Management of Laboratory Data and Information Exchange in the Electronic Health Record

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• In the era of the electronic health record, the success of laboratories and pathologists will depend on effective presentation and management of laboratory information, including test orders and results, and effective exchange of data between the laboratory information system and the electronic health record. In this third paper of a series that explores empowerment of pathology in the era of the electronic health record, we review key elements of managing laboratory information within the electronic health record and examine functional issues pertinent to pathologists and laboratories in the exchange of laboratory information between electronic health records and both anatomic and clinical pathology laboratory information systems. Issues with electronic order-entry and results-reporting interfaces are described, and considerations for setting up these interfaces are detailed in tables. The role of the laboratory medical director as mandated by the Clinical Laboratory Improvement Amendments of 1988 and the impacts of discordance between laboratory results and their display in the electronic health record are also discussed.

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Laboratory information systems (LISs) are designed to meet workflow needs within the laboratory as well as interface with electronic health record (EHR) and billing systems. Configuration and maintenance of appropriate communication between an LIS and an EHR are very much institution dependent and beyond the scope of this document; however, understanding the complexity of the problem is not.

Although anatomic pathology (AP) and clinical pathology (CP) specimens, workflows, and results reporting share many common electronic communications issues, the complexity of the LIS-EHR data flow problem is increased as AP and CP each also have unique information management requirements. Most institutions will have an AP LIS (APLIS) to handle data and workflows related to testing of surgical and cytology specimens, as well as a separate CP LIS (CPLIS) to facilitate testing and reporting of blood and other specimen types. In an attempt to more effectively address these complexities, we will first examine shared issues and then explore issues unique to each type of system.

ISSUES SHARED BETWEEN APLIS AND CPLIS

Patient Identification

Positive patient identification is essential at every step of the care life cycle, from the time a patient presents to a clinic through ordering, phlebotomy or biopsy, testing, result transmission, result review, billing, and taking action based on a result. Unique patient identifiers that always associate patient identity with the correct patient data are a crucial problem that has not yet been successfully addressed by legislation. This association is critical when an LIS transmits patient data across multiple institutional, office, health information exchange, and personal health records, as well as state and federal registries for mandatory reporting (eg, communicable infectious diseases for population surveillance).

Patient identification error rates in laboratory medicine occur in the preanalytical phase with misidentification errors ranging from 1% to 2% for inpatients and from 0.2% to 6% for outpatients.[1] A College of American Pathologists Q-Probes study indicated patient misidentification errors occur 324 times per 1 000 000 billable tests, although most errors (85.5%) are caught and corrected prior to results reporting, leaving a postverification rate of 55 misidentification errors per 1 000 000 billable tests. Primary specimen labeling errors account for 50% of misidentification errors, and 22% occur during computer registration or order entry.[2]

Implementation of a universal health identifier would facilitate the intent of current and anticipated health care legislation related to continuity of care, transitions of care, and portability of information.[3] Many individual institutions use an enterprise-wide master patient indexing system,[4] but

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Table 1. Laboratory Order Types in Computerized Physician Order Entry		
Order Name	**Specimen Collection**	**Expected TAT**
STAT	Immediately	30 min–1 h
ASAP	30 min–1 h	1–2 h
Routine	Same day	Same day
Timed	Specified time requested	1–2 h from time of draw
Standing or recurring	Specified frequency (eg, daily, once per shift, with morning draw)	Same day
Future	Not always specified (eg, prior to next appointment)	Same day

Abbreviations: ASAP, as soon as possible; TAT, turnaround time for results reporting.

enterprise-wide master patient indexing systems do not address cross-institutional positive patient identification. A standards-based voluntary universal health care identification system is being developed,[5,6] and the Office of the National Coordinator recently announced the launch of their Patient Matching Initiative, which will focus on identifying key matching attributes and defining best practices to support positive patient identification.

Universal health identifiers, enterprise-wide master patient indexing systems,[7] and voluntary universal health care identification all present significant technical challenges, especially given the need for data exchange that goes beyond institutional boundaries. These approaches to positive patient identification also raise patient privacy concerns, which have been the topic of debate in the public media.[8] Obviously, patient identification is a serious issue for all laboratories, and informatically, a standard patient identifier would simplify the exchange of information between the EHR and LIS.

Splitting Samples

Often, samples must be split between AP and CP areas of the laboratory for analysis, such as a spinal fluid that may need to be analyzed in hematology for cell count and differential, in chemistry for protein and glucose, in microbiology for culture, and in cytology for the presence of abnormal cells. Although specimen tracking and proper identification throughout the entire testing process are recognized as critical patient safety issues, these split specimens still present difficulties in asset tracking, ordering, and test performance within the window of appropriate specimen integrity. It is generally acknowledged that specimen tracking tools are better developed in CPLISs, and instrument interfaces in CP may aid in monitoring and correcting these problems. Anatomic pathology traditionally does not have instruments interfaced with the APLIS; however, the need to interface instruments with the APLIS, and to validate those interfaces, is becoming more common as more automation is incorporated into AP workflows.

ISSUES PREDOMINANTLY FOR CP TESTING

CP Order Entry

Ordering laboratory tests is a complex process, and EHR systems vary in their ability to handle these orders in a manner satisfactory to ensure best patient care. Computerized physician/provider order entry (CPOE) is required to meet stage 2 meaningful use criteria,[9] but neither the regulation for hospitals and providers nor the Office of the National Coordinator EHR certification criteria define standards for test ordering, the information required to place an order, the types of orders that can be placed, or definitions for them (see Table 1); common naming conventions for tests and panels or batteries of tests are also not yet defined. The Clinical Laboratory Improvement Amendments of 1988 mandate only that certain data items be provided in a test request,[10] and these are also applicable to electronic orders; however, these represent, at best, a minimum to ensure appropriate display of laboratory data in electronic systems.

Crucial to CPOE for laboratory tests is the process of managing the test menu, that is, the choices for laboratory tests from which the clinician chooses when placing an order. The EHR setting will dictate the test name/codes and the manner in which the choices appear for CPOE. Test definitions in the EHR must match or be mapped appropriately to the correct test codes in the LIS. In addition, laboratories frequently create different codes based on the technology used, such as an in-laboratory chemistry analyzer versus a bedside point-of-care device, causing even more confusion. The Logical Observation Identifiers Names and Codes (LOINC) standard,[11,12] which is endorsed and mandated in the Office of the National Coordinator EHR certification criteria, aims to standardize laboratory test codes across health information technology systems. Defining LOINC codes in a laboratory's LIS can be cumbersome and subject to variation,[13] and pathologists should be aware that implementation of LOINC in their LIS will require laboratory resources (and possibly a third party), and even when fully implemented, may not solve all interoperability issues.[14,15]

The CPOE process is further complicated in the EHR when the workflow requires performance of an order release function before the order is sent through the interface to the LIS, as these functions are often executed by nursing, clerical, or other staff. For example, add-on test requests, where additional tests are ordered for specimens known to be already collected and present in the laboratory, may not be supported by the EHR. Similarly, orders to be executed at a future time (ie, future orders) are also problematic as they may have a limited retention time in the system, so that if a patient returns for the testing after this time has expired, there is no record of any orders for the visit.

Explanations or special instructions for orders may have been entered into a comment field in the EHR order form, but that information may not be effectively passed through the interface into the LIS. This often results in calls to clinician offices for clarification, potentially missed test orders, performance of tests on the wrong date, and disruption of normal laboratory specimen processing and workflow,[16] all of which create customer dissatisfaction with laboratory services. Furthermore, if an order is released in error, a test performed, and a charge generated, the laboratory typically must write off the charge because the work was not required during that visit,[17] creating compliance issues and increasing laboratory costs.

Table 2. Considerations for Setting Up a Computerized Physician Order-Entry Interface Between the Electronic Health Record (EHR) and Clinical Pathology Laboratory Information System

If the EHR system is assigning an order number(s), what is the scope of that order number?
How does information flow from the EHR to the LIS?
If the requisition is electronic, how is the pertinent clinical history being provided?
Are labels printed for the specimen containers, and what is on them? Do they follow the CLSI guideline?[36]
Are requisitions printed at all and do they have the order number?
How are outpatient and/or outreach orders handled?
How are patient and clinician demographic updates handled?
How are new orders, add-on tests, and cancelled orders handled?
How does duplicate checking/combining of orders occur?
Is there an ability to differentiate between laboratory-to-collect orders and provider-to-collect orders?
How are institutions, facilities, performing locations, and patient locations defined in each system?
How are test codes/names assigned in each system?
How are test list choices kept reconciled with what is available in the LIS?
How are test name aliases cross-referenced for order entry?
Can a variety of date formats be supported?
After an order is placed, is it released automatically to the LIS or manually?
What version of the HL7 standard is used?
How are orders routed to collection lists, handheld collection devices, and label printers?
How frequently do upgrades/updates occur to the interface and what maintenance is required?
What audit trail capabilities and reports are included?
What levels of vendor support are available and at what cost?

Abbreviations: CLSI, Clinical and Laboratory Standards Institute; HL7, Health Level 7; LIS, laboratory information system.

Order duplication in the EHR presents particular difficulties for the laboratory. Many EHRs have logic built in to cancel duplicate orders, but if these cancellations are not properly communicated through the interface to the LIS, laboratory staff may have to manually cancel duplicate orders in the LIS and reorder them with new accession numbers to force the results back to the EHR so they can be filed appropriately. Similar problems arise when duplicate orders from the same phlebotomy event have different accession numbers, potentially forcing technologists to manually enter the test results to have them flow back appropriately to the EHR, increasing the potential for error. Clearly, the potential for error and unnecessary work makes it crucial for duplicate orders to be corrected at the time they are placed. Depending on test volume, the laboratory may be able to implement duplicate order checking in the LIS and communicate cancellations to the ordering provider, or they may simply perform the duplicate testing and write off the charge when the duplicate service is detected in the billing process.

Additional functions performed at the time of CPOE may include medical necessity checking for a payer on a case-by-case basis, Advance Beneficiary Notice creation for Medicare enrollees, and routing of laboratory orders based on test menu or payer contracts.[18,19] Although some EHRs provide help with these functions, many do not, and laboratory registration staff must determine whether or not these assessments are necessary prior to sending the patient for phlebotomy. This type of information will not typically be present in the LIS.

Reworking orders that are incorrectly coded, have missing information, or are missing medical necessity checks is expensive. It has been estimated that each order requiring rework by laboratory personnel costs approximately $25.[18] The volume of problem orders that need to be reworked can have a significant financial impact on a laboratory, and it is critical that ordering standards be developed for EHRs, LISs, and their interfaces.

Only a few example issues associated with an EHR to CPLIS order-entry interface have been presented here. A more complete list is included in Table 2.

CP Results in the EHR

Because of the central importance of laboratory data for clinical decision making, the presentation of laboratory data in EHRs must be appropriate and merits specific attention. First and foremost, laboratory medical directors are obligated to comply with Clinical Laboratory Improvement Amendments of 1988 regulations that state the laboratory medical director must verify accurate data transmission between an LIS and the first downstream interfaced system in which an ordering provider is expected to routinely access that data.[20] In addition, laboratories have traditionally provided results to clinicians at no charge, and because there is an expectation to continue to do so, the burden of providing the LIS-to-EHR interface continues to fall on the laboratory. This is becoming an increasingly complex and expensive problem as both commercial and hospital laboratories are expected to interface with multiple EHRs, many of which were purchased by physician practices as eligible providers under stage 1 of meaningful use.[21] As of September 24, 2013, the Office of the National Coordinator has certified 3678 ambulatory and 1255 inpatient EHR products.[22] Along with the number of potential LIS applications that may be used, the combinatorial potential for interface development is daunting. For each CPLIS and APLIS in a laboratory, a unique results interface must be established between the system and each EHR used by test orderers. A typical results interface costs $10 000 to $40 000 to implement[23] and subsequently requires upgrades, maintenance, and ongoing validation, adding to the cost.

A typical physician practice may also wish to interface to multiple laboratories, each of which must set up unique interfaces with the EHR(s) used by that practice. Once laboratory results are delivered to the appropriate EHR, laboratory data in EHRs must be an accurate representation of what was reported, and EHRs vary widely in their ability to effectively and appropriately present laboratory data. Because of the lack of standardization discussed above, and the use of different test methodologies, it is likely that the various laboratories use different test code names and reference ranges. Clinicians may also choose to display only a subset of data, often in graphical or tabular form, and pertinent laboratory comments may not be displayed. Additionally, clinicians may choose to review the same results in different systems—in a hospital EHR, on an outreach portal system, in an in-office EHR, on a mobile device, or on a hard copy via mail or fax, each of which carries its own set of caveats and idiosyncrasies. Pathologists can attest to many instances of inadequate or poorly designed display of laboratory results in EHRs that would at best be inconveniences and at worst represent significant risk for misinterpretation by the health care provider.[24]

Table 3. Key Questions for Pathologists to Ask About the Electronic Health Record (EHR) New Test Result Notification Function

Are there any types of results that do not qualify for the function?
Can the function be configured differently in the inpatient versus outpatient setting?
Do notifications go to all physicians listed on a test order (as "copy to") or just to the ordering physician?
Do corrected reports and addenda trigger notifications as new results?
Are there conditions under which test results end up in an EHR error queue, and who monitors such a queue?

These issues also raise the question of how much accountability under Clinical Laboratory Improvement Amendments of 1988 regulations should be assigned to the laboratory medical director for verification of data transfer when they generally have no opportunity to participate in the selection of EHRs used by physician practices.

The appropriate and timely communication of laboratory results to the clinician is also impacted by the specific EHR with which the CPLIS is interfaced. Historically, the arrival of a paper report was the notification to the clinician that new laboratory results were available. However, in an environment without printed reports, EHRs now provide functions that notify clinicians of new test results with varying efficacy. A lack of understanding of these notification functions on the part of the laboratory, and/or poor coordination with EHR support personnel, can lead to outcomes that might include (1) ordering clinicians being unaware of new results, (2) results being routed to the incorrect clinician, or (3) test result notifications not being delivered to any clinician.[24–28] Key questions for pathologists to ask about the EHR test notification function are listed in Table 3.

Flagging of abnormal test results presents a special problem as there is no standardized manner in which to electronically indicate abnormal or problematic results. "Low," "High," "L," "H," "up arrow," "down arrow," "*See Comment," and colored fonts or highlighting are all common ways to provide a visual indicator of abnormal results in traditional paper reports generated by the CPLIS. In the EHR, the display indicator, commonly called a flag, used by the LIS may not be compatible, and this information may be simply lost upon data transfer through the Health Level 7 interface.[29] Results of qualitative tests (eg, microbiology and blood bank) may not have flags attached to them because the result is not a numerical data point (see Table 4), and interpretive reports are typically not flagged because no quantitative value or discrete criterion is available to define a normal range. Ordering providers often have the option to apply display filters when viewing results in an EHR, and filtering to display only abnormal results is a common feature. It is important for clinicians to understand that indiscriminate use of such filters and reliance on proper transfer of flags from the LIS poses the risk of missing relevant test results, and this should be addressed during training. Additional elements of laboratory reports that may be prone to suboptimal handling in EHRs are listed in Table 5. A more complete list of issues associated with the CPLIS-to-EHR results interface is included in Table 6.

Table 4. Laboratory Test Results With Nonnumeric Data

Microbiology
Blood bank/transfusion medicine
Molecular pathology and genetic testing
Interpretive testing that combines numerical results with interpretive text (eg, coagulation panel interpretation, serum protein electrophoresis)

Table 5. Report Elements That Are Problematic in the Electronic Health Record

Reference ranges (normal ranges)
Abnormal flags
Units of measure
Explanatory footnotes or comments
Name and address of performing laboratory
Corrected, amended, and addended reports

Special Considerations

The blood product administration module in many EHRs is not well developed, creating problems when attempting to perform audits required by accrediting agencies. More

Table 6. Considerations for Setting Up a Results Interface Between the Clinical Pathology Laboratory Information System and the Electronic Health Record (EHR)

How will outside reference laboratory results flow to the EHR?
How are patient merge transactions handled (eg, trauma patients assigned a temporary medical record number until correctly identified, name changes due to change in marital status, neonates)?
What are the options for reporting the status of an order prior to completion?
Can reference ranges be defined and displayed by:
Age
Sex
Race
Specialty or provider specific abnormal ranges
Test method
Are test-specific calculations supported?
How are comments displayed, can they use both uppercase and lowercase letters, and what is the character length limitation?
Can dilution factors be accommodated?
Is reflex test ordering and cancellation available based on test results?
How are results sent to the EHR, remote printers/fax machines, encrypted e-mail, and pagers?
What happens to ASCII characters, mathematical symbols, and other special characters (eg, Greek alphabet) through the interface into results display?
What are the options for flagging abnormal results and how do they display in results review?
What version of the HL7 standard is used?
Can LOINC codes be transmitted simultaneously with the result?
What options does the provider have for viewing results?
How frequently do upgrades/updates occur to the interface and what maintenance is required?
What audit trail capabilities and reports are included?
What levels of vendor support are available and at what cost?

Abbreviations: HL7, Health Level 7; LOINC, Logical Observation Identifiers Names and Codes.

An elderly man had preoperative blood work, including a blood type and antibody screen. The antibody screen was positive. Antibody panels demonstrated a high-incidence antigen, subsequently identified as anti-k (Cellano). The Cellano antigen is present in 99.8% of Caucasiab donors and 100% of African American donors.[35] The blood bank director was concerned that the health care provides and the patient plus his family understand the significance of this information in case he would ever require transfusion, particularly at another institution that would not have this on record. The director contacted the surgeon as well as the primary care provider and documented these findings in the progress notes section of the patient's electronic health record (EHR), explaining the need for advance notice of transfusion requirements since compatible components would have to be obtained from a rare donor bank and would likely require special processing such as thawing and deglycerolization. The director also documented this as a blood bank consult under the laboratory results section in the EHR, hoping that providers would have 2 chances to view this information. Because the laboratory does billing in a different systen than the hospital uses, the director's consult notes must be entered into a laboratory information system (LIS), usually the anatomic pathology LIS because the clinical pathology LIS cannot handle several paragraphs of free text. The director wanted to document this in the patient's problem list, but an appropriate diagnosis and code was not available. The closest available diagnosis and International Classification of Diseases revision 9 (ICD-9) code in the EHR was "Hemolysis, transfusion [999.83B]," but the director felt this did not accurately indicate the serious nature of the Cellano antibody. The director then researched the appropriate ICD-9 code, but found that one does not exist for high-incidence antigens and antibodies. The closest appropriate diagnosis and code was "Other and unspecified nonspecific immuological findings [795.79]." The director submitted a request to have this added to the problem pick list in the EHR, along with the text "Red blood cell antibody, compatible PRBC [packed red blood cells] difficult to obtain."

Figure 1. *Clinical pathology laboratory information system/electronic health record documentation issue in transfusion medicine.*

importantly, patient safety issues are associated with these modules (Figure 1). Transfusion reactions, special needs, and significant antibody problems may be difficult both for nursing and laboratory personnel to document and for clinicians to interpret.

Microbiology ordering, testing, and results reporting also deserve special mention. EHRs often have limited ability to require the ordering physician to answer necessary questions regarding patient history.[30] History for appropriate microbiology testing can be crucial and extensive (travel, immune status, pets, transplant status, occupation, etc), and this information is usually buried within EHR notes rather than being presented in searchable data fields that can be viewed in either the EHR or the CPLIS at the time of culture to assist with appropriate culture and serologic test selection. Appropriate clinical and historical information would also be useful to incorporate into interpretive algorithms, as this would help prevent misguided treatment and overlooking important microbes.

Review of microbiology test results is problematic in that results on the same specimen are reported in serial fashion, providing new information as to growth or absence of organisms over time and antibiotic sensitivities of any clinically significant organisms recovered in culture. Providers may easily overlook new information. In addition, changes or result modifications may occur on the EHR side of the results interface without laboratory input, especially for results placed into the EHR via a direct interface from reference laboratories (Figure 2) that bypass the LIS.

The rapid growth in genetic testing is producing new challenges for information management. Although traditional ordering and reporting processes are adequate for some single-gene tests, somatic mutation analysis in cancer and next-generation sequencing techniques do not fit well into these standard workflows. Further, many of these tests have the potential to generate huge amounts of raw data that neither the LIS nor the EHR is equipped to accommodate. In the future, it is easy to imagine that an LIS and EHR will need the ability to interact with and integrate data from multiple sources that provide clinical, molecular, social, and environmental data. This ability is necessary in order to discretely store, track, and summarize mutations and other sequence variants identified; associate these with metabolic pathways; visually represent these pathways to the ordering physician contextually with transcriptomic and epigenomic profiles; and guide them toward selection of appropriate personalized therapies.

ISSUES PREDOMINANTLY FOR AP TESTING

AP Order Entry

Computerized physician/provider order-entry interfaces from the EHR are much less common with APLIS than with CPLIS. In CP, an order-entry interface with the EHR is valuable in assuring that the correct specimens are collected (eg, placing the order generates a label with specimen requirements like the appropriate blood tube type) and the correct tests are performed on those specimens. In contrast, the AP laboratory is not responsible for obtaining the specimen from the patient.

A patient had serologic testing sent out to a reference laboratory for several organisms including Rocky Mountain spotted fever. The various results were reported back over several days and the hospital sent out the status of all results, including those that were "pending" through their reporting interface. The electronic health record interface switched the word "pending" to "partial" because an interface programmer had decided sometime in the past that these words were similar and did not seek laboratory input as to whether this was appropriate. The physician assumed the report meant "partially positive" and treated the patient for Rocky Mountain spotted fever; subsequently, this report came back as "negative," causing great confusion.

Figure 2. *Microbiology reporting.*

Table 7. Complex Items That May Be Required in Anatomic Pathology Orders
Organ of origin
Specified location, or multiple locations, within one organ
Multiple biopsies from multiple organs
Additional descriptors (eg, nodule)
Clinical information relevant to entire case, as well as individual parts within a case
Clinical Laboratory Improvement Amendments requirements for cervical cytology

Specimen handling is almost always defined by what is received, requiring minimal further specification by the ordering physician. An AP order-entry interface can be helpful to the laboratory in tracking specimens that have not yet arrived, but much of the impetus for setting up EHR-to-APLIS order-entry interfaces comes from EHR systems. The purpose of the order in some EHRs is largely to create a placeholder for the result, and the order interface exists predominantly to communicate that placeholder (order number) to the APLIS so that, when the result arrives, it can be associated with the appropriate context. Other EHRs can accept results without an order, but they lack the ability to track the status of orders that have been placed.

Different ordering procedures may exist for AP orders entered in the operating room (eg, resection specimens), surgery centers (eg, endoscopic biopsies), and outpatient clinics (eg, skin biopsies, cervical cytology). Common to all these environments is the need to create a process by which appropriate clinical information will accompany the specimen to pathology. With paper requisitions, the form is largely completed prior to the procedure in which the specimen is acquired, and then the final list of specimens is completed at the end, often by support staff. In operating room settings, the paperwork is often filled in by the attending surgeon or a resident while the patient is being brought into the room and put under anesthesia. With electronic order entry, there is usually not an option to partially complete the form in advance, so the form is typically completed at the end of the procedure when all of the specimens have been identified. In this case, it is often a circulating nurse who completes the form, and he or she may not know the pertinent clinical history or specific questions to be addressed. Either the specimen may not have any accompanying clinical history or impression, or the accompanying information may be incorrect. Therefore, in setting up an order-entry interface into an APLIS, it is important for the pathologist to examine the workflow in the setting where the order will be placed to assure that there is provision for including pertinent history. Surgeons and other procedural specialists may incorrectly assume that because the order is being placed into the EHR, all of the pertinent information from the EHR will be forwarded to the pathologist with the specimen. Finding this information in the EHR can be very time-consuming, and it may not be practical for the pathologist to do this for every specimen in a high-volume practice.

Frozen section workflow in the operating room environment needs to be considered in setting up an AP order interface. Will an electronic order be created in the EHR for the frozen section or not? If so, will the order message arrive and be processed by the LIS before the specimen arrives? If not, does the workflow exist in pathology to accession the specimen without the order, and once the order is later created and sent to the LIS, is there a way to associate the order with an already existing specimen? How are subsequent specimens sent for frozen sections from the same case handled? Do they get the same order number, or a new one? What about the specimens sent only for permanent sections?

Specimen type also has to be addressed in an order interface. Elements of the AP workflow in the LIS are determined by the specimen type assigned for each part received. For example, the number of cassettes printed and fee codes entered may default based upon the specified part type. In setting up an order-entry interface, a decision will have to be made whether the part type will be specified by the ordering clinician or by pathology. If it is specified by the ordering clinician as part of the order, how is the list of possible choices kept synchronized with the LIS? Is this list of choices granular enough to be useful? How reliably will the correct specimen type be selected? These questions point out the need for careful validation of the AP CPOE module to ensure reliability, as well as thorough training of the ordering clinicians. See Table 7 for a list of data items that need to be associated with an AP order.

Anatomic pathology laboratories that maintain an outreach business still need to be able to accommodate paper requisitions, because specimens from private physician offices typically will not have an associated electronic order. These pathology departments will need two different workflows for receiving and accessioning specimens, although this problem will gradually decline as more providers comply with stage 2 of meaningful use and fulfill the requirements of complying with electronic transmission of all orders.[31]

Only a few of the issues associated with an EHR to APLIS order-entry interface have been discussed here. A more complete list is included in Table 8.

AP Results in the EHR

In considering some of the issues that arise in transferring results from an APLIS (or APLIS module) to an EHR (or the portion of the EHR from which treating physicians will view the results), it is illustrative to follow a typical specimen result.

When a pathologist signs out a surgical pathology case, the first decision the APLIS needs to make is whether or not this result should go to the EHR. If it is an outreach specimen on a nonhospital patient, the LIS may not have a hospital/system medical record number for the patient, so the result cannot be filed in the EHR. If the LIS does have a medical record number for the patient, but the specimen was received from a physician's office, whether or not the result should be filed in the hospital EHR may depend upon the established relationship between the physician and the hospital, and may be impacted by Health Insurance Portability and Accountability Act considerations.

Once it is determined where to send the result, the APLIS must know how the results will be sent. As AP results are generally unstructured free text, formatting such as fonts, indentations, tabs, line breaks, colors, and highlighting are used by the pathologist to organize observations and highlight key findings. In addition, graphics and images may also be used to clarify AP results. Preservation of these

Table 8. Considerations for Setting Up a Computerized Physician Order-Entry Interface Between the Electronic Health Record (EHR) and Anatomic Pathology Laboratory Information System (APLIS)

What is the structure of the order (ie, is each specimen part its own order, or is the order for the entire surgical procedure)?
If the EHR system is assigning an order number(s), what is the scope of that order number?
How are frozen sections handled?
If the requisition is electronic, how is the pertinent clinical history being provided?
For some specimens (eg, cervical cytology), what specific elements of clinical history are required?
What options are available for the ordering person to specify the "specimen type"?
Free text entry
Selection from a list—limited choices (surgical, gynecologic cytology, nongynecologic cytology)
Selection from a list—detailed choices (part types)
Combination
How are test list choices kept reconciled with what is available in the laboratory information system (LIS)?
Is laterality specified in the order-entry process?
How are multiple specimens from the same procedure handled? They need to be kept together as a single order, because only a single report will be generated for all the parts. Is there an ability to specify additional information about each specimen/part (such as organ, location within the organ, etc)?
If the laboratory has developed customized requisition forms for certain specimen types (eg, endoscopy), how are those handled in the ordering EHR?
Are labels printed for the specimen containers, and what is on them?
Are requisitions printed at all and do they have the order number?
How are outpatient and/or outreach orders handled?
Is there a place to store the order number in the APLIS?
If part type fields are made available in the EHR for ordering, what are the consequences of an incorrect selection by the ordering provider?
If an order is placed but no specimen shows up in Pathology, whose responsibility is it to address that?
If a specimen shows up but no order was placed for it, then what happens?
If an order is placed but no result is reported, how is the order closed out in the EHR?
Can a variety of date formats be supported?
How are patient and clinician demographic updates handled?
How are institutions, facilities, performing locations, and patient locations defined in each system?
How frequently do upgrades/updates occur to the interface and what maintenance is required?
What audit trail capabilities and reports are included?
What levels of vendor support are available and at what cost?

features of an AP result report is crucial to avoiding the risk of misleading display of results in the EHR and misinterpretation by clinicians.[32] Current standards for transmitting text data between the LIS and the EHR, such as Health Level 7 messages, are not well suited for maintaining these details. Alternative options, such as the PDF, ensure retention of appropriate formatting and embedded graphics, but are not always displayed consistently.[33]

The EHR and APLIS may not use the same formats or mechanisms for results display. Rich text formatting by many APLIS for results display may not be supported by the EHR and only the text of the report may be accepted through the results interface. As such, a multitude of changes, such as truncations due to character limits, unintended text wrapping and concatenation, and the stripping of special characters, such as the Greek letters kappa and lambda, can occur during transfer through the APLIS-EHR interface, making the displayed result unintelligible with respect to the pathologist's original document.

Once the results arrive in the EHR and are parsed and associated with the correct patient, there is typically the need to associate the result with a test order. In a CPLIS, a finite list of all possible tests for which results might be recorded can preexist in the EHR, but this is not the case for AP. Even if all possible ways of labeling specimens could be encoded in the EHR (eg, left kidney, colon at 25 cm, new superior-lateral margin, etc), a specimen can consist of any number of parts, and the resulting array of possible combinations is essentially infinite. Therefore, a common practice is to reduce these to a small number of tests, such as "surgical specimen" and "cytology specimen." Although this seemingly simplifies the interface, there are display consequences on the receiving end. If all of the AP specimens are simply listed as "surgical specimen" in the EHR, this can be very inconvenient for the treating physicians looking for a particular result, as each report has to be individually opened to find the one desired. Some receiving systems do allow a free-text description of the specimen to be sent, received, and displayed.

A major concern with AP results in the EHR is the amount of screen space available to display the results, especially if exporting to mobile devices. In many EHR systems, AP is treated much like CP, and the display area may consist of only 1 or 2 lines, necessitating scrolling (sometimes horizontally as well as vertically). Important information can be easily overlooked in these situations, constituting a significant patient safety risk.

Finally, a clear understanding needs to be established between the sending APLIS and the receiving EHR as to how amended reports will be handled.[34] Typically, a set of metadata transmitted in the Health Level 7 message needs to match with corresponding fields in the receiving EHR so that it recognizes that the newly arriving report should replace the existing report and not be added as a second report. If the original (now replaced) report is saved in the EHR for documentation purposes, it needs to be clearly marked as a replaced version so that a subsequent viewer does not mistake it as the final version. In contrast, results of additional testing may need to be appropriately added to the result already sent. This will depend upon whether the sending system resends the entire report or just the result of the additional testing.

Only a few of the issues associated with an APLIS-to-EHR results interface have been discussed here. A more complete list is included in Table 9.

SUMMARY AND CONCLUSION

The environment of the EHR has changed the paradigm by which test results are communicated and interpreted by clinicians. Misleading or suboptimal display of laboratory results in EHR systems creates potential risks for patient care. Clinical decision making relies upon accurate information, and the EHR alters the traditional flow of information between the laboratory and the physician, creating the potential for suboptimal decisions due to missing, misrepresented, or misinterpreted information.

Table 9. Considerations for Setting Up a Results Interface Between the Anatomic Pathology Laboratory Information System (APLIS) and the Electronic Health Record (EHR)

Should the result go to the EHR?
How are results sent to the EHR, remote printers/fax machines, encrypted e-mail, and pagers?
What format can the EHR handle for results: eg, PDF, images, or only plain text?
Where do AP results display in the EHR (own tab, or buried among laboratory results)
What is the display area for AP results, and can it be enlarged?
What are the issues related to formatting, notes, and scrolling?
What happens to ASCII characters, mathematical symbols, and other special characters (eg, Greek alphabet) through the interface into results display?
There will often be multiple submitting providers for the specimen; how is this handled?
Does the result go into the inbox for all of them or just the primary ordering provider?
Whose responsibility is it to follow up on an important result?
How is identification of the providers in the two systems reconciled?
What happens if some of the providers on the result are not in the EHR?
How are amended and/or addended reports handled?
Does the new version overlay the original or do they coexist?
If a PDF is provided, is the old PDF replaced by the new one or do the two coexist?
Is the modified report flagged as modified?
Does the modified report go to just the primary ordering physician or to all?
Can the report be printed from the EHR, and if so, what does it look like?
If synoptic information is available, is it sent as discrete elements or as text?
If the APLIS collects discrete data elements (synoptic), can they be transmitted and stored?
How frequently do upgrades/updates occur to the interface and what maintenance is required?
What audit trail capabilities and reports are included?
What levels of vendor support are available and at what cost?

Abbreviation: AP, anatomic pathology.

EMR adoption introduces CPOE as the mechanism for initiating the laboratory test cycle. As a result, pathologists and laboratories may lose the ability to control aspects of the ordering process if careful attention is not paid to EHR/LIS interface development, ensuring laboratory test orders are complete, accurate, and sufficient to facilitate efficient laboratory workflow processing.

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