

# Health IT Safe Practices for Closing the Loop

Mitigating Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes Using Health IT



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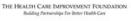


























































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# Closing the Loop: Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes

### **EXECUTIVE SUMMARY**

The Partnership for Health IT Patient Safety, established in 2013, is a multistakeholder collaborative convened and operated by ECRI Institute. The collaboration is made up of healthcare providers, health information technology (IT) developers, academic researchers, patient safety organizations, patient advocates, malpractice insurers, and professional societies. In keeping with the goal of collaboration to make health IT safer, the Partnership convened a workgroup chaired by Dr. Christoph U. Lehmann to address the topic of closing the loop.

Regardless of the means of communication used, tracking test results and medication changes has long been a challenge in all practice settings. This is evidenced by events reported to ECRI Institute's Patient Safety Organization (PSO) and medical liability claims reviewed by the workgroup.

Health technology holds the promise of improving this process. The Closing the Loop workgroup's objective was to identify ways that technology can mitigate the safety issues surrounding the "Failure to Close the Loop" that compromises safe and timely care.

The Joint Commission's National Patient Safety Goals published in 2018 include ensuring that important test results are provided to the right person in a timely manner (NPSG.02.03.01). The example Delayed Diagnosis, illustrates how results can be—and often are—missed when the loop of receipt, acknowledgment, and action remains open. The resulting consequences stem from these now delayed, missed, and incorrect diagnoses. A closed loop provides timely and effective therapies and mitigates diagnostic error.





### **DELAYED DIAGNOSIS**

A patient was seen for evaluation of testicular pain from possible testicular torsion. An ultrasound was performed. The initial verbal report stated that no torsion was seen. One week later, the written report noted "suspicious mass," with recommendation for the patient to follow up with a urologist. The report was signed by both the nurse practitioner and the physician. The patient was never informed.

The patient returned seven months later complaining of pain. A large testicular mass was discovered on physical examination.

This example shows multiple points of failure. First, the verbal report had not provided all of the information. Second, despite the fact that the written report was signed, its recommendations were not acknowledged. Finally, no actions were taken. As a result, this patient was not made aware of the "suspicious mass" for seven months.

Another important safety action is brought forth in another safety goal, NPSG.03.06.01,<sup>1</sup> which emphasizes the importance maintaining and communicating accurate patient medication information. As seen in the example, Automatic Refills, notification of the discontinuation of a medication resulted in consequences for this patient. Discontinuation of a therapy or a change in medications also requires closing the loop. Providers, patients, and those assisting with the essentials of therapies are all part of closing this loop.

### **AUTOMATIC REFILLS**

A patient's recent lab results indicated an elevated potassium level. The physician discontinued the patient's oral potassium in the electronic health record (EHR).

However, there was no mechanism to transmit this discontinuation to the patient's pharmacy. The oral potassium refill information resulted in an automatic refill in the pharmacy system. The patient was notified by the pharmacy to pick up the medication, and she did so.

This error went undiscovered until the patient's next office visit when corresponding lab work indicated a rise in the potassium level prompting further investigation.

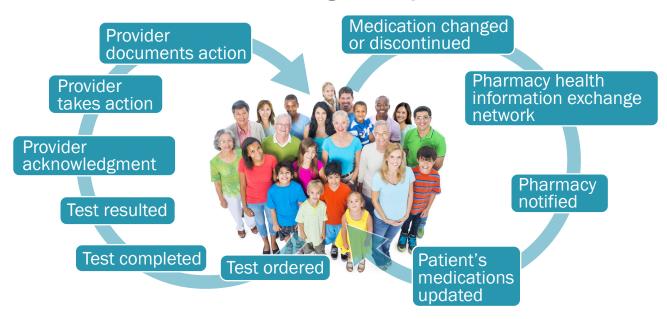
The workgroup's goal was to develop recommendations to ensure that all patient data and information that may require an action are delivered and communicated to the right individuals, at the right time, through the right mode to allow interpretation, critical review, reconciliation, initiation of action, acknowledgment, and appropriate documentation.

During this process, the workgroup recognized that often, new information requires more than one loop to close. Information throughout the healthcare delivery process is transmitted between entities such as laboratory, radiology, and pathology testing facilities, pharmacies, and other providers, all with a potential for interruptions of communication, which result in broken loops. In fact, a cascade of potentially interruptible loops may exist (e.g., diagnostic testing facility to provider, provider to pharmacy, provider to provider, and ultimately provider to patient). Figure 1 shows communication loops that can take place.





Figure 1. Patients are Central to Closing the Loop



To begin designing solutions, the workgroup refined the definition of "closing the loop" as follows.

Closing the loop includes all mechanisms\* that ensure that all patient data and information that may require an action are delivered and communicated to the right individuals, at the right time, through the right mode to allow interpretation, critical review, reconciliation, initiation of action, acknowledgment, and appropriate documentation.

The workgroup then turned its focus to identifying ways that health IT can be used to mitigate risk and improve safety by closing the loop on diagnostic testing results and medication changes, developing three recommendations:

- 1. Develop and apply IT solutions to communicate the right information (including data needed for interpretation), to the right people, at the right time, in the right format
- 2. Implement health IT solutions to track key areas
- 3. Use health IT to link and acknowledge the review of information and the documentation of the action taken

The following toolkit addresses the consequences of failing to close the loop by looking at evidence from PSO hazards and events, an evidence-based literature review, and methodical analysis by a multistakeholder workgroup as they identified safe practices and supported the recommendations with tools and suggestions that reflect the concept that safety is a shared responsibility.

<sup>\*</sup> Workflow and management tools, interventions, electronic and verbal notifications, checklists, alerts, and dashboards.





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# Introduction

### **DIAGNOSTIC ERROR**

Beginning in 1999, the Institute of Medicine (IOM) published a set of reports describing the burden of healthcare-associated harm<sup>2,3</sup> and defined four types of errors contributing to patient harm: diagnostic, treatment, preventive, and other.2 The IOM report, "Improving Diagnosis in Health Care,"4 highlighted the significance of diagnostic errors (DEs), and defined them as "the failure to establish an accurate and timely explanation of the patient's health problem(s) or communicate that explanation to the patient." The report further asserted that, statistically, every U.S. citizen will experience a meaningful DE in his or her lifetime. One other estimate suggested that DEs affect 1 in 20 outpatient adults annually.5

DEs are also responsible for about \$34 billion in annual U.S. malpractice payments. In surveys, 35% to 54% of pediatricians reported a DE occurring at least monthly and 33% to 45% reported DEs that harmed a patient at least annually. More than half (55%) reported they would be "very interested" and 33% "somewhat interested" in participating in a project to reduce diagnostic errors.

### **FAILURE TO CLOSE THE LOOP**

One particular insidious DE is based on the failure to respond to new, actionable information in the appropriate manner. We will call this particular DE "failure to close the loop." This failure can result in missed diagnostic opportunity. For example, overlooking an elevated blood pressure in the electronic health record (EHR) may lead to the missed diagnosis of hypertension, and not responding to a low hemoglobin level may lead to the missed opportunity to diagnose and treat anemia. In a recent study, missed diagnostic opportunities arising from failure to close the loop in pediatric primary care were found to be 54% for patients with elevated blood pressure (N = 389), 11% for patients with abnormal laboratory values, and 62% for adolescents with an opportunity to evaluate for depression.9

The reasons for errors in failing to close the loop are multifactorial. In the case of an ordered laboratory test, a multitude of failures may occur: a test may not have been sent, not received in the laboratory, or not reported. The result may not have been received, not tracked within the office, reported

to the incorrect provider, misfiled, or missed by the provider. Alternatively, the provider may have forgotten to follow up or performed an incorrect follow-up action.

Closing the loop implies that novel information has been delivered to the right person in order to initiate action based on the new information, which is important for timely and effective therapies. Errors in failing to close the loop may not only result in missed diagnostic opportunities, but may lead to treatment failure—for instance, in a case of a patient who continues to take both a new medication and a discontinued but inappropriately refilled medication.

This manuscript is the work product of the *Partnership for Health IT Patient Safety*. Armed with knowledge of patient harm due to lack of closing the loop and charged with exploring potential technological solutions, the *Partnership's* Closing the Loop workgroup identified strategies to leverage health technology to empower developers, providers, provider organizations, information technology (IT) professionals, professional organizations, regulators, policymakers, and patients to develop technology solutions to close the loop.





# **Methods**

# CLOSING THE LOOP WORKGROUP

Meeting monthly from May through October 2017, the workgroup used collaboration software to collect and review various sources of information. The workgroup deliberations provided an opportunity to integrate and synthesize information used in drafting safe practice recommendations for Closing the Loop. The workgroup first defined the problem and its scope and then reviewed event and malpractice claims data, identified various causes of potential failures in closing the loop, studied successful programs and solutions, and explored standards available for addressing diagnostic results and medication changes. Finally, the workgroup drafted safe practice recommendations for Partnership consideration.

The recommendations are meant for the following stakeholder groups:

 Public and private organizations and government authorities, including the Office of the National Coordinator for Health IT (ONC)

- National patient safety initiatives, such as ECRI Institute
- Professional organizations and societies, such as the American Medical Association (AMA)
- Standard-setting organizations, such as Health Level Seven International (HL7)
- · Patient advocacy groups
- Healthcare stakeholders, such as providers, provider organizations, and healthcare systems
- Vendor stakeholders, such as healthcare IT developers and vendors

#### LITERATURE REVIEW

To support the workgroup, an evidence report to identify interventions assessed in the literature was performed. Specifically, this literature review addressed the following key questions:

Key Question 1: What interventions are effective for improving (1) communication of test results to providers and patients and (2) follow-up of actionable results by providers?

 Key Question 2: What interventions are effective for communicating provider changes to patient medication regimens to other providers, pharmacies, and the patient?

An ECRI Institute master's level medical librarian conducted searches of PubMed, MEDLINE, EMBASE, CINAHL, and Scopus to identify studies published from January 2009 to April 2017. Investigators used both medical-subject headings and keywords to address four broad concepts: electronic medical records, diagnostic tests, communication, and ambulatory care. The full search strategy is available in Appendix D of the ECRI Institute Special Report.<sup>10</sup>

A physician analyst screened all studies using specified inclusion criteria. For Key Question 1 (diagnostic tests) studies had to assess an intervention. Studies performed outside of the United States were excluded as were noncomparative studies. Searches identified 200 citations, of which 33 met inclusion criteria. With regard to Key Question 2, searches identified 40 citations; however, no





studies met inclusion criteria. Even after dropping the requirement for studies to test an intervention, no studies were identified. See Figure 2.

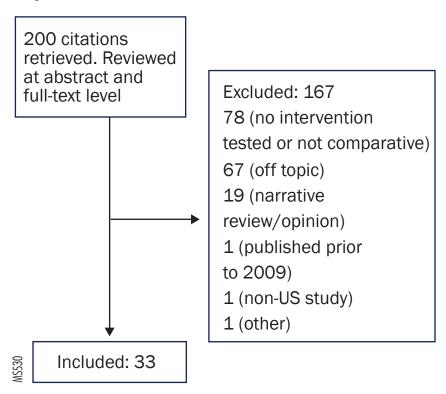
For randomized controlled trials (RCTs), analysts used the U.S. Preventive Services Task Force (USPSTF) criteria for grading study quality. For pre/post studies, which comprised the majority of studies, analysts selected six items (pertaining to study design and conduct) to assess study quality. A single physician analyst performed all quality assessments.

# ECRI INSTITUTE PATIENT SAFETY ORGANIZATION (PSO) DATA REVIEW

ECRI Institute Patient Safety
Organization (PSO) is recognized
as a federal patient safety organization by the U.S. Department of
Health and Human Services under
the Patient Safety and Quality
Improvement Act of 2005. A keyword
search of the PSO database's event
description field was used to identify
patient safety events related to failure to close the loop for test results.
ECRI Institute analysts reviewed

more than 800 relevant events from the PSO database from February 2011 through January 2017. The events were reviewed and tagged using a taxonomy developed by analysts working with ECRI Institute PSO and the *Partnership*. An additional review of more than 80 medical malpractice closed claim reports for the years 2002 through 2014 was performed, and the same taxonomy was applied to these examples of failure to close the loop.

# Figure 2. Identification of Studies for Key Question 1







# Results

While reviewing the literature and PSO data on failure-to-close-theloop cases, we identified the type of information not communicated (what), players involved in the communication failure (who), and the failed communication modality (how). The information that was not communicated included laboratory tests, pathology, imaging, other diagnostic results as well as changes to treatments and other (Table 1). The intended recipients of the information included physicians, staff, patients, and others. The communication mode that failed included verbal and electronic communication, provider-patient interaction, and unknown.

# RESULTS FROM THE LITERATURE DATA REVIEW

Medical analysts included 33 research articles: 27 articles (describing 24 interventions) and 6 studies validating potential EHR-based tools in their results. Of intervention studies, 5 were RCTs and 19 were before/after (pre/post) studies.

Interventions attempted to improve closing the loop for

diagnostic tests in the five following clinical contexts:

- Inpatient-to-outpatient transitions
- Outpatient-to-inpatient transitions
- Communication of actionable radiology findings
- Follow-up of abnormal outpatient studies
- Detection of abnormal inpatient results

An overview of intervention and validations studies is provided in Table 1.

No studies assessed interventions for improving communication of provider-initiated medication changes. However, a small but substantive literature base described interventions to close the loop for diagnostic tests across diverse clinical contexts. Specifically, identified were six overarching IT strategies with some evidence of efficacy: alerts (email, pager, EHR), audits, data gathering (i.e., improving discharge summaries), identifying the responsible provider, integrating systems, and automatic consultations/referrals.

Results from the literature review can be found in the ECRI Special Report.

# RESULTS FROM THE PSO DATA REVIEW

The PSO data provided evidence to support the concept that closing the loop is a pressing concern both in its immediate consequences (e.g., delay in diagnosis and treatment) and in its long-term consequences (missed or incorrect diagnoses). The ramifications of failing to close the loop are prevalent throughout the continuum of care.

The PSO data revealed that the majority of safety events primarily occurred in the acute care **inpatient** setting while the majority of the malpractice claims originate in the **ambulatory** care setting. Further, PSO safety event data focused on failure to close the loop for laboratory testing and medication changes, which appear to be more prevalent, while imaging, laboratory, and pathology information, which appear to carry a higher liability risk when the loop is not closed, were the areas of focus in malpractice claims data.





**Table 1. Overview of Clinical Contexts and Interventions** 

Clinical Context	Number of Studies	Interventions	References
Inpatient to outpatient	7	Improved discharge summaries	Cadwallader et al. 2012 <sup>12</sup> Gilliam et al. 2017 <sup>13</sup> Kantor et al. 2014 <sup>14</sup> Watkins et al. 2014 <sup>15</sup>
		Automated email notification of physicians	Dalal et al. 2014 <sup>16*</sup> El-Kareh et al. 2012 <sup>17*</sup>
		New review protocol for pending urine cultures, followed by nurse phone call	Saha et al. 2017 <sup>18</sup>
Outpatient to inpatient	1	Electronic medical record (EMR)	Pham-Thomas et al. 2014 <sup>19</sup>
Communicating action- able radiology findings	6	Secure messaging capability integrated directly into radiology workflow; automated identification of responsible provider contact information; electronic health record (EHR) alerts	Filice 2017 <sup>20*</sup> Lacson et al. 2015 <sup>21†</sup> Lacson et al. 2014 <sup>22†</sup> O'Connor et al. 2012 <sup>23†</sup>
		Alert to provider, but also surgical oncology clinic for results concerning for malignancy	Browning et al. 2013 <sup>24</sup>
		Direct messaging plus alerts, with dedicated team to follow up with communication	Dibble et al. 2017 <sup>25</sup>
Follow-up of abnormal outpatient studies	12	Fecal occult blood test (FOBT)  EHR alert, multifaceted quality improvement initiative, including monitoring by preventive medicine coordinator (Singh et al. <sup>28</sup> )  Automated referral to gastrointestinal clinic (Humphrey et al.)  EHR software reconfigured to ensure results returned to primary care physician (Singh et al. <sup>29</sup> )  EHR audit; weekly monitoring for follow-up, with alerts (Larson et al.)	Humphrey et al. 2011 <sup>26</sup> * Larson et al. 2009 <sup>27</sup> Singh et al. 2009 <sup>28</sup> Singh et al. 2009 <sup>29</sup>
		Tests raising concern for lung, colorectal, or prostate cancer EHR audit, with manual chart review; secure email alerts for follow-up	Murphy et al. 2015 <sup>30*</sup> also de scribed in Meyer et al. 2016 <sup>3</sup>
		Pathology tests EHR alerts	Laxmisan et al. 2012 <sup>32</sup>
		Abnormal Papanicolaou (Pap) smear EHR-based tracking reports for each provider; with EHR alert and tracking form	Dupuis et al. 2010 <sup>33</sup>
		Hyperkalemia (potassium [K] ≥6) EHR alert	Lin et al. 2011 <sup>34</sup>
		HIV labs EHR modified to interface between clinic and commercial laboratory (LabCorp)	Bell et al. 2012 <sup>35</sup>
		General laboratory/radiology tests EHR	Elder et al. 2010 <sup>36</sup>
		Abnormal laboratory tests (creatinine >1.8, K >5.4, thyroid-stimulating hormone [TSH] >10, international normalized ratio [INR] >4, prostate-specific antigen [PSA] >5) PROMISES (Proactive Reduction of Outpatient Malpractice: Improving Safety, Efficiency, and Satisfaction) project; quality-improvement initiative with education and on-site support	Schiff et al. 2017 <sup>37</sup>
Detection of abnormal inpatient results	1	Decision rule to detect new atrial fibrillation from inpatient electrocardiograms (EKGs) and clinical decision support	Cook et al. 2015 <sup>38</sup>
Validation studies (multiple clinical contexts)	6	Tools to identify potential delays in follow-up for abnormal chest imaging, FOBT, hematuria, iron deficiency anemia, PSA, radiology reports with critical findings, TSH	Lakhani et al. 2012 <sup>39</sup> Meyer et al. 2017 <sup>40</sup> Murphy et al. 2017 <sup>41</sup> Murphy et al. 2016 <sup>42</sup> Murphy et al. 2016 <sup>43</sup> Murphy et al. 2013 <sup>44</sup>

 $\textbf{Source:} \ \textbf{ECRI Institute.} \ \textbf{Special Report:} \ \textbf{Closing the Loop on Diagnostic Tests:} \ \textbf{Information Technology Solution.} \\ \textbf{^{.10}}$ 

<sup>\*</sup> Denotes randomized controlled trial.

 $<sup>^{\</sup>dagger}$  These three studies describe the same or iterative interventions.





Failure to close the loop is primarily seen with six types of information (Table 2). The most common failures for safety events occurred in laboratory testing (61%), followed by events related to imaging (12%). Data from closed medical malpractice claims suggest that imaging (36%) was the information most vulnerable to not being communicated, followed by laboratory testing (23%) and pathology (18%).

We used the following definition of a critical result: A critical result is a result from test that must be reported immediately to a care provider because it may require urgent therapeutic action. Using this definition, we also grouped information that was not communicated by criticality. Both for events and malpractice claims, significantly abnormal **noncritical** results were more likely to not be communicated (Table 3).

Most failures to close the loop had multiple targets for notification. In reported safety events, staff (65%) was the most common target of communication, followed by physicians (62%). For claims, the most common target was the physician (89%), followed by the patient (71%), and staff (46%).

Not surprisingly, only 19% of reported events resulted in a delay in treatment or diagnosis, while 96% of malpractice claims included a claim of delay. This delay was triggered mostly by failure to report or communicate (80%) and delay in reporting or awareness (19%) for events. For claims, the most common reason was that a provider acknowledged information and failed to follow up (39%), followed by failure to report or communicate (30%), delay in reporting (21%), and unclear/ambiguous communication (16%).

Table 2. Prevalence of Reported Safety Events and Closed Malpractice Claims

Area for Failure to Close the Loop	Events (%) (N = 848)	Malpractice Closed Claims (%) (N = 82)
Laboratory testing	61	23
Imaging	12	36
Other diagnostics	5	8
Pathology	2	18
Treatment	2	5
Other	18	11

**Source:** Data were presented at the Closing the Loop Workgroup. 2017 Jul 11.

**Note:** Event reports in the ECRI Institute PSO database disproportionately represent the acute care setting, as opposed to the ambulatory care setting. Malpractice closed claims were primarily from the ambulatory setting.

Table 3. Events and Claims by Criticality

Results	Events (%) (N = 848)	Claims (%) (N = 82)
Critical value	28	0
Noncritical value but significantly abnormal result	55	84
Critical value with test not specified	5	0
Other	12	16





## Recommendations

### **OVERVIEW**

The Partnership's safe practice recommendations for "Closing the Loop: Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes" are focused on three domains: communication, tracking, and linking acknowledgment to action taken.

# COMMUNICATE USING HEALTH IT TO CLOSE THE LOOP

Effective and efficient communication between testing facilities, pharmacies, providers, and patients can enhance care across disparate health systems. Designing, testing, deploying, and implementing health IT solutions to improve these communication pathways has the potential to make closing the loop a seamless and elegant process, with all diagnostic results and medications communicated to the provider, the pharmacy, and the patient. But this is possible only when the information is clearly communicated, transmitted, interpreted, and expressed.

The workgroup recommendation is to develop and apply IT solutions to communicate the right information (including data needed for interpretation), to the right people, at the right time, in the right format, using the right channel. The workgroup developed recommendations for diagnostic results and medication changes. These recommendations involve using health IT for communicating, tracking, and linking.

### Improve the Transmission of Information Using Standards for the Formatting of Normal, Critical, Abnormal-Noncritical, and Abnormal Results

To permit effective analysis and routing of results to the appropriate providers, rules and decision support should be applicable to all results. One basic requirement for effective implementation is the use of standard clinical vocabulary and definitions for reporting of diagnostic results using SNOMED CT (e.g., normal, critical, noncritical, and incidental findings) for discrete reporting of diagnostic results. Further findings must be entered in a structured format to permit automatic processing.

### **COMMUNICATE**

- Improve the transmission of information using standards for the formatting of normal, critical, abnormal-noncritical, and abnormal results
- Improve reporting of actionable findings to include results priority and the required timing of responses to diagnostic testing through adoption of standards
- Improve the transmission of information using universally recognizable display icons in the EHR for alerts and notifications
- Enhance the usability of communication of diagnostic results
- Use existing EHR functionality to automate the notification process
- Improve notification and reduce alert fatigue through optimizations of alerts
- · Communication of diagnostic results should not be interrupted
- · Communicate diagnostic findings directly to the patient





This recommendation requires rule-making by government authorities, development of standards by provider and professional organizations, implementation of these standards into commercial solutions, and enforcing the use of these standards by organizational leadership and health IT developers.

### Improve Reporting of Actionable Findings to Include Results Priority and the Required Timing of Responses to Diagnostic Testing Through Adoption of Standards

Routing of results and escalation of critical results requires that systems must understand the priority of the results and the required response time for a provider to be notified and react. Standardized clinical vocabularies and definitions for reporting diagnostic findings (through mapping, using SNOMED CT and logical observation identifiers names and codes [LOINC]), must be mandated, selected, implemented, maintained, and enforced—both organization- and industry-wide.

### Improve the Transmission of Information using Universally Recognizable Display Icons in the EHR for Alerts and Notifications

It helps providers to recognize that information requires their attention when the symbols that convey that message are identical and uniform in all health information systems. The workgroup recommends that developers agree upon and adopt universal display icons that have been determined most effective by usability experts and researchers. These icons will transfer to clinicians

the urgency, criticality, and risk associated with new result information.

# Enhance the Usability of Communication of Diagnostic Results

Improving the usability of the way diagnostic results are transmitted will improve understanding and response to critical information. A number of actions can be taken to improve the likelihood that the information received is delivered via the right channel and in the right format for the individual user.

The workgroup recommends implementing multiple channels that allow secure transmission of results including direct messaging, email notification, messages within the EHR, and direct phone communication. Using a plethora of mechanisms to contact providers requires that these channels must be optimized to meet the provider's needs, which will vary significantly between individuals and even for a single individual based on time, current responsibilities, and communication preferences. The workgroup recommends that providers be given the option to customize their channel preferences based on time (weekday, weekend), message type (page for elevated potassium, email radiology results), and medium preference (email, text, page).

Functionality must be developed to generate reminders and to escalate and delegate a result in the event that receipt and response are not received within a reasonable time for highly critical results. This includes the recipient temporarily rerouting of responsibilities in regards to results

to a colleague. Because of the complexity, training in setting these communication preferences must involve providers and staff.

Not all results must be received, processed, and acknowledged by a provider. The goal of result-processing systems should be to optimize each member of the team to practice at the top of his or her scope of practice. The workgroup recommends automatic triage to route results to the appropriate member of the team based on urgency, criticality, and required type of response.

For results to reach providers, provider directories must be maintained and updated with accurate information, including patient-provider relationships. Further, provider availability must be maintained as well, to allow for accurate triggering of escalation policies.

# Use Existing EHR Functionality to Automate the Notification Process

Existing EHR functions can be modified to improve the delivery of results, including automatic messages/emails to providers to alert them to critical results. This process should be separate from the mechanism used to transmit noncritical, nonurgent results.

For critical results, systems may request and document delivery receipts that can include responses or actions taken by the provider in response to the novel result. For example, a result may automatically offer the provider an appropriate action (e.g., send a message to the patient, order another test, consult a specialist) that would then be





documented in connection with the result.

The EHR must be able to handle these reminders and escalation procedures.

### Improve Notification and Reduce Alert Fatigue Through Optimization of Alerts

The workgroup concluded that alerts must be differentiated by severity, including low, medium, and high severity. The criticality of an alert should be in direct correlation with how intrusive it may appear to users. Low criticality alerts, for example, may be silent, while high criticality alerts might interrupt a user. Users should be given the opportunity to generate automatic responses to low-level alerts.

# Communication of Diagnostic Results Should not be Interrupted

The workgroup is aware of the intrusion of health IT into the off time of providers, and it balanced the desire to be unavailable with the need to respond to critical information in a timely manner. Therefore, the workgroup recommends that secure, ubiquitous, off-site access be available for providers by which they can communicate in a manner compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

### Communicate Diagnostic Findings Directly to the Patient

The workgroup recommends the use of existing patient facing communication technologies, such as patient portals, mobile applications, secure email, and secure text messaging,

to notify the patient directly of diagnostic findings. Review of these notifications could trigger automatic acknowledgments. Providers must use judgment for which types of diagnostic results these methods are appropriate (normal results, confirmatory information) and for which results a direct encounter is more appropriate. For patients without access to digital tools, alternatives such as postal mail must be available.

### MEDICATION CHANGE COMMUNICATION STRATEGIES

For changes in the patient's medication regime, the workgroup had a number of recommendations:

- Adoption of the National Council for Prescription Drug Programs (NCPDP) SCRIPT (e.g., CancelRx) as a standard to ensure communication of electronic discontinuation of a prescription to the pharmacy, acknowledgment by the pharmacy, and automatic discontinuation of renewals.
- Adoption of the NCPDP (e.g., RxChange) as a standard to improve communication

### **MEDICATION STRATEGIES**

- Adopt NCPDP SCRIPT CancelRX for discontinuation of medication
- Adopt NCPDP SCRIPT for RXChange clarification of prescription
- Adopt NCPDP Script RXFILL to notify the prescriber of the status of the prescription
- Adopt NCPDP standards via incentives

- between the pharmacy and the prescriber, including change requests and clarification requests for any prescription.
- Adoption of the NCPDP SCRIPT for prescription-fill status notification (e.g., RXFILL) from the pharmacy to the prescriber to notify the prescriber of the status of a prescription. NCPDP version 10.6 allows the standard to be patient-specific, eliminating an overabundance of notifications.
- Adoption of NCPDP standards by all parties through government incentive programs, and promotion by professional organizations and societies and patient advocacy groups.

# TRACKING OF LOOP CLOSURE USING HEALTH INFORMATION TECHNOLOGY

The workgroup concluded that it is essential to implement health IT solutions to track key areas. Providers, organizations, and leadership all want to know when a loop remains open. Accurate tracking and monitoring of diagnostic results and medication changes including occurrence, transmission of information, acknowledgment, documentation, and responses are essential to identify closed loops. Tracking of diagnostic results and medication changes is a time-consuming, burdensome task, but necessary to ensure a closed loop. Identification of interruptions and potential failure points in the process is critical to find and react to failures to close the loop.





### **TRACK**

- Explore opportunities for tracking, determining where health IT can be used to correct deficiencies and improve tracking
- Assign accountability for and ensure oversight of tracking
- Improve tracking by implementing laboratory standards
- Improve tracking by implementing bi-directional communication

# Exploring Opportunities for Tracking

The workgroup recommends that organizations determine where health IT can be used to correct deficiencies and improve tracking to close the loop. This can be accomplished by reviewing and revising existing organizational diagnostic-results management processes and procedures and conducting gap and workflow analyses, as well as updating and publicizing policies and contingency plans.

### Assign Accountability for and Ensure Oversight of Tracking

Organizations must use existing EHR functionality to initiate tracking of issues related to closing the loop, including review of incomplete orders, results not reviewed, missing acknowledgments by providers on critical results, results not transmitted to the provider or patient, and results not reviewed by the patient on the portal. Automatic tracking of these events and using a dashboard to show the prevalence of these events would be helpful.

In addition, audits of EHR data, using redefined triggers to identify failures to close the loop, should be implemented. Example triggers are critical results not followed by an appointment or medication change, lack of repeat testing, actionable items remaining incomplete, or lack of any communication with the patient. Although these triggers may identify false-positive events where the loop has been closed, fine-tuning and combining with additional data may improve accuracy.

# Improve Tracking by Implemeting Laboratory Standards

The workgroup recommends using standards such as LOINC to automate accurate matching of results to ordered tests to enable automatic detection of loops closed.

### Improve Tracking by Implementing Bi-Directional Communication

The workgroup recommends integrating interfaces to third-party systems (such as laboratory systems) to not only simplify the ordering and reporting of laboratory, radiology, pathology, and hospital diagnostic results but return results corresponding to the requests.

Interfaces should be routinely and automatically monitored for failures and performance degradation using interface-specific tracking options (e.g., system failure alerts, email notifications, reports, error logs, queues). Prior to deployment, interface-monitoring tools should be tested, including usability testing, to ensure accuracy and correct interpretations by human observers.

Combining the monitoring of multiple interfaces is preferably aggregated in a single application to allow responsible parties to monitor the health of the system.

# Track the Status of Medication Changes

Adopting and implementing NCPDP's SCRIPT standards for prescription-fill status notifications will reassure the provider that the information has been communicated and received. The workgroup recommends that the NCPDP SCRIPT for prescription-fill status notification (e.g., RXFILL) be adopted. NCPDP version 10.6 allows for the standard to be patient-specific, eliminating an overabundance of notifications.

### LINK AND ACKNOWLEDGE

The final recommendation is to use health IT to link and acknowledge the review of information and to document the action taken. This step includes the actor reviewing and acknowledging or acting upon information.

### Optimize Health IT to Link and Store an Acknowledgment and to Record the Action Taken

The workgroup recommends that organizations take an active role to improve interoperability by integrating systems connecting information across the care continuum. This is to facilitate communication and acknowledgment, including the use of application programming interfaces (APIs) to allow laboratory systems and hospitals to communicate, as well as the use of HL7 and fast healthcare interoperability resources (FHIR) to aggregate and merge patient data from separate data sources. When systems communicate, acknowledgment or





### LINK

- Optimize health IT to link and store an acknowledgment and to record the action taken
- Develop functionality to communicate actions taken along with or instead of acknowledgments

documented actions can flow back, allowing automatic confirmation of loop closure.

### Develop Functionality to Communicate Actions Taken Along with or Instead of Acknowledgments

Allowing the action taken in response to a notification (e.g., ordered another test, notified the patient, ordered biopsy, modified medication) to be documented in combination with the novel information will improve the determination that a loop was closed. The workgroup recommends that diagnostic-results notification messages be modifiable by the recipient to add the action performed to close the loop (e.g., read, acknowledged, patient notified, follow-up complete, consultation requested and confirmed).

### CONCLUSION

Closing the loop is a multistep. multistakeholder process. Adding a plethora of technology alerts and reminders to an already dysfunctional process for results management or medication discontinuation will only obfuscate matters. Stakeholders are tasked with implementing practices to close the loop, because failure to do so has the potential to result in missed and delayed diagnoses and patient harm. Clinical workflows should align with electronic workflows. The workgroup's recommendations are directed at providers, provider organizations, developers, and those implementing IT within facilities. These safe practice recommendations are a call to action. Although the EHR and its technology components have the potential to facilitate timely follow-up across all healthcare settings, it may take regulatory efforts to make this possible.

The Partnership for Health IT Patient Safety offers three recommendations for communicating, tracking, and linking, along with references and tools to facilitate their implementation to improve closing the loop for diagnostic testing and medication changes.

When executing the safe practice recommendations, stakeholders must be cognizant not to complicate an already complex workflow. By executing these recommendations, people and organizations across healthcare (including patients) can help ensure that providers have the most accurate and up-to-date information, which is necessary to provide the most effective and efficient care to patients, leading to an improvement in outcomes.

As we move forward in crafting solutions, we must recognize all of the stakeholders, including government regulators, policymakers, healthcare organizations, IT developers, patients, and others. They all play a role in developing solutions to effectively close the loop to mitigate delayed, missed, and incorrect diagnoses related to diagnostic testing and medication changes.





	Tools/References	ies The Joint Commission's 2018 National Patient Safety Goals ONC: Interoperability Standard Acceleration What is SNOMED CT? LOINC from Regenstrief nations National Quality Forum's Improving Diagnostic Quality and Safety Consider using Use Cases. For example Use Case: A Closed Loop		See also Regenstrief's How is LOINC Like EMOJI?	Samal L, Stavroudis T, Miller R, Lehmann H, Lehmann C. Effect of a laboratory result pager on provider behavior in a neonatal intensive care unit. Appl Clin Inform 2011 Sep 28;2(3):384-94.
_	Stakeholder	Government authorities Developers Provider/provider organizations Leadership Information technology (IT) Professional organizations		Developers Researchers IT Providers/provider organizations	Leadership IT Developers Providers/provider organizations
COMMENDATIONS FOR CLOSING THE LOOP USING HEALTH IT	Diagnostic results—strategies	Improve the transmission of information using standards for the formatting of normal, critical, abnormal-noncritical, and abnormal results  • Implement standard clinical vocabulary and definitions for reporting of diagnostic results using SNOMED CT for reporting (e.g., normal, critical, noncritical, and incidental findings) for discrete reporting of diagnostic results  • Findings must be entered in a structured format to permit automatic processing	Improve reporting of actionable findings to include results priority and the required timing of responses to diagnostic testing through adoption of standards  • Standardized clinical vocabularies and definitions for reporting of diagnostic findings—through mapping, using SNOMED CT and LOINC—must be mandated, selected, implemented, maintained, and enforced	Improve the transmission of information using universally recognizable display icons in the electronic health record (EHR) for alerts and notifications  • Agree upon and adopt universal display icons that have been determined most effective by usability experts and researchers  • Icons will transfer to clinicians the urgency, criticality, and risk associated with new result information	Enhance the usability of communication of diagnostic results  • Implement multiple channels that allow secure transmission of results, including direct messaging, email notifications, message within the EHR, and direct phone communication  • Providers should be given the option to customize their channel preferences based on time (weekday, weekend), message type (page for elevated potassium, email radiology results), and medium preference (email, text, page)  • Develop functionality to generate reminders and to escalate and delegate a result in the event that receipt and response are not received within a reasonable time for highly critical results  • Implement automatic triage to route results to the appropriate member of the team based on urgency, criticality, and required type of response  • Provider directories must be maintained and updated with accurate information, including patient-provider relationships  • Provider availability must be maintained as well, to allow for accurate trispering escalation bolicies.
SAFE PRACTICE RECOMMENDAT	Communicate	Develop and apply information technology (IT) solutions to communicate the right information (including data needed for interpretation), to the right people, at the right format the right format			

Table 4. Recommendations from the Work Group



Table 4. Recommendations from the Work Group (cont.)



SAFE PRACTICE RECOMMENDAT	RACTICE RECOMMENDATIONS FOR CLOSING THE LOOP USING HEALTH IT	<b>-</b>	
Communicate	Diagnostic results—strategies	Stakeholder	Tools/References
	Use existing functionality to automate the notification process  • Modify existing functionality to improve the delivery of critical results, including automated messages/email to providers to alert them to critical results	Provider/provider organizations Leadership	American Medical Association's EHR In-Basket Restructuring for Improved Efficiency
	The process for delivery of critical results should be separate from the mechanism used to transmit noncritical, nonurgent results     For critical results, systems may request and document delivery receipts that can include responses or actions taken by the provider in response to the novel result     Ensure that the existing EHR functionality is capable of reminders and escalation procedures		
	Improve notification and reduce alert fatigue by optimizing alerts  • Alert must be differentiated by severity, including low, medium, and high severity  • The criticality of the alerts should be in direct correlation with how intrusive it may appear to users  • Users should be given the opportunity to generate automated responses to low-level alerts	Developers Provider/provider organizations Leadership IT Professional organizations	EHRA Electronic Record Design Patterns for Patient Safety Paterno MD, Maviglia SM, Gorman PN, Seger DL, Yoshida E, Seger AC, Bates DW, Gandhi TK. Tiering drug-drug interaction alerts. J Am Med Inform Assoc 2009 Jan-Feb;16(1):40-6.
	Communication of diagnostic results should not be interrupted  • Provide secure ubiquitous off-site access for providers where they can communicate in a manner compliant with the Health Insurance Portability and Accountability Act of 1996 (HIPAA)	IT Developers Leadership	Health information privacy (HIPAA)
	Communicate diagnostic results directly to the patient  • Use exiting patient-facing communication, technologies such as patient portals, mobile applications, secure email, and secure text messaging to notify patients directly of diagnostic findings  • Review of these notifications could trigger automatic acknowledgment	IT Developers Leadership	Shultz SK, Wu R, Matelski JJ, Lu X, Cram P. Patient prefer- ences for test result notifica- tion. J Gen Intern Med 2015 Nov;30(11):1651-6. HIMSS Patient Engagement Framework
	Medication changes—strategies		
	<ul> <li>Adopt National Council for Prescription Drug Programs (NCPDP) SCRIPT         (e.g., CancelRx) as a standard to ensure that the electronic discontinuation         of a prescription is transmitted to the pharmacy and acknowledged by the         pharmacy and that renewals are automatically discontinued         Adopt NCPDP (e.g., RXCHANGE) as a standard to improve communication         between the pharmacy and the prescriber, including change requests and         clarification request for any prescription</li> <li>Adopt NCPDP SCRIPT for prescription-fill status notification (e.g., RXFILL)         from the pharmacy to the prescriber to notify the prescriber of the status of         a prescription. NCPDP version 1.0.6 allows for the standard to be patient-         specific, eliminating an overabundance of notifications         Adoption of NCPDP standards by all parties through government incentive         programs and promotion by professional organizations and societies and         patient advocacy groups</li> </ul>	Government authorities Provider/provider organizations Leadership Pharmacist Professional organizations	NCPDP Standards Information





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Track	Diagnostic results—strategies	Person	How
Implement IT solutions to track key areas	Determine where health IT can be used to correct deficiencies and improve tracking to close the loop  • Improve tracking to close the loop by reviewing and revising existing organizational diagnostic-results management processes and procedures  • Conduct gap analyses  • Conduct workflow analyses  • Update and publicize policies and contingency plans  Assign dedicated accountability for and ensure oversight of tracking  • Use the existing EHR functionality to initiate tracking of issues related to closing the loop, including incomplete orders, results not reviewed, missing acknowledgements by provider on critical results, results not transmitted to the provider, and results not reviewed by the patient on the portal  • Audits of EHR data using redefined triggers to identify failure to close the loop should be implemented (e.g. critical results not followed by an appointment or medication change, lack of repeat testing, actionable items remaining incomplete, or lack of any communication with the patient)  • Apply EHR audits using redefined triggers to identify breaks in the process (e.g., no follow-up appointment scheduled to review testing results or medication-change effects, result not acknowledged, absence of follow-up, actionable items)	Provider organizations Leadership Providers and staff Developers	ouc's SAFER Guides: Test Results Reporting and Follow-Up National Learning Consortium's Workflow Process Mapping for EHR Implementation The Agency for Healthcare Research and Quality's (AHRQ) PCP Facilitation Curriculum—Mapping and Redesigning Workflow AHRQ's Improving Your Office Testing Process EHRA Electronic Record Design Patterns for Patient Safety Murphy DR, Meyer AND, Vaghani V, Russo E, Sittig DF, Wei L, Wu L, Singh H. Electronic triggers to identify delays in follow-up of mammography: harnessing the power of big data in health care. Am Coll Radiol 2018 Feb;15(2):287-95.
	Improve tracking by implementing laboratory standards  • Use applicable standards such as LOINC to automate accurate matching of result to ordered test to enable automated detection of loops closed	Developers Professional organizations	LOINC's The universal standard for identifying health measurements, observations, and documents
	Improve tracking by implementing bi-directional communication  Integrate interfaces to third-party systems (such as laboratory systems) to simplify the ordering and reporting of laboratory, radiology, pathology, and hospital diagnostic results, returning results corresponding to the requests  Interfaces should be automatically monitored for failures and performance degradation using interface-specific tracking options  Prior to deployment, interface-monitoring tools should be tested including usability testing  Combining the monitoring of multiple interfaces is preferably aggregated in a single application to allow responsible parties to monitor the health of the system	Developers Provider organizations Government authorities	ONC's SAFER Guides System Interfaces Surescripts.com
	Medication-strategies and potential implementations		
	<ul> <li>Track the status medication changes through the adoption and implementation of NCPDP SCRIPT standards for prescription-fill status notifications to be certain that information is communicated and received via the same electronic format</li> <li>Adopt NCPDP SCRIPT for prescription-fill status notification (e.g., RXFILL). This transaction is sent from the pharmacy to the prescriber to notify the prescriber of the status of a prescription. NCPDP version 10.6 allows for the standard to be patient-specific, eliminating an overabundance of notifications</li> </ul>	Government authorities Provider/provider organizations Leadership Pharmacist Professional organizations	NCPDP Standards Information

SAFE PRACTICE RECOMMENDATIONS FOR CLOSING THE LOOP USING HEALTH IT

Table 4. Recommendations from the Work Group (cont.)



Table 4. Recommendations from the Work Group (cont.)



SAFE PRACTICE RECOMMENDATIONS FOR CLOSING THE LOOP USING HEALTH IT	Person How	Government authorities ONC's About APIs Developers FHIR's FHIR Release 3 Provider organizations	Professional organizations steiner K, Newmark LP, Samal L, Rothschild JM. Linking acknowledgement to action: closing the loop on non-urgent, clinically significant test results in the electronic health record. J Am Med Inform Assoc 2015 Jul;22(4):905-8.  AHRQ's Improving Your Labora-
	Diagnostic results—strategies and potential implementations	<ul> <li>Take an active role to improve interoperability through the integration of systems, connecting information across the care continuum to facilitate communication and acknowledgment</li> <li>Include the use of application programming interfaces (APIs) to allow laboratory systems and hospitals to communicate</li> <li>Use Health Level Seven International (HLZ) and fast healthcare interoperability resources (FHIR) to aggregate and merge patient data from separate data sources</li> </ul>	<ul> <li>Develop functionality to communicate actions taken along with or instead of acknowledgments</li> <li>Allowing the action taken in response to a notification (e.g., ordered another test, notified the patient, ordered biopsy, modified medication) to be documented in combination with the novel information will improve the determination that a loop was closed</li> <li>Diagnostic results notification messages must be modifiable by the recipient to add the action performed to close the loop (e.g., read, acknowledged, patient notified, follow-up complete, consultation requested and confirmed)</li> </ul>
	Link	Use health IT to link and acknowledge the review of information and documentation of the action taken	





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## **Additional Resources**

**Note:** This list includes some citations that are also listed under References.

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## **Tools**

The following section of the toolkit contains implementation resources for all stakeholders. Please identify those resources that will facilitate implementation of the safe practice recommendations for communication, tracking, and linking in your particular situation.

### **Tools and Resources**

**Risk Assessment Tools: Know Your Risk** 

Provider/Provider Organization/Healthcare Systems

**Developers** 

**Conducting a Process Gap Analysis** 

Closing the Loop: Dashboard

Five Things We Can Do Now to Close the Loop

**Patient Scenarios: A Closed Loop** 

**Educational PowerPoint Presentations** 

Safe Practice Recommendations for Providers and Provider Organizations

Safe Practice Recommendations for Health IT Developers





### Risk Assessment Tools: Know Your Risk

### PROVIDER/PROVIDER ORGANIZATION/HEALTHCARE SYSTEMS

#### WHY IS CLOSING THE LOOP IMPORTANT?

Missed, delayed, and incorrect diagnosis leading to patient harm and possible malpractice actions can result from the failure to "close the loop." In the outpatient setting, 35% of the time this is attributed to a breakdown in the results management process. (MMIC Brink Spring/Summer 2017) For providers, this may mean they did not receive the information necessary to make decision about their patients in a timely manner; for patients, this may mean they were unaware that tests were abnormal or inconclusive and that further action was necessary.

#### **DID YOU KNOW?**

	Electronic tools are available to ensure that the diagnostic results populate correctly, including tracking and auditing tools, and interfaces with laboratory and testing facilities.
	Standardized coding (e.g., LOINC codes and SNOMED CT) can ensure that information is interoperable across systems.
	Common terminology regarding critical and emergent findings is essential for proper escalation (e.g., LOINC codes and SNOMED CT).
	A triage process for diagnostic-results management with clear delineation of accountability for acknowledgment and action can help reduce provider burden.
	Standards and software are available to transmit discontinuation messages to the patient's pharmacy indicating the medication has been discontinued in the patient's electronic health record (EHR). (http://www.ncpdp.org/Standards-Development/Standards-Information, Odukoya et al.)
	The pharmacy automatic-refill function may notify patients to pick up prescriptions that have been discontinued by the provider.
DIE	YOU ASK?
	Do we have a process to ensure that diagnostic results are received, acknowledged, and acted upon?
	Will anyone notice if the diagnostic results management process fails?
	Is all available functionality for communicating, tracking and monitoring, and linking acknowledgment to action operational and working as intended?
	Are we working with vendors to develop improved communication, results tracking and monitoring, and linking acknowledgment to action?

MMIC, Brink magazine. 2017 Spring. http://www.mmicgroup.com/docs/brinkmagazine/2017\_02Spring\_MMIC\_Brink\_Magazine.pdf

Odukoya OK, Stone JA, Chui MA. E-prescribing errors in community pharmacies: exploring consequences and contributing factors. Int J Med Inform 2014 Jun;83(6):427-37. Epub 2014 Mar 4. PubMed: https://www.ncbi.nlm.nih.gov/pubmed/24657055 doi: 10.1016/j.ijmedinf.2014.02.00





### Risk Assessment Tools: Know Your Risk

### **DEVELOPERS**

#### WHAT CAN DEVELOPERS DO TO CLOSE THE LOOP?

The potential of health IT to close the loop is not yet fully realized. There are a multitude of reasons for this—including complicated workflows and usability issues, the functionality being inactive or not being used as intended, misaligned workflows, or lack of interoperability—that may impede maximization of the technology's potential. Often providers have put hybrid systems in place for managing diagnostic results, further complicating this process.

### **DID YOU KNOW?**

	Providers consider the loop closed when the patient is notified and a follow-up plan is put in place.
	When clinical workflow and electronic health record (EHR) workflows are improperly aligned, results can be overlooked (e.g., the physician may never realize that diagnostic results have been received. (Casalino et al.)
	Outpatient test results are especially vulnerable to falling through the cracks. (Hysong et al.)
	Closely tethering acknowledgment to other EHR functionally could enhance patient safety by ensuring the closed loop communication process prompts timely action.
DID	YOU ASK?
	Have the providers communicated their needs and concerns regarding diagnostic results management?
	Are users aware of all available functionalities?
	Are the auditing, tracking, and monitoring functions being used as intended?
	Are providers encouraged to test audit tracking and monitoring functions to ensure that they are working as intended?

Casalino LP, Dunham D, Chin MH, Bielang R, Kistner EO, Karrison TG, Ong MK, Sarkar U, McLaughlin MA, Meltzer DO. Frequency of failure to inform patients of clinically significant outpatient test results. Arch Intern Med 2009 Jun 22;169(12):1123-9. PubMed: https://www.ncbi.nlm.nih.gov/pubmed/19546413 doi: 10.1001/archinternmed.2009.130

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### **Conducting a Process Gap Analysis**

### **BACKGROUND**

Before beginning a quality improvement initiative, you need to understand your current methods. This tool can be used to describe the key processes of closing the loop in your organization where improvement activities could or should happen. An Excel version of the tool can be accessed at https://www.ecri.org/Resources/HIT/Closing\_Loop/Closing%20the%20Loop\_Gap%20Analysis.xlsx.

#### **HOW TO USE THIS TOOL**

- Identify a leader who will conduct the process mapping and gap analysis and facilitate the Closing the Loop analysis team. The team should include frontline staff who have experience with the current process.
- Have the team identify and define every step in the current process for closing the loop.
- Define a beginning, an end, and a methodology for all of the processes to be mapped. For example, some processes are mapped through the method of direct observation of the process taking place, while others can be mapped by knowledgeable stakeholders talking through and documenting each step in the process.
- When defining a process, think about staff roles in the process, the tools or materials staff use, and the flow of activities.
- Everything is a process, whether it is admitting a patient, serving meals, assessing pain, or managing a nursing
  unit. Identify key processes involving closing the loop on test results. The goal of defining a process is to hone in on
  patient safety vulnerabilities and potential failures in the current process.
- Determine whether there are any gaps or problems in your current processes, and use the results of this analysis to change these processes systematically.

#### PROCESS ANALYSIS PROCEDURES

### **BACKGROUND**

Before beginning a quality improvement initiative, ensure that you understand your current methods. This tool can be used to describe the key processes of closing the loop in your organization where improvement activities could or should happen.

### PROCESS ANALYSIS PROCEDURES

- Take time to brainstorm and listen to every team member.
- · Make sure the process is understood and documented.
- Make sure each step in the process is very specific.
- Use one post-it note, index card, or piece of paper for each step in the process.
- · Lay out each step, move steps, and add and remove steps until the team agrees on the final process.
- If a process does not exist (for example, there is no process to assess communication of noncritical test results), identify related processes. If the process is different for different staff or shifts, identify each individual process.





### **EVALUATE YOUR CURRENT PROCESS AS YOU DEFINE IT**

- What policies and procedures do we have in place for this process?
- · What forms do we use?
- How does our physical environment support or hinder this process?
- Which staff members are involved in this process?
- · Which parts of this process do not work?
- · Do we duplicate any work unnecessarily? Where?
- · Are there any delays in the process? Why?

# CONTINUE ASKING QUESTIONS, WHICH ARE IMPORTANT IN LEARNING MORE ABOUT YOUR PROCESSES.

	Process (What happens) Work-as-Done	What Should happen Work-as-Imagined	Gap(s) Identified	Corrective Action	Responsible Party	Due Date
1.	Test ordered [insert process step]					
	a. [insert sub-process]					
	b. [insert sub-process]					
2.	Test performed					
	a.					
	b.					
3.	Test tracked in the EHR					
	a.					
	b.					

Partnership for Health IT Patient Safety Closing the Loop: Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes





### Closing the Loop: Dashboard

The Closing the Loop (CLT) Dashboard helps gather data and information about closing the loop for tracking, trend analysis, and dissemination of data throughout the organization. It provides the opportunity to look at the CTL processes to ensure the right people get the right information at the right time. It also provides the ability to assess and track the patient-safety risk level of CTL issues in order to develop a mitigation plan. The Dashboard can be accessed online at: https://www.ecri.org/Resources/HIT/Closing\_Loop/Closing\_the\_Loop\_Dashboard.xlsx.





## Five Things We Can Do Now to Close the Loop

#### 1. REVIEW CURRENT RESULTS MANAGEMENT PROCESSES

Perform a risk assessment

- · Implement a standard/centralized process
- · Assign responsibility and oversight of each step in the process
- Allow for preferred and customized methods for transmission of notifications
- · Maintain and update provider directories and availability

SAFER Guides: Test Results Reporting and Follow-Up

**ONC Workflow Process Mapping** 

AHRQ Mapping and Redesigning Workflow

### 2. USE AVAILABLE TECHNOLOGIES

- Ensure that all technology has been tested prior to deployment and implementation
- · Continue to monitor and evaluate tools for safety and reliability
- Implement systems that can acknowledge receipt and completion of required tasks
- · Use existing functionality to automate the notification process

## 3. TRAIN PROVIDERS AND STAFF ABOUT THE SAFE USE OF TECHNOLOGY TO COMMUNICATE DIAGNOSTIC RESULTS

- Use standard use cases to clarify processes
- · Align clinical workflows with electronic workflows
- Improve reporting of actionable findings to include results priority and the required timing of responses

SAFER Guides: Clinician Communication

SAFER Guides: System Interfaces

AHRQ Improving Your Office Testing process

AMA EHR In-Basket Restructuring for Improved Efficiency

Use Cases, Scenarios, and Studies

# 4. IMPROVE THE USE OF PATIENT-CENTERED TECHNOLOGIES (E.G., PORTALS, APPS, TEXTING, SECURE MESSAGING)

- Use a reminder system similar to the Open Table app
- Use patient-centered technology for notification of results, reminders to have tests performed, requests for follow-ups, and discontinuation of medications
- · Integrate patients, families, and caregivers, as part of the notification process
- Provide alternate method for those without electronic access

## 5. BECOME AWARE OF AND THEN APPROPRIATELY USE NEW TOOLS AND TECHNOLOGIES TO CLOSE THE LOOP

- Improve the transmission of information
  - o Use standards for the formatting of normal, critical, abnormal noncritical, and abnormal results
  - Use standard terminology
- Implement use of LOINC codes where available
- · Expand use of SNOMED CT

HIMSS Patient Engagement Framework





## Patient Scenario: A Closed Loop

### **PATIENT PRESENTS**



The patient is a 65-year-old Hispanic male who presents to the physician with vague complaints of general malaise for a few weeks with mild shortness of breath ( $O_2$  saturation 92%), intermittent fever (101 degrees), productive cough, and fatigue. The patient has a known medical history of type 2 diabetes mellitus (T2DM) and hypercholesterolemia. He has a 30-pack year smoking history (15x40)/20 = 300). There is no history of alcohol or drug abuse.

## **CLOSE THE LOOP**

#### **Track**

• Electronic health record (EHR) set to automatically flag overdue test

#### Link

Monitor error logs for test that do not match to a patient or an outstanding order

### **Communicate**

- · Follow up with patients using portals and/or direct contact to remind them of the importance of having the recommended tests
- · Lab services should adhere to protocols for communication of critical results to providers, including flags, alerts, and direct contact

**Source:** Eder M, Smith SG, Cappelman J, Orzano J, Poon E, Seils G, Solberg L. Improving your office testing process. A toolkit for rapid-cycle patient safety and quality improvement. AHRQ Publication No. 13-0035. Rockville, MD: Agency for Healthcare Research and Quality; 2013 Aug. http://www.ahrq.gov/sites/default/files/publications/files/officetesting-toolkit.pdf





### **TEST ORDERED**

The physician's preliminary diagnosis is bronchitis. Guaifenesin is prescribed for the patient, who is also instructed to have a complete blood count (CBC) drawn and a chest x-ray study performed to rule out pneumonia.

#### **TEST PERFORMED**

The patient schedules the CBC and the chest x-ray. The tests are performed and results completed within the week.

#### **TEST TRACKED IN THE EHR**

The patient's CBC results are uploaded to the electronic health record (EHR) via the interface with the laboratory information system (LIS). They are matched to the initial order.

The patient's chest x-ray report is uploaded to the EHR via the interface with the radiology information system (RIS).

#### RESULTS POSTED AND DOCUMENTED IN THE PATIENT'S RECORD

The CBC results are reported as normal. The CBC results are made available on the patient's portal.

The chest x-ray report is flagged as abnormal. This was unavailable on the patient portal pending review by the physician.

#### PROVIDER NOTIFIED ELECTRONICALLY THAT RESULTS ARE AVAILABLE

The physician receives an alert message the chest x-ray result is available and flagged as abnormal.

The chest x-ray reveals bilateral patchy consolidation consistent with bronchopneumonia. Incidental finding of a 2.2 cm right upper lobe nodule requiring further testing to rule out malignancy.

## RESULTS REVIEWED BY PROVIDER AND ACKNOWLEDGED IN THE EHR

The physician notifies the patient of the abnormal study. A computerize tomography (CT) scan is ordered and a follow-up appointment is scheduled to discuss the results.

### **PATIENT NOTIFIED**

The patient is sent a message though the patient portal to remind him of this upcoming appointment. CT scan results are posted to the patient portal with a message they will be discussed in further detail at the follow-up visit.

### PATIENT TREATED OR MONITORED

The patient is seen in the office to discuss the results of the CT scan. A treatment plan is agreed upon and documented in the patient's chart.





## **Educational PowerPoint Presentation**

### SAFE PRACTICE RECOMMENDATIONS FOR PROVIDERS AND PROVIDER ORGANIZATIONS

## Closing the Loop:

Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes









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## **Learning Objectives**

- ▶ Review what is needed to close the loop
  - Diagnostic testing
  - Discontinuation of medication
- ▶ Review safe practice recommendations
- Learn what can be done now to close the loop
- ▶ Identify consequences of failure to close the loop
- ► Understand how health IT can help







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## **Diagnostic Error**

- ▶ To Err is Human: Building a Safer Health System (1999)
  - Diagnostic error
    - > Failure to establish an accurate and timely diagnosis
    - ▶ Failure to communicate the diagnosis to the patient
  - Every U.S. citizen will experience a diagnostic error in their lifetime
  - 1 in 20 outpatient adults are affected by diagnostic error annually







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# Obstacles to Closing the Loop: Interventions and Outcomes

- ▶ Reasons for failure to close the loop are multifactorial
  - eRx not discontinued
  - Test not done
  - Test not performed correctly
  - Test not tracked
  - Physician does not review all results
  - Test not returned to physician
  - Systems not used to capacity
  - Discontinued medicine automatically refilled
  - Chart not updated
  - Abnormal results not monitored through follow-up
  - Patient not notified

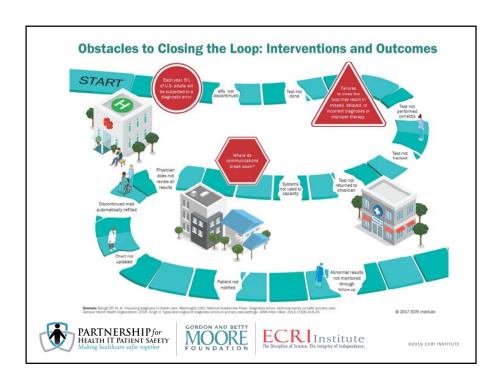












## **Closing the Loop**

Closing the loop includes all mechanisms\* that ensure that all patient data and information that may require an action are delivered and communicated to the right individuals, at the right time, through the right mode, to allow interpretation, critical review, reconciliation, initiation of action, acknowledgment, and appropriate documentation.

\* Workflow management tools, interventions, electronic and verbal notifications, checklists, alerts, and dashboards













## Closing the Loop: Using Health IT to Mitigate Delayed, Missed, and Incorrect Diagnoses Related to Diagnostic Testing and Medication Changes

- ▶ Develop and apply information technology (IT) solutions to communicate, the right information (including data needed for interpretation), to the right people, at the right time, in the right format
- ▶ Implement IT solutions to **track** key areas
- ▶ Use health IT to **link** and acknowledge the review of information and documentation of the action taken







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# Closing the Loop Recommendations: Communicate

- ► Improve the transmission of information using standards for formatting normal, critical, abnormalnoncritical, and abnormal results
- Improve reporting of actionable findings to include results priority and the required timing of responses for diagnostic testing through adoption of standards
- ► Improve the transmission of information using universally recognizable display icons in the electronic health record (EHR) for alerts and notifications







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# Closing the Loop Recommendations: Communicate (cont.)

- ▶ Enhance the usability of communication of diagnostic results
- ▶ Use existing functionality to automate the notification process
- Improve notification and reduce alert fatigue by optimizing alerts
- Communication of diagnostic results should not be interrupted
- ▶ Communicate diagnostic directly to the patient
- ► Adopt National Council for Prescription Drug Programs (NCPDP) SCRIPT standards







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# **Closing the Loop Recommendations:** Track

- ▶ Determine where health IT can be used to correct deficiencies and improve tracking to close the loop
- Assign dedicated accountability for and ensure oversight of tracking
- Improve tracking through the implementation of laboratory standards
- Improve tracking through the implementation of bi-directional communication











# Closing the Loop Recommendations: Link and Acknowledge

- ► Take an active role to improve interoperability through the integration of systems, connecting information across the care continuum to facilitate communication and acknowledgment
- ▶ Develop functionality to communicate actions taken with or instead of acknowledgments







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## Five Things To Do Now To Close the Loop



- Review current results management processes
- Use the available technologies
- ▶ Train providers and staff about the safe use of technology to communicate diagnostic results
- ▶ Improve the use of patient-centered technologies (e.g., portals, apps, texting, secure messaging)
- ▶ Become aware of and then appropriately use new tools and technologies to close the loop











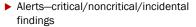
# The Road to Closing the Loop: Interventions and Outcomes

- Look for failures in communication, decision-making, and patient involvement that can be prevented or mitigated through technology
- ▶ Reinforce processes
- ► Revise processes
- Simplify processes
- ▶ Refine organizational processes
- ► Enhance office testing processes
- ▶ Optimize medication reconciliation
- Leverage technology

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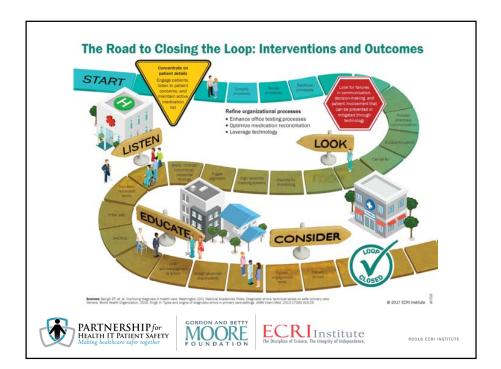
- Employ order sets
- Create MACROs
- ▶ Use e-discontinuation, Cancel Rx





- ▶ Trigger algorithm
- ▶ High reliability tracking systems
- Reports for monitoring
- ▶ Decrease redundant alerts
- ► Link acknowledgement to action
- ▶ Patient portals
- ▶ Patient engagement tools
- Assign physician responsibility









## Failure to Close the Loop: Case Studies and Strategies

- ► Failure to close the loop has the potential to result in patient harm due to diagnostic error
  - Case studies
  - Recommendations
  - Strategies to close the loop







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## Case Study: Delayed Diagnosis

- Family explained upon admission that the patient had experienced shortness of breath
- ► Pneumonia was diagnosed
- Radiology identified a lung lesion
- ► There was no further mention of or workup related to the lung lesion
- The patient was admitted to the hospital six months later and informed at that time of the lung lesion
- Additional follow-up revealed adenocarcinoma

#### **Recommendation:**

Develop and apply IT solutions to **communicate** 

## Strategies to close the loop:

- Diagnostic services should adhere to protocols for communicating critical results to providers, including flags, alerts, and direct contact
- Enable all alerts, messages, and flags for abnormal or critical results
- Communicate results directly to the patient











## Case Study: Delayed Diagnosis

- A patient was seen for evaluation of testicular pain from possible testicular torsion
- An ultrasound was performed
- The initial verbal report stated that no torsion was seen
- One week later, the written report noted "suspicious mass," with recommendation for the patient to follow up with a urologist
- The report was signed with no action taken by provider
- The patient was not informed

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The patient returned seven months later complaining of pain

A large testicular mass was discovered on physical examination

Recommendation: Use health IT to link and acknowledge the review of information and documentation of the action taken

#### Strategies to close the loop:

- Use EHR functionality to implement hard stops to monitor provider acknowledgement of results
- For critical and abnormal results, make every effort to contact the patient and document all attempts in the chart



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## Case Study: Automatic Refills

- ▶ The patient's lab results indicated an elevated potassium level
- ▶ The physician discontinued the patient's oral potassium in the **EHR**
- ▶ The pharmacy was not notified to discontinue the medication
- ▶ The oral potassium was refilled
- ▶ The patient was notified by the pharmacy to pick up the medication
- ▶ At the patient's next office visit the lab work indicated an elevated potassium level

## **Recommendation:**

Implement IT solutions to track key areas

## Strategies to close the loop:

 Adopt NCPDP SCRIPT (e.g., CancelRx) as a standard to ensure that the electronic discontinuation of a prescription is transmitted to the pharmacy; acknowledgment by the pharmacy with automatic discontinuation of renewals











## Case Study: Missed Diagnosis

- A fecal occult blood test (FOBT) was ordered to be done at home
- ► The test was performed and returned as instructed
- All three tests were positive for occult blood
- ▶ The provider never saw the result
- No follow-up or action was taken
- Two years later, the provider reviewing the chart discovered the positive FOBT test result
- Adenocarcinoma of the colon was diagnosed in the patient

### **Recommendation:**

Develop and apply IT solutions to **communicate** 

Implement IT solutions to **track** key areas

### Strategies to close the loop:

- Enable EHR to automatically flag overdue diagnostic tests
- Assign dedicated accountability for and ensure oversight of tracking of diagnostic tests and results







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## Case Study: Missed Diagnosis

- A routine mammography was ordered
- ► The patient failed to have the test performed
- Routine visits continued over the next five years
- ► Five years later, another routine mammogram was ordered
- The results indicated a breast lump with infiltrating ductal carcinoma
- Chart review uncovered a note from five years earlier, stating "mammo pending no result"

#### **Recommendation:**

- Develop and apply IT solutions to communicate
- Implement IT solutions to track key areas

## Strategies to close the loop:

- Enable EHR to automatically flag overdue diagnostic tests
- Assign dedicated accountability for and ensure oversight of tracking diagnostic tests and results











## **Workgroup Members for Closing the Loop**

Chair: Christoph U. Lehmann, MD, Vanderbilt University

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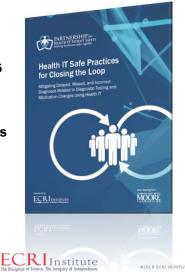


## **Educational PowerPoint Presentation**

## SAFE PRACTICE RECOMMENDATIONS FOR HEALTH IT DEVELOPERS

# Health IT Safe Practices for Closing the Loop

**Safe Practice Recommendations** for Health IT Developers









## **Learning Objectives**

- ► Understand steps developers can take to close the loop for diagnostic results and medication changes to ensure patient safety
- ► Recognize technology's role in closing the loop failures and identify tools to mitigate such failures
- Review safe practice recommendations for implementation by health IT developers
- ▶ Identify technologies currently available to facilitate closing the loop
- Consider what technologies and measurements could be used in the future to assist in closing the loop













## **Background**

- ▶ In 1999, the Institute of Medicine defined diagnostic errors as the failure to establish an accurate and timely explanation of the patient's health problem(s) or communicate that explanation to the patient; and asserted that statistically:
  - Every U.S. citizen will experience a diagnostic error in their lifetime
  - 1 in 20 outpatients adults are affected by a diagnostic error annually
- ▶ Regardless of the means of communication used, the tracking of test results and medication changes has long been a challenge in all practice settings
- ▶ Then and now there is the belief that health technology can mitigate the safety issues that compromise safe and timely care









## What is the Concept and Definition of Closing the Loop?

Closing the loop includes all mechanisms\* which ensure that all patient data and information that may require an action are delivered and communicated to the right individuals at the right time, through the right mode, to allow interpretation, critical review, reconciliation, initiation of action, acknowledgement, and appropriate documentation.

\* Workflow management tools, interventions, electronic and verbal notifications, checklist, alert, and dashboards













## **Potential for Treatment Delays and Diagnostic Errors**

- ▶ The causes of failure to close the loop are multifactorial
  - Orders for tests not received
  - Results not reported
  - Results reported to the incorrect provider
  - Results missed by the provider
- ▶ Failure to close the loop may lead to treatment delays
- Results can be missed when the loop—of receipt, acknowledgment, and action—remains open
  - For example, treating a patient's pneumonia, but failing to follow up and address the incidental x-ray finding of a lung nodule that requires further testing to rule out malignancy with the patient









## What Steps Can Developers Take to Mitigate Closing the Loop?

- ▶ Improve opportunities for interoperability between
  - Diagnostic testing facilities/provider and provider organizations
  - Pharmacies/provider and provider organizations
  - Provider/provider and provider organizations
  - Provider/patient portal















## What Steps Can Developers Take to Mitigate Closing the Loop?

- ▶ Identify tools to improve the core elements of closing the loop: communication, tracking, and acknowledgement
  - A clinical vocabulary standard (e.g., SNOMED CT)
    - ▶ Ensures that terms that mean the same thing map to the correct field (e.g., MI/Myocardial Infarction/heart attack)
    - Ensures standard descriptions for results priority (e.g., normal, critical, abnormal-noncritical, and abnormal)
  - Alerts, notifications, reminders
  - Provider and patient receipt of information

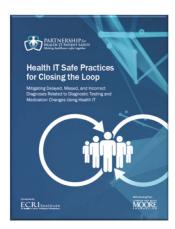








## **Workgroup Developed Safe Practice Recommendations** to Close the Loop



- Develop and apply IT solutions to communicate the right information, to the right people, at the right time, in the right format
- Implement IT solutions to track key areas
- ▶ Use health IT to link and acknowledge the review of information and documentation of the action taken













## Implement Safe Practices Through IT Solutions to Communicate Appropriate Information to the Appropriate Individual in a Timely Manner

- ▶ Implement structured formats and findings
  - Display latest results first; date of test associated with result
- ▶ Correlate the criticality of alerts with intrusiveness to reduce alert fatigue
- ➤ Consider the use of tools (e.g., icons, colored flags, tiered alerts) to help providers recognize critical/urgent results
- ► Facilitate multichannel secure communications (to providers; to patients)
  - Direct messaging; messages within EHR; email notifications
- ▶ Develop tools that facilitate communication and acknowledgment
  - Route results to appropriate care team member
  - Signal provider if acknowledgment does not occur in set time
  - Escalate critical results if no response occurs
  - Provide report card of responses to providers for process improvement









## Implement Safe Practices Through IT Solutions to Track Key Areas

- ► Map local test codes to a universal standard (e.g., LOINC), so that every system can understand (e.g., CBC/Complete Blood Count)
- ▶ Develop system integration of third-party interfaces so that results from laboratories, radiology, etc., automatically return to the corresponding order
- Design an application that provider organizations can use to monitor multiple interfaces
- ▶ Develop interface-specific tracking options
  - System failure alerts
  - Email notifications
  - Error logs
  - Reports













## Implement Safe Practices Through IT Solutions to Link and Acknowledge the Review of Information and Action Taken

- Incorporate existing tools that optimize interoperability to facilitate the direct communication and acknowledgment of results from disparate systems across the continuum of care
  - API
  - HL7
  - FHIR
- ▶ Develop a mechanism that lets the provider document if/how they reacted to the alert or notification
  - Action performed: read, acknowledged, patient notified, follow-up complete
  - Actions taken: ordered another test, notified the patient, ordered biopsy









## **Summary: Safe Practice Recommendations to Close the Loop**

#### ▶ Communicate

- Implement a standard vocabulary; structured formats and findings
- Consider tools to help recognize critical results (tiered alerts, icons, flags)
- Facilitate multichannel secure communications (to providers/patients)
- Develop tools that facilitate communication and acknowledgement

## ► Track

- Integrate interfaces so that results return to their corresponding orders
- Design an application that helps organizations monitor interfaces
- Develop interface specific tracking options

#### ► Link and Acknowledge

- Incorporate tools that optimize the interoperability of disparate systems
- Develop a way for providers/patients to document if/how they reacted to alerts/notifications













## When Health IT Successfully Closes the Loop: A Patient Care and Treatment Scenario

Patient is a 65-year-old Hispanic male who presents to his physician with vague complaints of general malaise for a few weeks with mild shortness of breath, intermittent fever, productive cough, and fatigue. Patient has a known medical history of type 2 diabetes (T2DM). Patient has a 30-pack year smoking history; and no history of alcohol or drug abuse.

**Tests ordered:** Preliminary diagnosis is bronchitis. Patient prescribed medication for cough; and instructed to have a complete blood count (CBC) drawn and a chest x-ray to rule out pneumonia.

**Tests performed:** Patient schedules the CBC and chest x-ray. Tests are performed and resulted within the week.

**Tests tracked in EHR:** CBC result is uploaded to EHR via Laboratory Information System interface. Chest x-ray report is uploaded to EHR via Radiology Information System interface.

Test results are matched to the corresponding orders. **Results posted in EHR and on Patient Portal:** CBC report is normal; results posted on the patient

Chest x-ray report is flagged as abnormal; result not posted on the patient portal pending review by the physician.

Provider notified electronically that results are available: Physician receives alert message that x-ray

available: Physician receives alert message that x-ray result is available; and flagged as abnormal. X-ray reveals information consistent with pneumonia; and an incidental finding of a 2.2 cm right upper lobe nodule requiring further testing to rule out malignancy.

Results reviewed by provider and acknowledged in EHR: Physician notifies the patient of the abnormal study. A computerize tomography (CT) scan is ordered; follow-up appointment is scheduled to discuss results.

Patient Notified: Patient is sent message though the patient portal to remind him of his upcoming appointment. CT scan results are posted on the patient portal with a message they will be discussed in further detail at the follower wist.

Patient treated/monitored: Patient is seen in the physician's office to discuss the results of the CT scan. A treatment plan is agreed upon and documented in the patient's chart.









## **Considerations for Developing Solutions to Close the Loop**

- Design and implement electronic workflows that align with clinical workflows
- When designing close-the-loop solutions, be cognizant not to complicate an already complex workflow
- Include members of the healthcare team when validating and testing health IT solutions
- Use technology solutions to ensure that providers have the most accurate and up-to-date information to improve patient outcomes













## What is the PARTNERSHIP for Health IT Patient Safety?

- ▶ The Partnership is a multistakeholder collaborative convened and operated by the ECRI Institute (est. 2013.) The Partnership is a collaboration of providers, health IT developers, academic researchers, patient safety organizations, patient advocates, malpractice insurers, and professional societies whose goal is to make health IT safer
- ▶ Safe practice recommendations are available at hitsafety.org
- Questions can be directed to hit@ecri.org









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