Communicating Test Results to Providers and Patients: An Overview of the VHA Directive 1088 and Electronic Test Result Communication in the Era of the 21st Century Cures Act

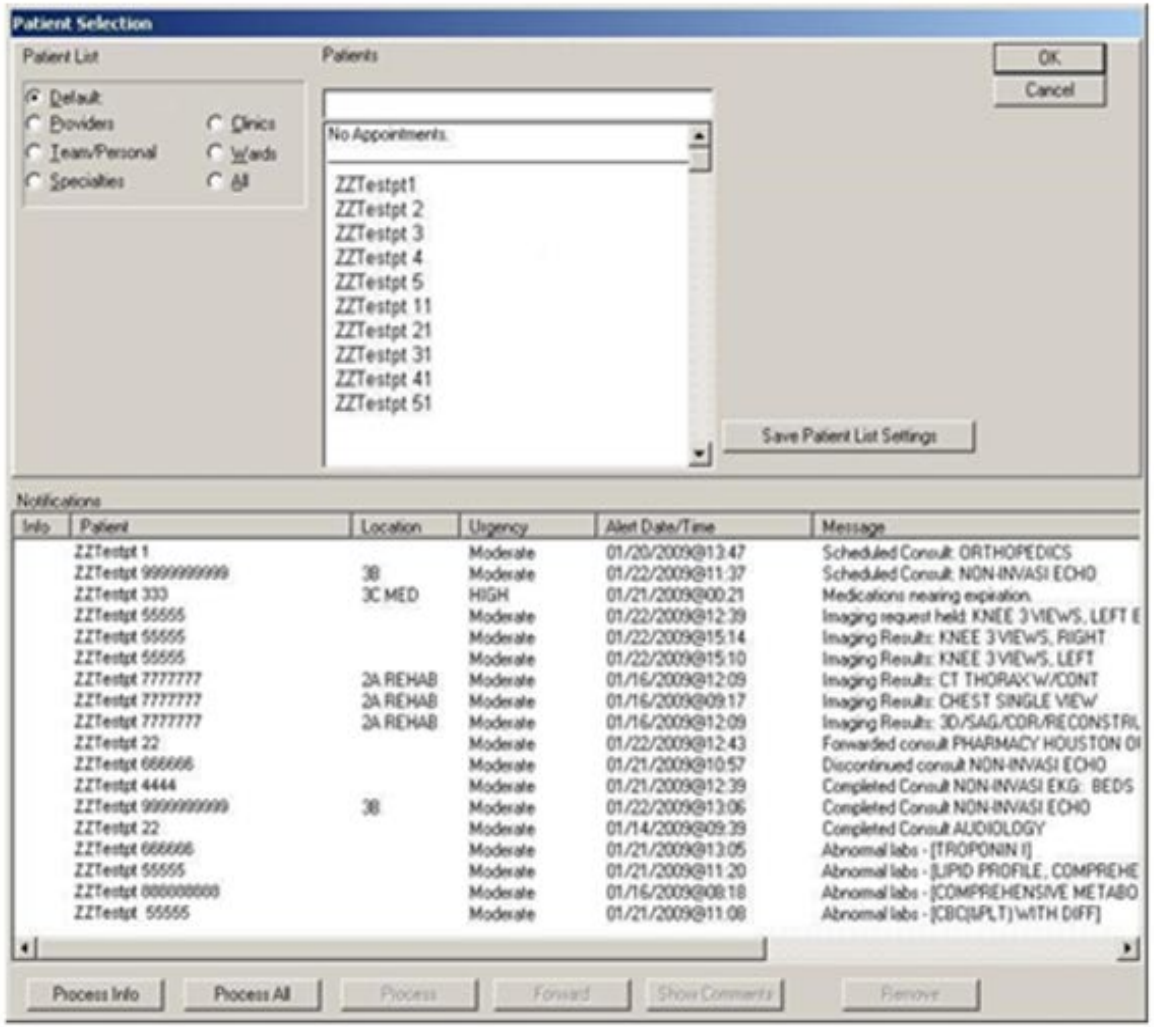
Hardeep Singh, MD, MPH

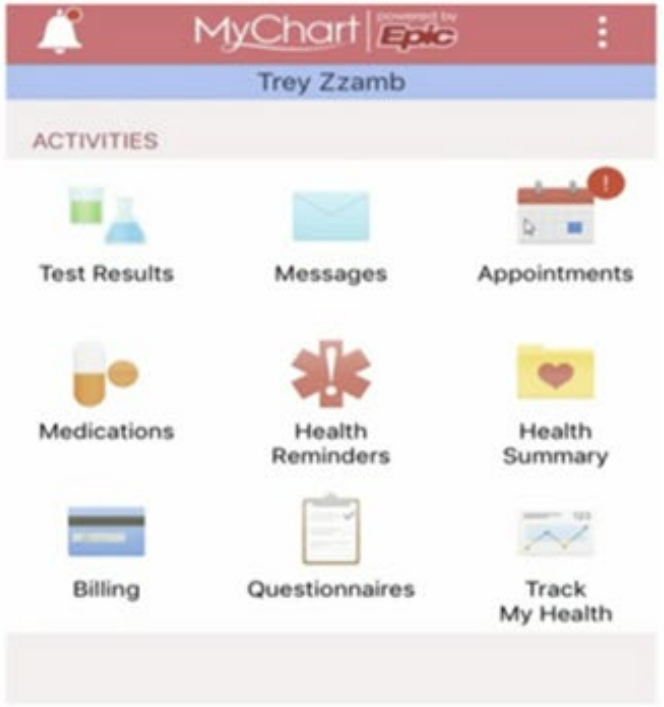
Center for Innovations in Quality, Effectiveness & Safety (IQuESt)
Michael E. DeBakey VA Medical Center
Baylor College of Medicine
@HardeepSinghMD

Reflections by David R. Hunt, MD, FACS

Medical Director,
Patient Safety and Health IT Adoption,
Office of Clinical Quality and Safety
Office of the National Coordinator for Health Information Technology

Post-Analytic Communication in EHR Era





EHRs NOT Reliably Closing Communication Loops

Evaluation of 1,163 outpatient abnormal lab and 1,196 abnormal imaging test result alerts

7% abnormal labs lacked timely follow-up	8% abnormal imaging lacked timely follow-up

Why abnormal test results continue to get missed in health IT-based settings

Singh et al *Am J Med 2010* & Singh et al *Archives of Int Med 2009*

CBSNews.com / CBS Evening News / CBS This Morning / 48 Hours / 60 Minutes / Sunday Morning / Face the Nation

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By MICHELLE CASTILLO | CBS NEWS | March 5, 2013, 1:16 PM

Too many electronic health record alerts may be leading doctors to skip them

Your doctor may be more likely to ignore your test results if they come electronically.

A new study published in the JAMA Internal Medicine on Mar. 4 revealed that doctors

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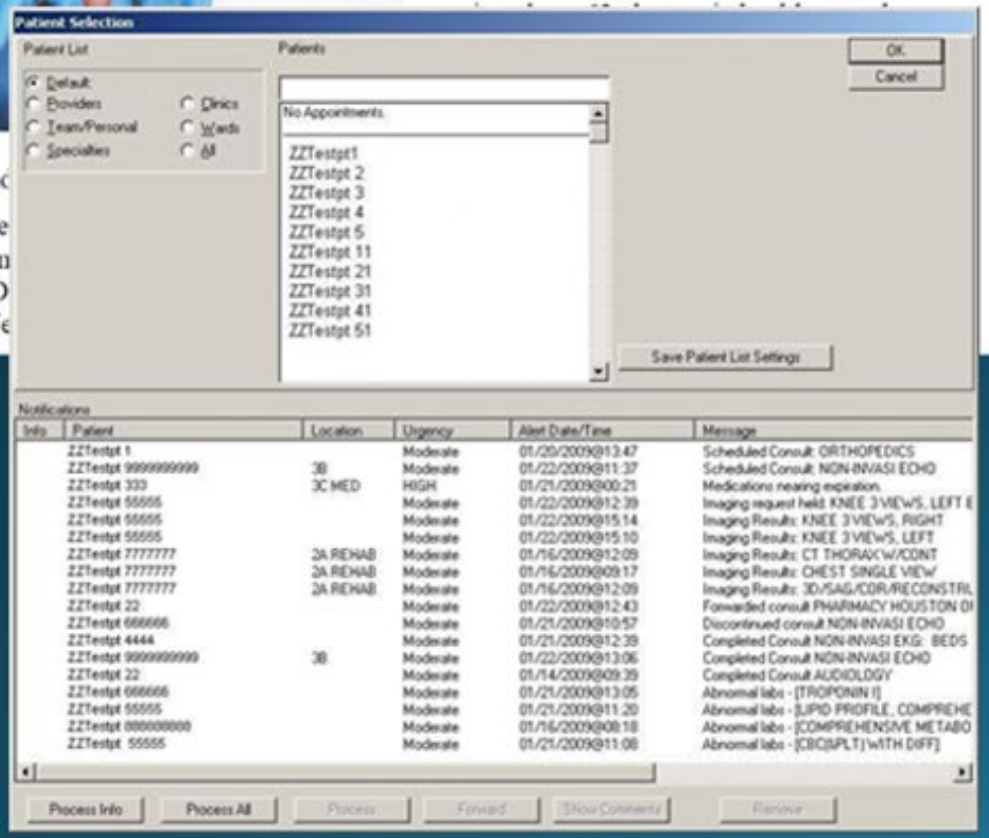

Research Letter

April 2016

JAMA Internal Medicine

The Burden of Inbox Notifications in Commercial Electronic Health Records

Daniel R. Murphy, MD, MBA[1,2]; Ashley N. D. Meyer, PhD[1,2]; Elise Russo, MPH[1,2]; et al

JAMA Intern Med. 2016;176(4):559-560. doi:10.1001/jamainternmed.2016.0209

Brief Report

Challenges in Communication from Referring Clinicians to Pathologists in the Electronic Health Record Era

Andrea Lynne Barbieri[1], Oluwole Fadare[2], Linda Fan[3], Hardeep Singh[4], Vinita Parkash[1,3]

Departments of [1]Pathology and [3]Obstetrics and Gynecology, Yale School of Medicine, New Haven, CT, [2]Department of Pathology, University of California San Diego, CA, [4]Center for Innovations in Quality, Effectiveness and Safety, Michael E. DeBakey Veterans Affairs Medical Center and the Department of Medicine, Baylor College of Medicine, Houston, Texas, United States of America

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Abstract

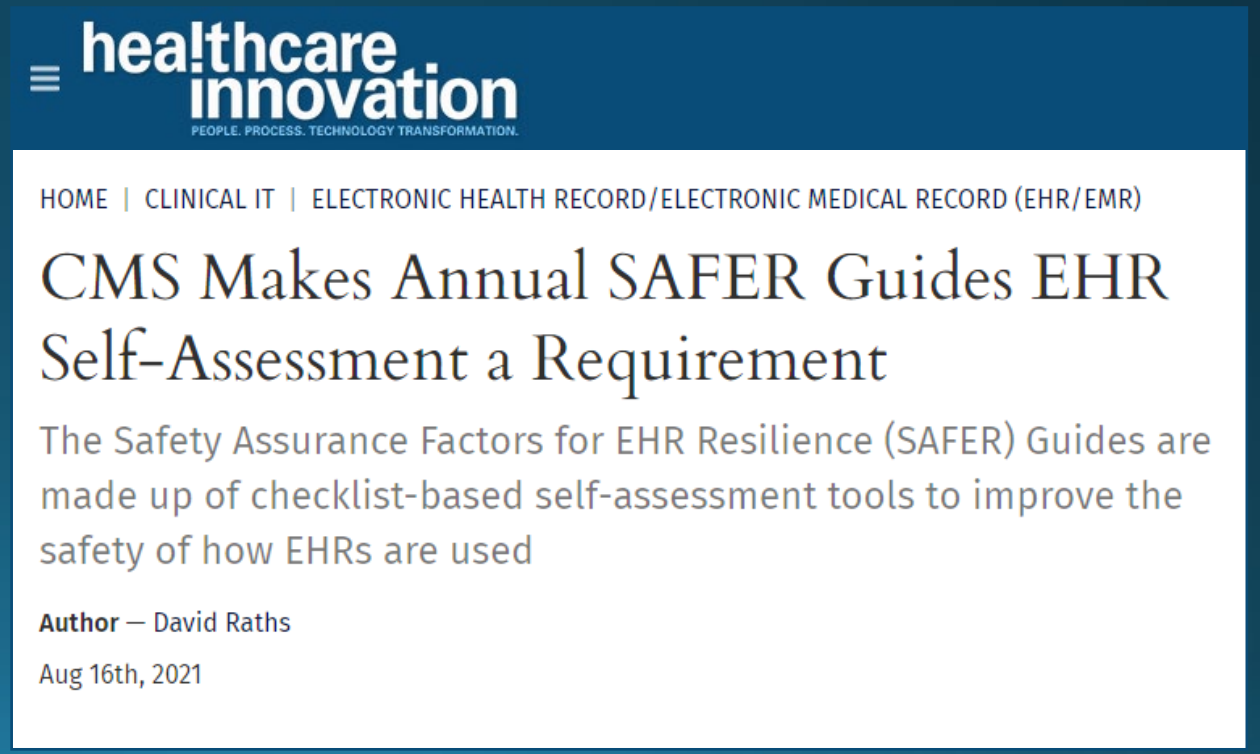
We report on the role played by electronic health record inbox messages (EHRmsg) in a safety event involving pathology. Evolving socio-cultural norms led to the coopting of EHRmsg for alternate use and oversight of a clinician to pathologist request. We retrospectively examined EHR inbox messages to pathologists over a 3 month block. 36 messages from 22 pathologists were assessed. 26 pertained to patient care including requests for report corrections and additional testing. 88% of requests had gone unaddressed. Clinicians assumed that pathologists used EHRmsg as clinical care team members, however, pathologists rarely did. Communication gaps exist between primary clinicians and pathologists in the EHR era and they have potential to result in patient harm. Different sociocultural norms and practice patterns between specialties underlie some of the breakdowns. Health information technology implementation needs to proactively look for new sociotechnical failure modes to avoid patient harm from communication lapses.

Keywords: Communication, electronic health record, pathology

e-Communication Needs a Sociotechnical Approach

Sittig Singh *Qual Saf Health Care. 2010 Oct; 19(Suppl 3): i68–i74.*

New CMS Policy



SAFER: Safety Assurance Factors for EHR Resilience

Foundational Guides

- High Priority Practices
- Organizational Responsibilities

Infrastructure Guides

- System Configuration
- System Interfaces
- Contingency Planning

Clinical Process Guides

- Patient Identification
- Computerized Provider Order Entry with CDS
- Test Results Reporting and Follow-up
- Clinician Communication

http://www.healthit.gov/safer

SAFER Self Assessment
Test Results Reporting and Follow-Up | Chec

*Recommended Practices for **Phase 1 — Safe Health IT***

			Implementation Status			
			Fully in all areas	Partially in some areas	Not implemented	
1	Test names, values, and interpretations for laboratory results are stored in the EHR as structured data using standardized nomenclature.	Worksheet				
2	Predominantly text-based test reports (e.g., radiology or pathology reports) have a coded (e.g., abnormal/ normal at a minimum) interpretation associated with them.	Worksheet 2				reset
3	Functionality for ordering tests and reporting results is tested pre- and post-go-live.	Worksheet 3				
4	After system changes in components or applications related to CPOE and diagnostic services, the data and data presentation are reviewed to ensure accuracy and completeness.	Worksheet 4				

*Recommended Practices for **Phase 2 — Using Health IT Safely***

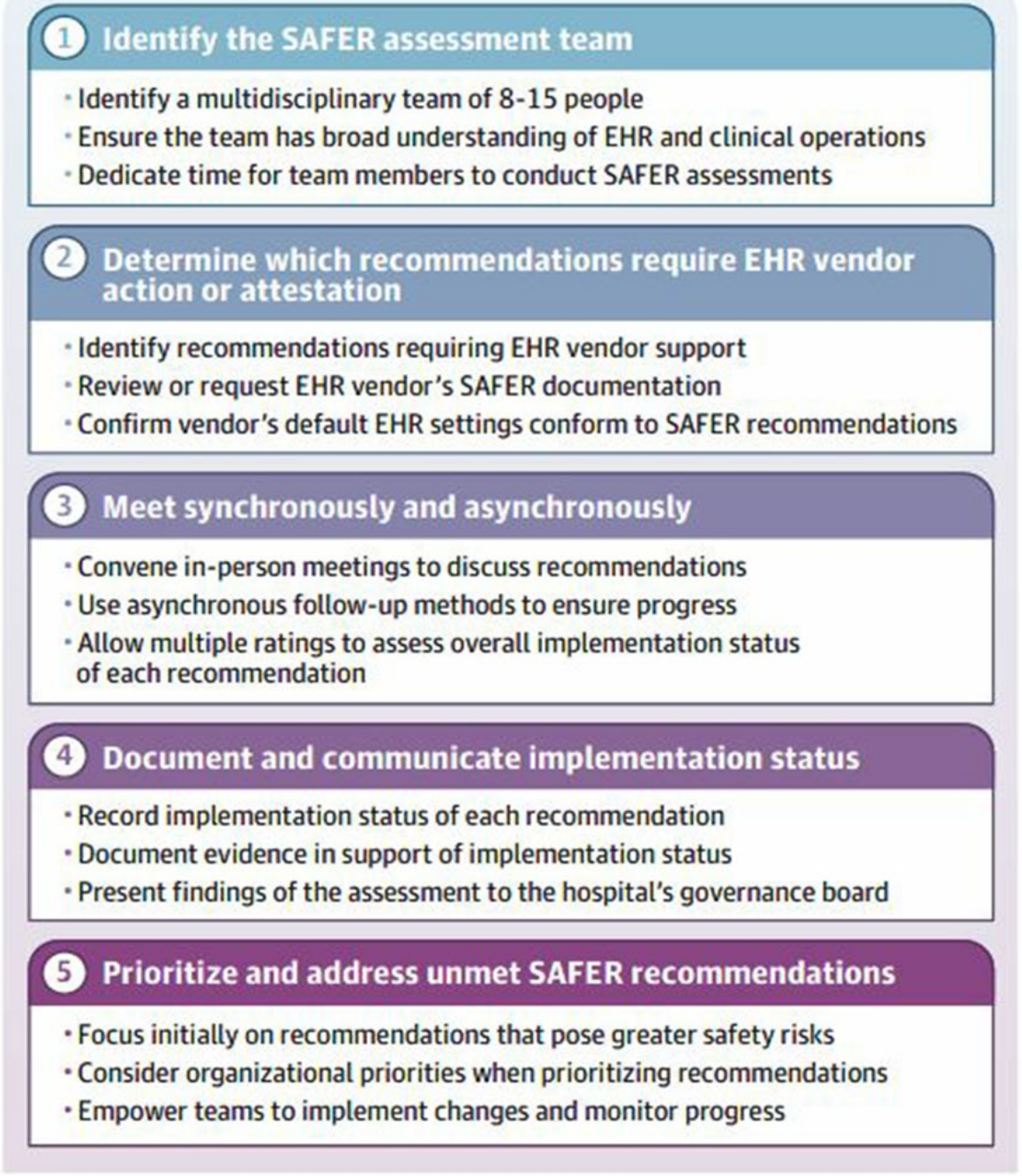
5	Orders for diagnostic tests are placed using CPOE and electronically transmitted to the diagnostic service provider (e.g., laboratory or radiology).	Worksheet 5				
6	The EHR is able to track the status of all orders and related procedures (e.g., specimen received and collected or test completed, reported, and acknowledged).	Worksheet 6				
7	The ordering clinician is identifiable on all ordered tests and test reports, and, if another clinician is responsible for follow-up, that clinician is also identified in the EHR.	Worksheet 7				reset
8	When test results are amended, the change is clearly visible in the EHR and printed reports.	Worksheet 8				reset
9	When test results are changed or amended, the ordering clinician and other clinicians responsible for follow-up are notified electronically. For clinically significant changes, the clinicians are also contacted directly.	Worksheet 9				reset

2 Predominantly text-based test reports (e.g., radiology or pathology reports) have a coded (e.g., abnormal/ normal at a minimum) interpretation associated with them.

Implementation Status: Fully in all areas | Partially in some areas | Not implemented

9 When test results are changed or amended, the ordering clinician and other clinicians responsible for follow-up are notified electronically. For clinically significant changes, the clinicians are also contacted directly.

Implementation Status: Fully in all areas | Partially in some areas | Not implemented



EHR indicates electronic health record, and SAFER indicates safety assurance factors for EHR resilience.

VIEWPOINT

February 7, 2022

Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides

Dean F. Sittig, PhD[1]; Patricia Sengstack, DNP, RN-BC[2]; Hardeep Singh, MD, MPH[3]

Author Affiliations

JAMA. 2022;327(8):719-720. doi:10.1001/jama.2022.0085

Sittig DF, Sengstack P, Singh H. Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides.

JAMA. 2022 Feb 7.
doi: 10.1001/jama.2022.0085.

VHA DIRECTIVE 1088 - Communicating Test Results to Providers and Patients

Developed by a multi-disciplinary workgroup

VHA Directive 1088, Communicating Test Results to Providers and Patients published on July 11, 2023

Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1088
Transmittal Sheet
July 11, 2023

COMMUNICATING TEST RESULTS TO PROVIDERS AND PATIENTS

1. SUMMARY OF MAJOR CHANGES: This directive:

a. Maintains that, with listed exceptions, test results requiring action must be communicated to patients within 7 calendar days from the date on which the results are available to the Department of Veterans Affairs (VA) medical facility ordering provider or designee and 14 days for those that do not require any action. Depending on the clinical context, the VA medical facility ordering provider or designee may need to review and communicate test results in shorter timeframes (see timeframe standards in paragraph 3 and definitions for abnormal and normal results in paragraph 9).

b. Adds responsibilities in paragraph 2 for the Under Secretary for Health; Assistant Under Secretary for Health for Clinical Services; Assistant Under Secretary for Health for Operations; Executive Director, Office of Primary Care.

Major Highlights

- Test results requiring action must be communicated to patients **within 7 calendar** days from the date on which the results are available and **14 days** for those that do not require any action.
- Ordering provider or designee may need to review and communicate test results in shorter timeframes, depending on clinical context
- Clarification on documentation requirements for test results communication
- Examples of back-up procedures (certified letter and escalation protocols)

Communication Requirements

Content and Method of Communication for *Results Requiring Action*

- Content might vary from case to case but must be sufficiently detailed to allow the patient to be informed and engaged in their health care
- Appropriate methods of communication may include a telephone call, a standard or certified letter or other synchronous and asynchronous methods, such as automated test results release or secure messaging via the patient portal, telehealth and face-to-face encounters

VHA DIRECTIVE 1088 - Communicating Test Results to Providers and Patients

Communication Requirements

Content and Method of Communication for *Results NOT Requiring Action*

- Content might vary from case to case but must be sufficiently detailed to allow the patient to be informed and engaged in their health care
- **Automated test result release via the patient portal is an acceptable method for communicating test results not requiring action**

Section 4004 information blocking rule

- When test results are finalized, they are made available to the patient immediately within the patient portal
  - often before the ordering clinician has had an opportunity to review the results
- Raised concerns among health care professionals
  - patients may become upset or confused

ONC "Information Blocking" Rules Cause Confusion, Patient Distress

July 27, 2021

AMGA Recommends Changes to Prevent Harm

Alexandria, VA – AMGA today offered recommendations to improve information blocking requirements to help strengthen and support the doctor-patient relationship in a letter to the U. S. Department of Health and Human Services Office of the National Coordinator (ONC) for Health Information Technology. The changes that AMGA is recommending furthers ONC's transparency goals while also ensuring that patients receive any concerning laboratory and other results in a thoughtful, compassionate way.

Direct Release to Patients

"The result was abnormal, but I didn't realize it. There's a comment section but the doctor never leaves a comment. My triglycerides are high. Ok, what does that mean? What am I supposed to do?"

"I had to figure out the sodium was low. There's a problem with low sodium, what can I do?"

"I'm not a doctor. I hope they'll call if it's problematic."

Giardina et al J of Pt Exp 2015

Patient Perspectives- Portal Usability

"The lab results are not organized in any logical order…like by date. I have trouble finding the newest result. And the graphs. They are just wrong."

"When I log in, I can see the new labs. But once I've viewed them already, it moves them to, somewhere else. I couldn't figure out where to go to find them. Not user friendly."

Giardina et al J of Pt Exp 2015

Key recommendations based on study results aligned with 8 dimensions of the Sittig and Singh sociotechnical model

Dimension	Recommendations
Hardware and software	Ensure that the portal is available on both large-format computers and hand-held devices. Enable search functionality of the site.
Clinical content	Provide easy access to high-quality educational websites.
Human-computer interface	Provide users with access to an explanation of test results directly from results screen.
People	Ensure that patients have direct, easy access to "human" support services that include people, such as patient navigators, advocates, social workers, or others who work in related educational services.
Workflow and communication	Provide personalized or contextual information to help patients know what to do in light of the results (eg, make lifestyle changes, send secure messages to their providers, or make follow-up appointments).
Internal organizational policies, procedures, environment	Develop local policies and procedures to create standardized language guiding patients to a specific follow-up contact for any questions. Provide patients with educational content on portal-related support when they are having face-to-face visits.
External rules and regulations	Create national consensus and standards on timing and best practices for portal release of normal and abnormal test results, especially those with sensitive results (eg, HIV status or cancer diagnosis), and on proxy portal access, such as for older relatives.
Measurement and monitoring	Create mechanisms to evaluate patients' experiences related to test result notification in portals and use this data to help developers improve portal usability and design innovations to promote patient understanding.

Giardina TD, et al. J Am Med Inform Assoc, Volume 25, Issue 4, April 2018, Pages 440–446

New Scoping Review for AHRQ

? Research question:

- What evidence currently exists on how clinicians and health systems can effectively provide patients with immediate access to their test results through electronic patient portals?

Forthcoming AHRQ Issue Brief – Bradford A, Shahid U, Blackall L, Singh H.

Findings

- Patients held mostly positive views of accessing results through portals but concerned about usability and equitable access
- Little objective data on negative or unintended consequences of accessing results through portals
- Best practices for result communication via portals remain ill-defined.
- Need for further development of practices to educate and set expectations with patients about their results both pre- and post-testing

Diagnosis is a Team Sport: Next Steps for CLIAC?

- Establish national standards for test results communication to both clinicians and patients
- Engage labs in developing robust institutional policies, procedures & workflows for 'sub-critical' results communication
- Engage labs in conducting risk-assessments via ONC SAFER Guides

Thank You

- **Funding Agencies that make research possible:**
  - Department of Veterans Affairs
  - Agency for Healthcare Research and Quality
  - ONC for SAFER Guides

- **Our multidisciplinary team at the Center for Innovations in Quality, Effectiveness and Safety (IQuESt):**
  - Email: hardeeps@bcm.edu
  - Web: http://www.houston.hsrd.research.va.gov/bios/singh.asp and www.bcm.edu/saferdx
  - Twitter: @HardeepSinghMD

Questions to CLIAC

- What opportunities and challenges exist for ensuring safe communication of test results to providers and patients?
- Should CLIA be updated to improve nationwide test reporting back to the healthcare provider, and if so, how?
- Is there educational information that should be provided to laboratory professionals to promote safe communication of all test results? If yes, what specific material should be developed and disseminated?