list included providers, other health care professionals, and administrative personnel such as clerical staff. Although these data do not indicate responsibility, they offer insights whether or not the incidents were disproportionately associated with any particular specialty or type of personnel.

## Data Analysis

We calculated descriptive statistics to determine the frequency of adverse events and close calls by personnel type, process breakdowns, contributory factors, and action plans. We calculated median delay time by determining the time difference between the date of the final diagnosis or the initiation of treatment and the first possible opportunity for the appropriate care to have been delivered, if sufficient data were available to make this assessment.

## Limitations

Although our results cannot be considered generalizable to other health systems, similar patient safety issues are present in other settings.<sup>26</sup> Our analysis was limited to a selected set of reports that looked into occurrences that were relatively severe. In addition, because of possible facility-level variability in categorizing reports as delays, our data did not reflect the overall rate or severity of delays in ambulatory settings. We did not control for additional variables such as patient and facility characteristics, resource availability, or the type of condition under evaluation. Finally, reports were not independently validated and so may reflect hindsight bias.<sup>27,28</sup> Nevertheless, our systematic analysis of the data highlighted key areas for improvement and common themes underlying delays in outpatient care.

## Study Results

During our study period 9,789 root cause analysis reports were submitted to the National Center for Patient Safety. Of the 223 reports categorized as involving delays in treatment and diagnosis in the outpatient setting, 111 met the study criteria. We identified 255 process breakdowns (2.3 breakdowns per report, on average) that were associated with delays. The dimension most frequently involved was follow-up and tracking of patients: that dimension appeared in seventy-seven reports and accounted for 30.2 percent of the breakdowns. This was followed by performance and interpretation of diagnostic tests, in seventy reports (27.5 percent of the breakdowns); referral and consultation processes, in sixty-eight reports (26.7 percent of the breakdowns); and the provider-patient encounter, in forty reports (15.7 percent of the breakdowns).

Reviewers were able to determine the time between diagnosis or initiation of treatment and the first possible opportunity for care in ninety-five reports. The median delay was 119 days (range: 1-1,539; interquartile range: 265).

### Types of Diagnostic Tests Across All Four Dimensions

Diagnostic imaging or laboratory tests were involved in seventy-seven of the reports (69.4 percent). Some of the tests were not ordered; others were not performed or not followed up on.

Some reports involved more than one test. The most common tests were computed tomographic scan ( $n = 22$ ; 28.6 percent), biopsy ( $n = 15$ ; 19.5 percent), x-ray ( $n = 13$ ; 16.9 percent), magnetic resonance imaging ( $n = 10$ ; 13.0 percent), and serum chemistries ( $n = 8$ ; 10.4 percent).

### Types of Individuals Involved

Specialists and generalists—that is, primary care providers—were the personnel most often identified in root cause analyses, although they did not necessarily contribute directly to the adverse event or close call (Exhibit 1). Within the specialist category, internal medicine subspecialties -- including pulmonary disease, hematology or oncology, cardiology, gastroenterology, endocrinology, nephrology, geriatrics, and infectious disease -- were most

commonly involved (in two-thirds of reports), followed by radiology and emergency medicine. Patients were identified as involved in just over half of the reports.

### **Contributory Factors**

Reviewers identified 1,013 contributory factors in the 111 reports (9.1 factors per report on average). The majority of these were related to coordination problems, followed fairly closely by team cognition issues (Exhibit 2).

The most common types of coordination problems included inadequate follow-up planning (for example, when no action was taken to initiate follow-up for a patient who needed it), delayed scheduling of follow-up care for unspecified reasons, an inadequate tracking system for test results, the absence of a follow-up tracking system to monitor patients in need of short-term follow-up, and failure to document a follow-up plan. The most common types of team cognition issues included miscommunication of urgency between providers (for example, the failure to flag a request as urgent), lack of awareness of or knowledge about the patient's situation, and poor documentation.

Communication factors were identified in all 111 reports. Most of these failures were noted as occurring in communication between providers (particularly between generalists and specialists) and between providers (particularly generalists) and patients. Nurses, administrative staff, and other health care professionals were also involved in communication failures.

Contributory factors classified as administrative issues included staff relocation or change, followed by the presence of inexperienced or untrained staff and difficulties in obtaining a specific service such as a consultation or procedure at an outside institution. Patient-related factors were present in more than one-third of the reports. Although no single patient-related factor was highly prevalent, the most common were patients' "no-shows" and cancellations of scheduled appointments, followed by misunderstanding of instructions and failure to seek care in a timely manner.

### **Action Plans**

The 111 reports presented a total of 478 recommended actions (Exhibit 3). The most common of these were related to staff training and education; changes to policy or procedure; and standardization of processes through protocols, clinical guidelines, or order sets. A full list of the actions appears in Appendix Exhibit 1.<sup>24</sup>

### **Discussion**

We studied 111 outpatient root cause analysis reports that were submitted to the VA's National Center for Patient Safety in 2005-12 and that involved delays in diagnosis, treatment, or both in the outpatient setting. We found that those delays arose from multiple dimensions of ambulatory care processes and involved a large number of contributory factors. Most contributory factors were related to communication and coordination among providers, nonproviders (including clerical and administrative support staff), and patients. Failures in the process of follow-up and tracking of patients were especially prominent, mentioned in more than half of the reports.

### **Policy Implications**

Our findings have implications for achieving goals found in the Affordable Care Act and the National Quality Strategy,<sup>29</sup> both of which aim to improve the quality of health and health care for all Americans. These policy initiatives prioritize the promotion of effective

communication and coordination of care. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 seeks to improve health care delivery and patient care “through an unprecedented investment in health information technology”.<sup>30</sup> Our study was not designed to assess the ability of electronic health record systems to reduce delays in diagnosis and treatment. However, our findings suggest that even a leading system that is relatively sophisticated by current standards, such as the one used by the VA, will require enhancements to support certain aspects of team-based care.

Hence, widespread adoption of electronic health record systems alone is not likely to resolve communication and coordination problems to the extent desired. Rather, the systems need to better support “shared” thinking processes for timely and safe patient care across a team. This could be accomplished by including in the system capabilities for reliable scheduling, tracking, and follow-up of patients across multiple settings and by multiple providers over time. In addition, improvement to technological capabilities should be accompanied by attention to the human factors that could help optimize individual and team performance, taking into account the complexity of the health care system.<sup>31</sup> This would make it easier to derive the maximum benefit possible from the use of electronic records, especially in increasingly resource-constrained settings.

As an indication of why attention to human factors is essential, we found that communication and coordination breakdowns among providers often reflected unclear responsibility for diagnosis or treatment. For example, a generalist and a specialist might each have felt that the other was responsible.<sup>5</sup> Because these breakdowns have been documented in other studies as well, it is important to establish robust policies and procedures to incentivize care coordination.<sup>32,33</sup>

The measurement of performance in this area—an essential step toward improvement—is still evolving. Currently used quality measures in the outpatient setting do not adequately address safety in terms of communication and coordination. More robust outpatient-specific measures are needed, and outpatient-specific measures would be essential for the implementation of certain initiatives proposed in the Affordable Care Act.<sup>34</sup> For example, bundled payments that incentivize better communication and coordination across several settings of care would require the development of new types of measures to reflect communication and coordination activities such as those highlighted by our study.

Our findings also highlight the need for better application of teamwork principles. The Institute of Medicine recommends that interdisciplinary team training programs be implemented to improve communication and coordination among staff.<sup>36</sup> Most strategies to improve teamwork have focused on inpatient settings. For example, medical team training that is based on Crew Resource Management teamwork and communication techniques—adapted from high-reliability industries such as commercial aviation—has been associated with improved patient outcomes, staff satisfaction, and “safety climate” survey scores for inpatient settings.<sup>37-39</sup> In contrast, best practices for team training in the outpatient setting are not well understood.<sup>2,40</sup> However, existing inpatient approaches could be adapted to include patients, nurses, administrative personnel and other types of healthcare professionals. Implementing rigorous principles of outpatient teamwork within the patient-centered medical home<sup>41,42</sup> and accountable care organization models of care<sup>43</sup> would require organizational changes and reimbursement strategies that supported these principles.

### Future Root Cause Analyses

Methods to detect and study delays in diagnosis and treatment are underdeveloped, especially in outpatient settings.<sup>2</sup> The Department of Veterans Affairs is one of the few health care entities that conducts outpatient root cause analyses of adverse events and close

calls in an effort to identify and address their causes. Our study used a robust sample of reports about distinct types of adverse events and close calls and thus provides unique insights into problems in outpatient care and actions that might be taken to address them.

Lessons learned include those related to the action steps recommended in the root cause analysis reports to reduce the frequency of adverse events and close calls. For example, we found that standardizing processes to achieve reliability and technological changes were common recommendations in action plans, but staff education and changes to policies and procedures were equally common. The literature suggests that staff education and changes in policy alone (often referred to as “low-hanging fruit” interventions) are generally not effective actions and not associated with clinical improvements.<sup>44</sup> It is thus essential to go beyond these actions and make more sustainable system improvements. Furthermore, institutions implementing changes should measure their effects on reducing outpatient care delays to ensure that they are producing the expected improvements.

### Implications For Patients

Root cause analyses do not focus on individuals; thus action plans are unlikely to focus on individual-level strategies for improvement. Nevertheless, we found that patient behaviors played a prominent role in process breakdowns associated with diagnostic and treatment delays for outpatients. This may be in part a result of low levels of patient engagement. Ambulatory patients often must make decisions on their own about when to seek care and how to navigate the health care system; in contrast, the inpatient receives continuous care from a team that is collected in one place.<sup>16</sup> Several efforts already under way may empower patients to become more active in their care.<sup>45</sup> For example, the VA has recently adopted an electronic personal health record, My HealtheVet, which allows patients to access their laboratory test results, schedule appointments, see clinical reminders related to diabetes and cancer screening, and refill prescriptions online.<sup>46</sup>

### Conclusion

In an examination of a subset of root cause analysis reports from a health system with an integrated electronic health record system, we found that delays in diagnosis and treatment in the outpatient setting had multiple and complex origins. Many delays were found to be related to communication and coordination failures. These findings suggest that, within the VA health system and possibly elsewhere, delays in ambulatory care are unlikely to be reduced to the extent desired unless multicomponent interventions concurrently address multiple process breakdowns and contributory factors.

Specifically, our findings indicate that policy-based initiatives to reduce such delays should promote the implementation of enhancements to electronic health record systems that would facilitate communication among providers and between providers and patients, as well as improve coordination of care; measure and possibly reward performance related to that communication and coordination; and adopt rigorous principles for interprofessional teamwork to bolster current models of outpatient care.<sup>47</sup>

### Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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**Exhibit 1**

Types Of People Identified In Root Cause Analysis Reports Of Delays In Outpatient Diagnosis, Treatment, Or Both, National Center for Patient Safety, 2005–12

<b>Involved in:</b>		
<b>Type</b>	<b>Number of reports</b>	<b>Percent of reports</b>
Medical and surgical specialists	100	90.1
Generalists	98	88.3
Patients	65	58.6
Nurses <sup>a</sup>	48	43.2
Clerical or administrative support staff	47	42.3
Nurse practitioner or clinical nurse specialist	10	9.0
Other Health Care Professionals <sup>b</sup>	33	29.7

Source Authors' analysis of 111 root cause analysis reports from the Department of Veterans Affairs National Center for Patient Safety, 2005–12.

<sup>a</sup>Includes registered nurses, licensed practical nurses, and unspecified types of nurses.

<sup>b</sup>Includes pharmacists, physical therapists, physician assistants and optometrists.

**Exhibit 2****Contributory Factors Associated With Process Breakdowns In Root Cause Analysis Reports Of Delays In Outpatient Diagnosis, Treatment, Or Both, National Center For Patient Safety, 2005–12**

<b>Type of factor (number of reports)</b>	<b>Number of factors</b>	<b>Percent of factors</b>
coordination of care (104)	339	33.5
Failure of team cognition (102)	316	31.2
Poor communication (111)	204	20.1
Patient-related behavior (43)	90	8.9
Administrative issues (48)	64	6.3

Source Authors' analysis of 111 root cause analysis reports from the Department of Veterans Affairs National Center for Patient Safety, 2005–12.

Note The categorization of contributory factors is explained more fully in the text.

**Exhibit 3****Top Five Categories Of Action Plan Recommendations To Address Delays In Outpatient Diagnosis And Treatment In Root Cause Analysis Reports, National Center For Patient Safety, 2005–12**

<b>Recommendation</b>	<b>Number of recommendations</b>	<b>Percent of recommendations</b>
Staff training or education: implementing new, additional, or different training or education	80	16.7
Policy or procedure changes: implementing, changing, developing, clarifying, or reviewing a procedure, policy, or process	78	16.3
Process changes: standardizing protocols, clinical guidelines, or order sets	78	16.3
Software or hardware changes: installing new, or modifying current, software or hardware	77	16.1
Enhanced documentation or communication: improving documentation of patient records or using and updating process and equipment manuals	35	7.3

Source Authors' analysis of 111 root cause analysis reports from the Department of Veterans Affairs National Center for Patient Safety, 2005–12.

Note  $N=478$  recommendations.