

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)

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**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

Patient Selection

Default
 Providers
 Teams/Personal
 Specialties
 Clinics
 Wards
 All

Patients

No Appointments.

ZZTestpt1
 ZZTestpt 2
 ZZTestpt 3
 ZZTestpt 4
 ZZTestpt 5
 ZZTestpt 11
 ZZTestpt 21
 ZZTestpt 31
 ZZTestpt 41
 ZZTestpt 51

Save Patient List Settings

OK
Cancel

Notifications

Info	Patient	Location	Urgency	Alert Date/Time	Message
	ZZTestpt 1		Moderate	01/20/2009@13:47	Scheduled Consult: ORTHOPEDICS
	ZZTestpt 9999999999	3B	Moderate	01/22/2009@11:37	Scheduled Consult: NON-INVASI ECHO
	ZZTestpt 333	3C MED	HIGH	01/21/2009@00:21	Medications nearing expiration.
	ZZTestpt 55555		Moderate	01/22/2009@12:39	Imaging request held: KNEE 3 VIEWS, LEFT E
	ZZTestpt 55555		Moderate	01/22/2009@15:14	Imaging Results: KNEE 3 VIEWS, RIGHT
	ZZTestpt 55555		Moderate	01/22/2009@15:10	Imaging Results: KNEE 3 VIEWS, LEFT
	ZZTestpt 7777777	2A REHAB	Moderate	01/16/2009@12:09	Imaging Results: CT THORAX/W/CONT
	ZZTestpt 7777777	2A REHAB	Moderate	01/16/2009@09:17	Imaging Results: CHEST SINGLE VIEW
	ZZTestpt 7777777	2A REHAB	Moderate	01/16/2009@12:09	Imaging Results: 3D/SAG/COR/RECONSTR
	ZZTestpt 22		Moderate	01/22/2009@12:43	Forwarded consult PHARMACY HOUSTON DI
	ZZTestpt 666666		Moderate	01/21/2009@10:57	Discontinued consult NON-INVASI ECHO
	ZZTestpt 4444		Moderate	01/21/2009@12:39	Completed Consult NON-INVASI EKG: BEDS
	ZZTestpt 9999999999	3B	Moderate	01/22/2009@13:06	Completed Consult NON-INVASI ECHO
	ZZTestpt 22		Moderate	01/14/2009@09:39	Completed Consult AUDIOLOGY
	ZZTestpt 666666		Moderate	01/21/2009@13:05	Abnormal labs - [TROPONIN I]
	ZZTestpt 55555		Moderate	01/21/2009@11:20	Abnormal labs - [LIPID PROFILE, COMPREHE
	ZZTestpt 000000000		Moderate	01/16/2009@08:18	Abnormal labs - [COMPREHENSIVE METABO
	ZZTestpt 55555		Moderate	01/21/2009@11:08	Abnormal labs - [CBC[PLT] WITH DIFF]

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Trey Zzamb

ACTIVITIES

Test Results
 Messages
 Appointments
 Medications
 Health Reminders
 Health Summary
 Billing
 Questionnaires
 Track My Health

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

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

that they had
"If you're ge
sometimes n
problem," D
DeBakey Ve

Patient Selection

Default: Default, Doctors, Inpatient/Personal, Specialties, Clinics, Wards, All

Patients: No Appointments, ZZTestpt 1, ZZTestpt 2, ZZTestpt 3, ZZTestpt 4, ZZTestpt 5, ZZTestpt 11, ZZTestpt 21, ZZTestpt 31, ZZTestpt 41, ZZTestpt 51

Buttons: OK, Cancel, Save Patient List Settings

Notifications

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	ZZTestpt 55555		Moderate	01/21/2009@11:08	Abnormal labs - [CBC[PLT]] WITH DIFF

Buttons: Process Info, Process All, Process, Forward, Show Comments, Remove

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

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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



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High Priority Practices

Organizational Responsibilities

Contingency Planning

System Configuration

System Interfaces

Patient Identification

Computerized Provider Order Entry with Decision Support

Test Results Reporting and Follow-Up

SAFER Guides

SAFER Guides for EHRs

The Office of the National Coordinator for Health Information Technology

Health IT Rules & Regulations

SAFER Safety Assurance Factors for EHR Resilience

Meaningful Use

Rural Health Care

Behavioral

Strategic

SAFER

High Priority Practices

Organizational Responsibilities

Contingency Planning

Safer EHRs: An Introduction to the SAFER Guides

The safety and safe use of electronic health records healthcare organizations

0:00 / 6:02

YouTube

New CMS Policy

healthcare
innovation

PEOPLE. PROCESS. TECHNOLOGY TRANSFORMATION.

HOME | CLINICAL IT | ELECTRONIC HEALTH RECORD/ELECTRONIC MEDICAL RECORD (EHR/EMR)

CMS Makes Annual SAFER Guides EHR Self-Assessment a Requirement

The Safety Assurance Factors for EHR Resilience (SAFER) Guides are made up of checklist-based self-assessment tools to improve the safety of how EHRs are used

Author – David Rath

Aug 16th, 2021

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



The Joint Commission
Journal on Quality and Patient Safety

COMMENTARY | VOLUME 43, ISSUE 10, P540-547, OCTOBER 01, 2017

Toward More Proactive Approaches to Safety in the Electronic Health Record Era

Dean F. Sittig, PhD ✉ + Hardeep Singh, MD, MPH



Recommended Practices for Phase 1 – Safe Health IT

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](#)

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](#)

8 When test results are amended, the change is clearly visible in the EHR and printed reports.

[Worksheet 8](#)

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](#)

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

1 Identify the SAFER assessment team

- Identify a multidisciplinary team of 8-15 people
- Ensure the team has broad understanding of EHR and clinical operations
- Dedicate time for team members to conduct SAFER assessments

2 Determine which recommendations require EHR vendor action or attestation

- Identify recommendations requiring EHR vendor support
- Review or request EHR vendor's SAFER documentation
- Confirm vendor's default EHR settings conform to SAFER recommendations

3 Meet synchronously and asynchronously

- Convene in-person meetings to discuss recommendations
- Use asynchronous follow-up methods to ensure progress
- Allow multiple ratings to assess overall implementation status of each recommendation

4 Document and communicate implementation status

- Record implementation status of each recommendation
- Document evidence in support of implementation status
- Present findings of the assessment to the hospital's governance board

5 Prioritize and address unmet SAFER recommendations

- Focus initially on recommendations that pose greater safety risks
- Consider organizational priorities when prioritizing recommendations
- Empower teams to implement changes and monitor progress

VIEWPOINT

February 7, 2022

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

Dean F. Sittig, PhD¹; Patricia Sengstack, DNP, RN-BC²; Hardeep Singh, MD, MPH³

[> 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.

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:

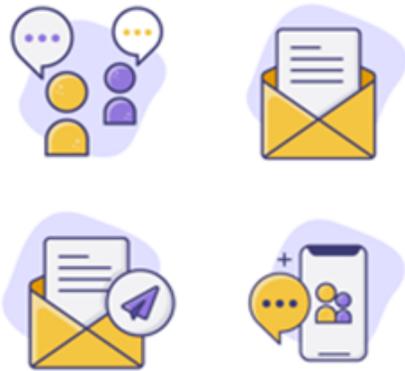
a. Maintains that, with listed exceptions, test results requiring action must be communicated to patients within 7 calendar days from the date on which the results are available to the Department of Veterans Affairs (VA) medical facility ordering provider or designee and 14 days for those that do not 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

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**



**Electronic Test Result
Communication in the
Era of the 21st Century
Cures Act**



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



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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.”



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.”

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 <u>in light of the results</u> (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.

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

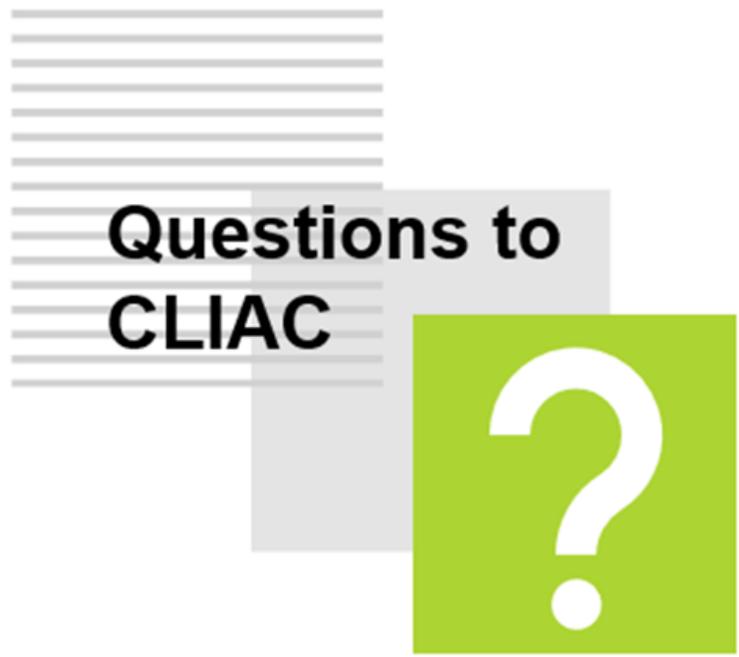
- Patients held mostly positive views of accessing results through portals but concerned about usability and equitable access
- Little objective data on negative or unintended consequences of accessing results through portals
- Best practices for result communication via portals remain ill-defined.
- 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.hsrdr.research.va.gov/bios/singh.asp> and www.bcm.edu/saferdx
 - ▶ Twitter: [@HardeepSinghMD](https://twitter.com/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?