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The Beacon

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Results Management: Are Your Patients Safe?

Introduction

In primary care, patient errors related to delayed or missed diagnosis continue to rise and have resulted in an increased risk of harm to patients. Claims related to delayed or missed diagnosis are the most prevalent and costly claims filed against primary care providers. Current literature review tells us the greatest risk for diagnostic error occurs when systems fail and there is a delay in the communication of a test result or delay in a patient referral.[1,3] MMIC established an initiative to determine how we could best assist our insureds in identifying opportunities to improve patient safety through reducing patient diagnosis-related errors. This *Beacon* addresses the risks associated with delayed or missed diagnosis and the steps MMIC has taken to assist our insureds in identifying opportunities to improve their office practice systems that manage patient results. The steps include:

1. Risk Identification of Common Factors in Delayed or Missed Diagnosis Claims
2. Performance of Onsite Results Management Patient Safety Assessments in Primary Care Practices
3. Recommendation of System Improvements When Indicated
4. Educational Seminar on Results Management and Developing Reliable Processes

In This Issue

Challenges in Results Management

Management of patient test results is a complex process that involves a number of office practice systems and requires continuous communication between staff, providers and the patient. Standardized processes in office practice systems are required to minimize the risk of lost or missed test results leading to a delayed or missed diagnosis. Identification of system improvement opportunities through quality monitoring, staff and provider involvement in system improvements and their heightened awareness of patient safety are required to reduce the risk of a system breakdown. Engagement of the patient in their care is essential to reduce the risk of noncompliance.[3,5]

Research studies have outlined the following common workflow for management of tests in the office practice setting[8]:

I. Ordering Process:
   a. Ordering the test
   b. Implementing the test order

II. Testing Process:
   a. Performing the test

III. Reporting Process:
   a. Results are received by the provider
   b. Provider reviews/responds to the results

IV. Patient Notification Process:
   a. Patient is notified of the results
   b. Patient is notified of required action

V. Patient Follow Up Process:
   a. Appropriate action was recommended
   b. Patient took appropriate action

These studies point out there are many process steps and many individuals involved in this complex workflow. Errors are reported by primary care practices in all workflow process steps.

When individuals manage multiple tasks, there is an increased opportunity for a missed step resulting in a missed test or lost result, leading to a possible adverse patient event and patient harm.[1,3]

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Studies indicate there is much variability between primary care practices on how the process for management of patient results is performed. Practices lack comprehensive written protocols for result management and when protocols do exist, consistent adherence to those protocols does not occur. Staff education and competencies on the process workflows is not comprehensive.[1,3]

Technology (EHRs and other) utilized by primary care practices to facilitate results management work flow was identified as error prone.[2] Issues identified as contributing to errors include:

- Lack of a complete interface for order entry
- Lack of a consistent process to electronically receive test results
- Lack of posting functions for all test results to the provider's desktop and the patient's EHR
- Lack of ability to generate patient communications
- Lack of a comprehensive electronic results management process
- Lack of an interface with the practice's appointment scheduler
- Reliance on manual processes such as scheduling to compensate for shortcomings of the technology

Patient interviews reveal patients do not always receive their test results. Examples of how patients are notified of their test results include provider telephone calls, assignment of staff to make telephone calls, patient portal, letters or copies of test results delivered by US mail, discussion at a follow up visit, or simply no patient notification.[5]

Quality reviews did not include identifying tasks or steps in the processes and implementing remedial actions vital to assure a high quality results management program. Recurrence of similar errors and system problems is not addressed. Practices rely on "work-arounds," staff memory, "check-ins" from patients and cheat sheets.[5]

Opportunities exist to provide safe patient care and reduce diagnosis-related error through adopting and monitoring a high quality results management program. A high quality results management program is essential to mitigate risk of patient harm and avoid claims of professional liability for missed or delayed diagnosis.

Malpractice Data

Patients want safe, efficient, person-centered care. They expect to receive information regarding their health and a treatment plan to address any concerns. A patient's missed or delayed diagnosis is not anticipated and may cause serious harm for the patient.

According to the Medical Professional Liability Association (MPL Association – previously the PIAA which is the insurance trade association representing medical professional liability insurers), diagnostic interview, evaluation or consultation was the top procedure provided and resulted in an average indemnity payment of $334,697 for closed claims from 2005-2014 for all provider types. Diagnostic error resulted in the highest average indemnity ($399,790) and ranked second among the top five chief medical factors during 2005-2014 for all provider types.

A five-year study of outpatient claims published in 2011 found 46% of all claims were diagnosis related.[5] A study of 190 cases indicated that most missed diagnoses in primary care were common conditions with the missed diagnosis being directly related to office system/process breakdowns. The process breakdowns contributing to these conditions were referral related (19.5%), patient related (16.3%), follow up and tracking of diagnostic information related (14.7%) and performance/interpretation of diagnostic tests related (13.7%). In 43.7% of the cases, more than one of these processes failed. Most errors in this study were associated with a potential for moderate to severe harm for the patient. The type of provider did not influence the success or failure of the office processes.[3]

For decades, missed and delayed diagnosis has been identified by providers, researchers and professional liability carriers as a high frequency error with the potential to cause severe harm to patients. The healthcare industry continues its struggle with diagnosis-related errors, timely patient notification and appropriate follow up. An increasing number of professional liability claims for diagnostic-related errors are filed against providers each year.

Family Practice

Fifty-six percent (56%) of paid claims and 58% of the total indemnity paid for all family practice claims occurred in the office setting. Diagnostic interview, evaluation, or consultation was the most prevalent (23%) and most expensive procedure for the period (2011-2015), of which 27% resulted in an average indemnity payment of $267,278. This represents 58% of the total indemnity paid for all family practice claims.[10]

Internal Medicine

Forty-four percent (44%) of the paid claims and 50% of the total indemnity paid for all internal medicine claims occurred in the office setting. Diagnostic interview, evaluation, or consultation was the most prevalent (24%) and most expensive procedure for the period (2011-2015), of which 19% resulted in an average indemnity payment of $347,850. This represents 47% of the total indemnity paid for all internal medicine claims.[10]

Midlevel Providers

Nurse practitioners were named in 46.6 % of National Practitioner Data Bank diagnosis-related malpractice allegations. Physician assistants were named in 52.8 % of National Practitioner Data Bank diagnosis-related malpractice allegations.

It is predicted that diagnosis-related claims against midlevel providers will increase as their scope of practice and professional numbers increase in response to patient care and access demands.[9]

Risk Identification

To begin our initiative the first step was to identify the most common areas of risk in MMIC claims. Risks identified were multifactorial and include clinical reasoning, misdiagnosis of test results and results management system failures that lead to the lack of appropriate patient follow up. These findings are consistent with those identified by other MPL insurers. In one analysis, a large professional liability company identified that 24% of diagnosis-related claims were received from primary care practices in a five-year period (2013-2017). When reviewing their key steps in the diagnostic process, failure in processes associated with testing was identified in 52% of claims and 55% of indemnity paid; failure in processes associated with patient referrals was identified in 9% of claims and 12% of indemnity paid; and failure in processes associated with patient follow-up was identified in 5% of claims and 7% of indemnity paid. In a separate report, diagnosis-related claims for midlevel providers ranked highest on the list of claims filed for 2011-2014 and included similar process breakdowns in the test ordering process, receipt/transmittal of tests, referral management and patient follow-up.[4]

The data reviewed in MPL insurer claims data varied from those in the medical research studies reviewed, when ranking the highest to lowest, the most common risks associated with office practice processes remained unchanged. They include failure to have:

- A comprehensive practice policy for results management
    - Ordering process
    - Test-tracking (obtained, received)
    - Patient notification
- Effective patient referral process
- Effective follow-up and appointment management process
- A system to monitor and address failures at critical points in office practice processes

Additional significant contributing factors include failure to:

- Engage the patient in their care
    - Educate the patient regarding the test and test process
    - Develop and review a treatment plan with the patient
- Provider documentation
    - Document discussions with the patient
    - Document review of test results
    - Document a rationale for clinical decision-making

Our second step was to provide an onsite results management patient safety assessment at 138 of our primary care practices between 2014 and 2018. Our goal was to identify risks in office practice systems that affected the results management process potentially leading to patient injury (harm) due to a diagnosis-related error and failure to follow up with a patient.

The data compiled from these assessments identified risks were found in the following five categories in 25% or more of the practices reviewed.

Area of Risk	Percentage of Practices Receiving Recommendations
I. Results Management Policy	42%
II. Outstanding Orders/Test & Referral Tracking	36%
III. Quality Improvement	28%
IV. Ordering Process	28%
V. Patient Notification	25%

The following provides a brief summary of each core area and offers recommendations to reduce risk and improve patient safety.

I. Results Management Policy

Lack of a comprehensive, written results management policy that mirrors best practice guidelines and articulates the practice's expectations for results management contributes to inefficient, error-prone practices on the part of clinicians and staff. Patient safety is improved when opportunities for error are reduced by a policy which provides step by step processes to capture the flow of patient data.

Recommendations:

- Develop a comprehensive, written results management policy which includes:
    - Ordering Process
    - Testing Process
    - Test/Results Tracking Process
    - Reporting Process
    - Patient Notification Process
    - Patient Follow-Up Process
- Provide structured staff education on the results management policy.
    - Orientation
    - Competency
    - Just-in-Time Training

II. Outstanding Orders/Test and Referral Tracking

A tracking process assures the patient receives the ordered consult/referral or procedure and the practice receives the result. This process avoids the potential of a missed or delayed diag-

nosis due to a missing result. Utilizing a log system (manual or electronic) to track ordered tests or referral and receipt of results identifies missing test results and intervention opportunities by the practice. Patients can be reminded to go for tests or referrals, be re-educated regarding the importance of the test if they have not received the test and staff can track down a misdirected or misfiled result.

Recommendation:

- Develop a process to track outstanding provider orders which includes:
    - Requirement for a log of all provider orders (tests, consultations, referrals)
    - Requirement for timely review of outstanding orders
    - Requirement for provider notification of outstanding orders
    - Requirement of action to assure the order is completed and result is received by the practice
    - Requirement of a documented rationale in the patient record for a canceled order by the provider

III. Quality Improvement

Monitoring outcomes of office practice processes validate that processes are functionally effective and identify points of process vulnerabilities and failures. Addressing points of process vulnerabilities and failures by implementing process improvements reduces the opportunity for a missed patient result or referral and decreases the possibility of an adverse patient event due to a process breakdown (failure).

Recommendations:

- Institute a quality improvement program that:
    - Monitors compliance with policies that support test/consult result and appointment management
    - Identifies points of vulnerability and failure
    - Requires implementation of an action plan to address identified risks
- Monitor the following indicators to identify process breakdown
    - Timeframe between ordered test and receipt of result
    - Timeframe between receipt of result and review by provider
    - Timeframe between practice receipt of abnormal results and patient notification
    - Patient compliance with having test performed
    - Patient compliance with appointments
    - Patient compliance with referrals
    - Patients not notified of results
    - Follow-up plan in place and completed by patient

IV. Ordering Process

The first step in a high quality results management program begins with a process that assures the provider's orders will be clear, efficiently completed and accurate results will be received timely by the practice for provider review. Office practices that consistently demonstrate high reliability in the ordering process have a written process that incorporates guidelines, customized templates, electronic alerts, and integration with testing and referral partners.

Recommendations:

- Develop procedures that outline the key steps in the ordering process; include in the written results management policy
- Utilize templates and customized order sets
- Utilize alerts to identify
    - Redundant orders
    - Corollary tests needed
    - Critical results received
- Assure abnormal results are flagged by sender
- Integrate systems

V. Patient Notification

Diagnosis-related claims associated with the results management process are reduced when patients are actively engaged in each step of their care. Patient noncompliance with provider orders and treatment plans decreases and outcomes improve when the patient understands the reason for tests and referrals. Patient factors and provider communication played a role in 40% of claims reviewed and failure in the patient notification process was identified 30% of the time.

Recommendations:

- Develop procedures that outline the key steps in the patient notification process; include in the written results management policy
    - Require each patient be notified of their test results
    - Identify notification method
    - Require only providers or clinicians notify patients of critical results
    - Require an appropriate follow up plan be discussed
    - Require patient notification and discussion be documented in the medical record
- Engage the patient in the notification process
    - Address questions
    - Address needs for follow up plan
    - Verify patient understanding through the use of "teach back"
    - Provide additional information/education when indicated
    - Document the discussion and any need for additional clarification in the medical record

System Improvements

Our third step was to provide each primary care practice with an individual report recommending system improvements based on MMIC best practices compiled from published studies and lessons learned from claims review. Practice Tips for insureds on key office practice processes critical to a high quality (reliability or functioning) results management program are published under Risk Management at www.medicalmutual.com. Presentations on results management are designed to address identified opportunities for improvement.

Practice Manager Education

Our fourth step is the 2018 Practice Manager Seminar. The seminar will address the ongoing challenges experienced by primary care in results management. Risks associated with each element of the results management process will be explored. Professional liability will be discussed as it relates to results management failures in review of two closed claims.

A review of two closed claims will outline examples of process failure points and the impact on patient outcomes. A tool, using the rapid-cycle for patient safety and quality improvement, will be presented as one method for improving the result management processes in primary care.

Achieving high quality results management requires fail-safe systems, team work, collaboration with testing and referral sources, patient engagement and excellent communication. Any failures in the process increases the danger there will be serious patient harm. Quality monitoring to identify process failure points and implementation of actions to immediately correct system failures is critical to mitigate risks for serious patient harm. We look forward to partnering with our primary care practices in addressing the ongoing challenges in achieving a high quality results management program. The results management initiative is not concluded; providing best practice recommendations and identifying "what works well" in results management is our ongoing commitment to our insureds.

Resources

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Case Reviews

The following cases are examples of claims that were reported to MMIC. Questions are posed after each case that can prompt conversations with your team.

Case Summary #1

This 58-year-old man visited his PCP on 11/4/2013, reporting a three week history of cough accompanied by fever and joint aches. He had a history of smoking 1 PPD for 30 years. He reported productive green sputum and clear nasal discharge. T 99.6 in the office, but reported to be 102 the night before. Lungs were noted to have mild rhonchi on exam. The physician diagnosed him with bronchitis, prescribed an antibiotic, and asked him to return if he did not improve.

On 11/22/2013, the patient called the office, indicating that he was still sick and was, in fact, coughing up blood. The PCP was not in the office that day, so the patient was directed to her covering physician, who ordered a chest x-ray, which revealed bilateral upper lobe opacities. Within the body of the report, the radiologist commented, "the differential considerations include a wide variety of infectious, inflammatory, or even neoplastic conditions, given this patient's history of cough and presumed hemoptysis. If these fail to resolve following treatment, CT examination would be recommended for further evaluation." The covering physician wrote "R/O neoplasm" on his copy of the radiology report and sent that report to the PCP.

The PCP saw the patient in the office on 11/23/2013. She tested the patient for TB and gave him a pneumonia vaccine. She asked the patient to return in 2 weeks, with the thought that he would have a repeat x-ray then. She later testified that she wanted to give the lungs a chance to clear, so there would be less risk of a false positive reading on imaging.

Unfortunately, the PCP did not have a "tickler" system for follow-up, should a patient not follow her instructions to return to the office. She also admitted at her deposition that she did not tell the patient of the possibility of cancer. There was no indication in her chart that she instructed her assistant to order the chest x-ray.

The patient did not return to his PCP's office for over a year and follow-up chest studies were not ordered.

In July of 2015, the patient reported to a local hospital emergency department with complaints of cough and increased BP. A chest x-ray identified a mass-like opacity in his left upper lung lobe, another mass density, and enlarged lymph nodes. After further testing, he was ultimately diagnosed with Stage IV, metastatic, non-small cell lung cancer. The patient died of his disease in December, 2016.

Questions:

1. At the 11/23 visit, was it reasonable that the PCP delayed her plan to x-ray the patient (though a CT scan was recommended in the report) to allow the lungs to clear?
2. In your office practice, do you require that a follow-up appointment be scheduled upon check-out?
3. If no, do you have a fail-safe process that would have identified that this patient did not return in 2 weeks as instructed?
4. Upon identifying that the patient did not schedule the follow-up appointment, is your process to notify the patient of their failure to establish an appointment and upon contact, set up the appointment at that time?
5. What is your process if you are unable to contact the patient or the patient refuses to establish an appointment?
6. Does your process include notification of the physician of a failed follow-up appointment or a patient refusal to schedule an appointment?
7. At the 11/23 visit instead of telling the patient to "return if no better," should the physician have been more descriptive, e.g., "Return in 2 weeks if you still feel ill and continue to have a fever and cough?"
8. Do you think the patient would have scheduled the follow-up appointment had he been informed of the results of the x-ray and the potential for lung cancer?

Comments:

This case was settled due to breach in the standard of care. Specifically, the physician had no dependable office practice system in place for follow-up should a patient not comply with the instructions to return and did not share with the patient the potential diagnosis of lung cancer.

Case Summary #2

This case begins in 2005, when the 29-year-old patient, became pregnant with her first child. As part of her prenatal workup, she underwent genetic testing for the cystic fibrosis (CF) mutation, for which neither she nor her husband had a family history. The results were reported by the laboratory as follows:

> **RESULTS: POSITIVE for one copy of the ΔF508 mutation and one copy of the D1152H mutation.**
>
> **INTERPRETATION:** This analysis identified two CF mutations. This individual may be affected with cystic fibrosis, a disorder with a wide range of clinical symptoms and variable age of onset. Further medical evaluation is recommended.

On 3/24/2005, an office nurse called the patient and told her that her CF test result indicated she had a single-gene mutation, which meant she had tested positive for being a CF carrier. It was recommended that her husband also be tested to see if he was a CF carrier. The husband was tested and his test was negative. The patient's pregnancy proceeded with regular prenatal visits and she gave birth on 10/20/2005.

In 2008, the patient again became pregnant and on 8/7/2008 she had her first prenatal visit. The office nurse discussed the patient's medical history and genetic screening/teratology counseling. The patient told the nurse that in 2005 she had tested positive for being a CF carrier, but was told that her own health could not be affected. The nurse reviewed the 2005 results and confirmed that the patient had tested positive for being a CF carrier and that neither husband nor wife needed to be tested again.

The patient's second pregnancy proceeded with regular visits until she gave birth on 3/12/2009. Several months later, the patient developed a cough, shortness of breath, excessive fatigue, and muscle aches. Her PCP diagnosed her with an upper respiratory infection. However, her symptoms never fully resolved. On 12/6/2009, the patient's PCP ordered a chest x-ray due to her shortness of breath, but the x-ray showed that the lungs were clear of infection or structural abnormalities.

On 4/27/2012, the patient underwent another chest x-ray, due to chronic cough and painful breathing. This showed significant bilateral infiltrative lung changes when compared to the 2009 study. The patient was referred to a pulmonologist who performed a bronchoscopy, obtained a detailed history, and ordered a CT scan. The results indicated that the patient had multiple infections in her lungs, Mycobacterium avium-intracellulare infection, and bronchiectasis.

After several months of treatments and referrals, the patient was again tested for CF. Several days later, the patient's pulmonologist told her she had two CF mutations, not one, and that she may have CF. She was then referred to a CF Clinic, where she was given a definitive diagnosis of CF and was told that if she had begun treatment when she first exhibited symptoms, she could have eliminated or suppressed her multiple infections, kept the bronchiectasis at a mild level, and prevented the MAI.

Questions:

1. What is the process in your office practice for communicating test results to patients?
2. Does the process include providing the patient with a complete copy of the report of their test results either via hard copy, portal or other means?
3. In your experience, what factors may have contributed to multiple providers and nurses misinterpreting the test result?
4. Do you think the formatting of the lab report contributed to the misinterpretation?
5. When reviewing the reports on test results, do providers in your practice thoroughly read the statements noted under "Results" and "Interpretations"? Or are they drawn to specific areas on reports and risk missing critical information? What is the solution?
6. If you were this patient's PCP and had been provided with a copy of the results in 2005, would anything in your medical record system have prompted you to look back at this test result when symptoms of CF occurred in 2009?
7. Having reviewed this case, is there anything you will change in your office practice to assure misinterpretation of results does not occur?

Comments:

The lab report clearly indicated that the patient had 2 genetic mutations for CF and specifically recommended a medical evaluation. The misinterpretation of the result and failure to follow-up with the patient was a breach in the standard of care and could not be defended. This claim was settled.

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