Commonwealth of Massachusetts
Board of Registration in Medicine
Quality and Patient Safety Division

Incidental Findings Advisory
August 2016

Background
The Quality and Patient Safety Division (QPSD) has received a number of Safety and Quality Review (SQR) reports of patient events associated with what are commonly referred to as incidental findings (IF) on imaging studies. The use of "incidental" in the term IF should not be interpreted as irrelevance or happenstance, which tends to minimize their significance. This Advisory supports health care facilities in the review and development of approaches to the management of imaging incidental findings resulting from treatment in inpatient and emergency departments (ED). While some references are provided, this Advisory does not include a comprehensive review of the literature, nor is it intended to provide recommendations for evidence-based practices.

Publication of this Advisory does not constitute the Board's endorsement of any studies or practices described, and none should be inferred.

Introduction
The increasing sensitivity and detail of CT, MRI, and other imaging modalities has greatly increased the odds of discovery of IFs. An IF is defined as a result that lies outside of a test or procedure's aim (e.g., a pulmonary nodule on a chest CT done to assess chest trauma). IFs are common and often benign: In one study, 15 percent of CTs done for trauma contained IFs, the majority of which were rated as not clinically significant.[1] Some IFs however do have concerning characteristics requiring further evaluation to rule out malignancy or other pathology. The literature on whether and how to pursue various types of IFs, however, is still evolving; frequently leaving patients and providers to make decisions on a case-by-case basis.

There are a number of confounding issues regarding appropriate management of IFs. Vigorous work-ups may provoke unnecessary anxiety in patients and families, lead to excessive exposure to radiation and procedures, and increased medical costs. But most agree that findings need to be reported to patients, and the ordering caregiver and patient

[1] Munk, MD, et al. Frequency and Follow-up of Incidental Findings on Trauma Computed Tomography Scans: Experience at a level one trauma center. J Emerg Med 2010;38(3): 346-50.

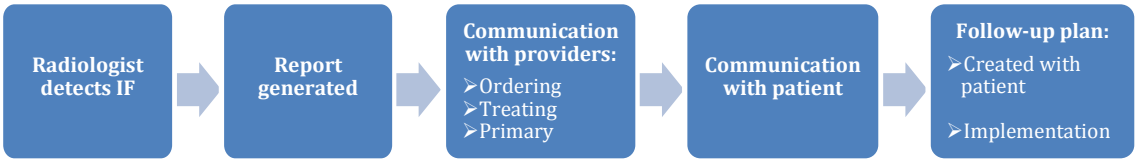
should jointly discuss how to proceed. Providers receiving imaging reports with vague guidance such as "clinical correlation suggested" may find it challenging to have appropriate discussions with patients and develop follow-up plans. Providers and/or patients may want to further investigate low-risk IFs due to the unwillingness to accept the uncertainty of the diagnosis. Radiologists also face the challenges of balancing the risks and benefits of further investigation of IFs, educating providers about the significance of IFs, and the potential medical-legal implications of an IF that may cause harm over time.

Significant incidental findings from inpatient or ED studies must be assessed appropriately either during the hospital stay or in a timely manner after discharge. These IFs must be consistently communicated to the appropriate providers who, in turn, must inform patients and ensure that any necessary follow-up testing is carried out. Unfortunately, studies have shown that IFs are often not communicated to providers and patients, documented in the medical record or followed up in a timely and appropriate manner.[2,3] In a survey of risk managers, patient safety officers and health care attorneys, the failure to follow up on abnormal test results due to computer or user input error was the most frequently cited concern about future clinical care in the hospital setting.[4]

Incidental findings can be the result of imaging studies, lab testing, direct-to-consumer testing, large-scale genetic sequencing, and research studies. This advisory is focused on IFs from imaging studies in ED/inpatient settings, however many of the principles discussed are applicable to other scenarios.

Figure 1 outlines the basic steps in the process from detection of IF through implementation of follow-up plan.

Figure 1.



Case/Lessons Learned

Case one: Prior to surgery, a routine CXR report read "very appreciable vein initially some prominence of the lungs which can be correlated with any concern of chronic interstitial disease, no other abnormality." The patient was asymptomatic, the surgeon did not appreciate the significance of the findings, and nothing further was done. Two years later the patient was diagnosed with pulmonary fibrosis.

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[2] Emerman, CL, et al. Incidental Radiology Findings: Effectiveness of a Radiology–Electronic Medical Records interface system for improving communication. J Clin Outcomes Manage 2012;19(3):111-15.

[3] Devine, AS, et at. Frequency of Incidental Findings on Computed Tomography of Trauma Patients. West J Emerg Med 2010;11(1):24-27.

[4] Menon S, et al. Electronic health record-related safety concerns: a cross-sectional survey. J Health Risk Manag 2014;34(1):14-26.

Case two: A patient was admitted with diverticulitis, treated and discharged with follow-up with PCP. Incidental CT finding of a lung nodule was noted on the radiology report, but was not addressed by the inpatient care team nor mentioned in the discharge summary. The patient presented two years later with metastatic lung cancer.

Lessons Learned:

- Ordering physicians may be aided in the decision-making process by clear descriptions and/or diagnoses and the placement of recommendations and references in a separate section of the radiology report. Formats depend upon clinical risk factors and physician preferences.
- Notification of the PCP and the patient may lead to increased awareness of the need for further evaluation.
- Tracking systems for IFs may allow for additional review of findings and successful notification of providers and patients.

Topics for Health Care Facility Systems Review

Various topics, references, and best practices that may be used to stimulate internal discussion and review of health care facility protocols for the management of incidental findings are outlined below.

1. **Challenges along the continuum of care.** Clear communication between providers with an accurate flow of information becomes increasingly difficult, as patients move from one care setting to another. Hospitals may improve patient safety through a variety of quality improvement activities that address issues such as:
    a. Communication of IFs is made more difficult by the general lack of involvement of PCPs in hospital care, the short length of hospital stays, and radiology reports that are posted after discharge.
    b. Who is responsible for ensuring that necessary follow-up occurs? The ordering provider, radiologist, PCP or patient? Often patients do not have or indicate primary care providers, should they be sent notifications of need for follow up? Hospitals protocols and systems should support the transfer of information, as well as assigned responsibility and recommendations along each step of the continuum of care.
    c. The need for standardized approaches to IFs can be addressed through the identification and education of available guidelines. The American College of Radiology white papers and the Fleischner Society recommendations for pulmonary nodules[5] are valuable tools for framing hospital approaches to IFs. (See references at end of advisory.)

2. **HIT/EHR barriers.** Healthcare Information Technology (HIT) and Electronic Healthcare Records (EHRs) have the potential to greatly improve follow up on incidental findings. Unfortunately a variety of factors keep these systems from working as effectively as possible. The Joint Commission cited human-computer

[5] Fleischner Society for Thoracic Imaging and Diagnosis. White papers. Accessed 2/23/16 at http://fleischnersociety.org/published-works-of-the-fleischner-society/white-papers/

interface, workflow, and communication problems as the most common HIT problems noted during hospital visits.[6]

a. Integration of EHR systems is often less than 100 percent, creating a gray area between differing EHRs and/or paper reports and electronic records where IFs may remain unnoticed by providers.
b. EHR workflow processes and user familiarity and comfort with EHR systems vary dramatically between users and hospitals.[7] The large volume of electronic messages about test results (e.g. regarding IFs and need for follow up) may challenge providers' ability to find and review each report thoroughly.
c. Clinical users may override decision support systems and alerts, reducing the effectiveness of HIT with regard to appropriate IF decision-making.
d. **SAFER guides.**[8] Developed by the Office of the National Coordinator for HIT, these guides provide a comprehensive set of HIT checklists for hospitals to review and help shape quality improvement activities. SAFER guides recognize the issues that occur at different stages of EHR/HIT implementation.

3. **Radiology and HIT systems.** Radiology reports can greatly impact the consistency, quality, and timeliness of IF follow-up. There are a number of report formats and HIT tools that may allow radiologists to provide clearer guidance and references to ordering providers and PCPs during or after hospital visits. These formats and tools have been used effectively by some hospitals but each facility must assess what is most appropriate for their systems and physician preferences.
    a. Use of **searchable macros** by radiologists during dictation can generate and send out notices to providers and patients about IFs.[9]
    b. **Enhanced radiology reports** reference evidence-based standard guidelines and provide recommendations for follow-up.[10]
    c. Make recommendations succinct and separate from the body of the report and findings. Use diagnoses, when possible, rather than simple descriptions of findings. Radiology findings should be sent to both the ordering caregiver and the patient, when requested.
    d. There should be clarity between the ordering physician and/or the radiologist to ensure that all requisite follow-up is performed with a closed loop system.

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[6] The Joint Commission. Investigations of Health IT-related Deaths, Serious Injuries or Unsafe Conditions. March, 2015. Accessed 2/21/16 at https://www.healthit.gov/sites/default/files/safer/pdfs/Investigations_HealthIT_related_SE_Report_033015.pdf

[7] Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care 2010;19 Suppl 3: i68-74.

[8] Office of the National Coordinator for Health Information Technology. SAFER guides.

[9] Emerman, CL, et al. Incidental Radiology Findings: Effectiveness of a Radiology–Electronic Medical Records interface system for improving communication. J Clin Outcomes Manage 2012;19(3):111-15.

[10] Woloshin, S, et al. Using Radiology Reports to Encourage Evidence-based Practice in the Evaluation of Small, Incidentally Detected Pulmonary Nodules. Ann Am Thorac Soc 2014;11(2):211–214.

e. Radiology departments can work collaboratively to develop more consistent approaches to reports and recommendations. This consistency regarding IFs may improve provider confidence and understanding of the findings and appropriate next steps.
f. Standardizing language can help non-radiologists. The American College of Radiology recommends consistent use of terms such as[11]
    i. Further evaluation: implies need to perform additional tests/procedures relatively soon (prompt further evaluation specifies greater urgency)
    ii. Follow-up: refers to further imaging after a certain interval of time.
g. The radiologist should be a resource, available to the caregiver and the patient to answer questions and provide consultation.

4. **Consider the risks of IFs prior to testing.** The best way to avoid IFs may be to minimize the use of imaging studies. When testing is needed, it is recommended that providers anticipate and communicate the risk of IFs to the patient and review how findings, their significance, and any recommendations will be shared.[12]
    a. Use an informed consent process, when possible, for ordering tests that allows for shared decision making and respects patients' wishes regarding how information about test results will be communicated.
    b. Consider the use of decision aids and graphic representations of evidence-based risks when describing IFs to patients.
    c. Ensure that all individuals have access to (literacy and language-appropriate) information and guidance needed to make informed decisions about IFs.
    d. Providers should consider the benefits, risks, and cost effectiveness of using bundled tests or batteries of tests rather than sequential, discrete diagnostic tests.[13,14] Practice changes can be made at the provider and system level requiring departmental, medical staff and hospital-wide collaborative discussions to identify priorities and concerns.
    e. Educational materials should be developed about the ethical, practical, and legal considerations of IFs.

Best practices

Choosing Wisely is a national educational effort developed by the American Board of Internal Medicine Foundation and more than 50 medical professional organizations. Numerous provider and patient lists provide evidence-based recommendations about the risks and benefits of a wide range of tests and procedures, including risks of IFs.

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[11] Berland, LL. Overview of White Papers of the ACR Incidental Findings Committee II on Adnexal, Vascular, Splenic, Nodal, Gallbladder, and Biliary Findings. J Am Coll Radiol 2013;10:672-4.
[12] Presidential Commission for the Study of Bioethical issues. Anticipate and Communicate: Ethical management of Incidental and Secondary Findings in the Clinical, Research and Direct-to-Consumer Contexts. December, 2013. Accessed 2/15/16 at http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf
[13] Presidential Commission for the Study of Bioethical Issues. Op. cit.
[14] Choosing Wisely, American College of Radiology. Five Things Physicians and Patients should question. April 4, 2012. Accessed 2/16/15 at http://www.choosingwisely.org/societies/american-college-of-radiology/

Review of relevant department or specialty lists may serve as an impetus for hospital quality and patient safety discussions and review of protocols.

- For example, both the American College of Radiology[15] and the American College of Emergency Physicians Choosing Wisely recommendations state that CT angiography should not be performed in patients without a moderate-high pre-test probability of PE that includes a positive D-dimer result.
- CT screening for lung cancer has high rates of false positive and incidental findings[16] that may lead to patient anxiety and distress, additional radiation exposure, and risks from biopsies. [17] Informed consent prior to screening is paramount for patient safety and shared-decision making.

Action Level Radiology Tags (ALRTs). To improve communication and follow-up of imaging IFs, one medical group in central Massachusetts developed the ALRTs program.

- The radiologist enters a standard dictation Macro for an IF, appropriate to the findings and follow-up plan, which contains the appropriate ALRT code. Each macro text includes follow-up recommendations for high-risk and non-high-risk patients as well as criteria for determining high-risk status. (These macros and codes are freely available for other organizations to set up similar systems, see References.)
- The performing hospital can flag abnormal studies to the ordering provider and give copies to the patient at discharge and/or by mail.
- All imaging studies from the affiliated hospital are cc'd electronically to the PCP at the medical group where most file silently into the EHR. However, the interface engine with the EHR identifies the ALRT code contained in abnormal studies and spawns an ALRT result component that the EHR recognizes and routes to the PCP's in-basket, flagging it as abnormal.
- The receiving and/or sending system can use this ALRT code to plan and track IF follow-up.
- For example, the medical group's Pulmonary Nodule Registry is auto-notified by the EHR recognizing the ALRT result component. Quality improvement staff can use the registry to confirm the actual performance of follow-up CT scans. The medical group's current registry management requires about 0.2 FTE staffing for 200,000 covered lives.
- The medical group's registry sends follow-up CT scan orders to the PCP for signing if not already done.
- The registry sends certified reminder letters to overdue patients, those that refuse testing, and patients who leave the network.

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[15] Choosing Wisely. Op. cit.

[16] U.S Preventive Services Task Force. Final Recommendations Statement, Lung Cancer: Screening, December 2013. Accessed 2/23/16 at http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/lung-cancer-screening

[17] Weiner, RS, et al. The Choosing Wisely Top Five List in Adult Pulmonary Medicine. CHEST 2014; 145(6):1383–1391

- The medical group's interface engine routes all results after hospital discharge to the PCP's in-basket as it is possible that no one has seen these results.
- This system works across multiple EHR vendor systems.
- Clinicians on the IT team have provided an important perspective that has elevated the importance of patient safety and improved usability of the solutions.

Conclusion

Increased use and sensitivity of imaging modalities have led to a steady rise in incidental findings. Rapid movement of patients between facilities, departments, and outpatient settings can diffuse care responsibilities and fragment patient information. Hospitals and providers should work together to identify barriers and use HIT tools, available guidelines, and provider and patient education to improve rates of effective and timely IF management. Radiology departments should examine various examples of report formatting, peer review, and emerging HIT tools to review and improve their own reporting and communication systems. Use of informed consent and avoidance of redundant or unnecessary imaging studies can reduce the risk of IFs and improve overall patient safety and satisfaction.

References

The American College of Radiology (ACR) Incidental Findings Committee developed a series of white papers on IFs with topics including:

- Overview of White Papers of the ACR Incidental Findings Committee II on Adnexal, Vascular, Splenic, Nodal, Gallbladder, and Biliary Findings
- Adnexal Findings
- Vascular Findings
- Splenic and Nodal Findings
- Gallbladder and Biliary Findings
- Managing Incidental Findings on Abdominal CT
- Managing Incidental Thyroid Nodules

http://www.acr.org

The Fleischner Society for Thoracic Imaging and Diagnosis has published references on the management of solid and subsolid pulmonary nodules as well as other white papers. http://fleischnersociety.org/published-works-of-the-fleischner-society/white-papers/

In *Anticipate and Communicate: Ethical management of Incidental and Secondary Findings in the Clinical, Research and Direct-to-Consumer Contexts* the Presidential Commission for the Study of Bioethical issues reviews a wide variety of practical and ethical issues around incidental findings and supply a number of references and best practices. http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf

In *Privacy and Progress in Whole Genome Sequencing*, the Presidential Commission for the Study of Bioethics Issues addressed incidental findings with regard to large-scale genetic sequencing. http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf

A presentation on ALRTs by Dr. Larry Garber to the Massachusetts Coalition for the Prevention of Medical Errors can be accessed here: http://www.macoalition.org/documents/tracking-imaging.ppt Dr. Garber is Medical Director for Informatics at Reliant and has graciously agreed to serve as a resource for additional information regarding this work and available resources:: Lawrence.Garber@ReliantMedicalGroup.org