COLLEGE of AMERICAN PATHOLOGISTS

COVID19 - Remote Sign-Out Guidance

AUDIENCE

CMS, Pathologists, and Laboratory Administrators

DEFINITIONS

Remote sign-out: Electronic verification of pathology and laboratory test results by pathologists from a location that is not a CLIA-licensed facility.
Remote facility: Location where remote sign-out occurs that is not a CLIA-licensed facility (e.g., a pathologist's home or hotel room).

INTENT OF DOCUMENT

To illustrate how immediately granting remote sign-out for primary diagnoses will enable pathologists to deliver timely and quality care for patients, ensure their own safety, and increase the probability of continuing to provide patient care during the COVID-19 crisis.

Almost all pathologists have the infrastructure to sign-out cases from remote facilities but do not currently because of requirements under CLIA'88 that state that tests must be performed at a CLIA-licensed facility. Remote sign out currently requires each remote location to have its own CLIA license. As such, large pathology departments could be required to obtain 50 or more separate CLIA licenses during the current pandemic if pathologists were to work remotely.

During the COVID-19 crisis, the requirement for pathologists to travel to work and unnecessarily expose themselves to the circulating SARS-CoV-2 virus puts them, their co-workers and their families at risk of a potentially deadly illness and puts patients at risk for delayed care should pathologists not be able to perform their work in their traditional workplace due to illness or quarantine. In addition, many pathologists may not be able to be physically present at work because of childcare or other commuting-related issues caused by the pandemic. For example, most if not all pathology departments have access to their laboratory information systems through secure web portals from outside their CLIA-licensed facilities. Anatomic pathologists can take the microscope and microscopic slides to their home or utilize a digital system validated by the laboratory to examine microscopic slides. Hematopathologists, molecular pathologists, and clinical pathologists can review laboratory data (e.g., flow cytometry dot plots, electropherograms, next-generation sequencing results) electronically from remote facilities and render diagnostic interpretations to be entered in the laboratory information system as well. It is important to emphasize that conducting the aforementioned diagnostic activities are contingent on the existence of validated Standard Operating

Procedures (SOP's) for remote sign out as approved by individual Laboratory Medical Directors.

SCOPE OF THIS DOCUMENT

Remote sign-out for pathology would include the following activities:

- Pathologists reviewing glass slides at home with a microscope.
- Pathologists reviewing whole slide images (WSI) using validated digital pathology platforms, including tissue sections, cytopathology preparations and other standard pathology specimens such as peripheral blood smears and gram stains.
- This is included in the above interpretation of electrophoretic gels, flow cytometry, molecular diagnostics, and related activities using secure remote access to laboratory systems.
- Access to additional information needed to support remote sign-out that may include reviewing clinical data, radiologic images, immunohistochemistry, molecular diagnostics, cancer cytogenetics, flow cytometry, fluorescence in situ hybridization (FISH) images, etc., using secure remote access to laboratory systems and electronic health records as needed.
- Remote review and signing of laboratory operational documents and procedures (not laboratory results themselves) using email in lieu of physical signatures.

EVIDENCE SUPPORTING THE LEGITIMACY OF THE REQUEST

1. There is an abundance of peer-reviewed literature reporting that WSI is non-inferior to glass slide review for rendering pathology diagnosis.[1]
2. The College of American Pathologists has published well-established and vetted guidelines on how to validate digital pathology systems for primary diagnostic work.[2]
3. The FDA has cleared two different vendor digital pathology systems approved for remote primary diagnosis in surgical pathology.[3] *(Note that FDA approval applies to how digital pathology systems are marketed by manufacturers. Pathologists may use a non-FDA approved system as long as it has been properly validated.)*
4. The FDA has cleared one vendor system that allows remote review, classification, and reporting of leukocyte differentials in peripheral blood smears.
5. FDA-cleared systems are available that support electronic display and sign out of protein electrophoresis gels.
6. Virtual Private Network (VPN) and secure remote access systems (e.g., Citrix) are available that together provide secure views into clinical/laboratory systems with faithful display of text, numbers, line graphics, and user interface elements.
7. Recent law and court cases suggest that the "from" field email messages can function as a legal signature if there is intent by the author to sign [4]. For laboratory operational and administration documents, it is recommended that a printed email message from an institutional system that contains a reference to a specific document and includes the email header information be acceptable in lieu of a physical signature.

8. Laboratory professionals typically have a private space whereby they can access patient data without exposing patient health information. Healthcare organizations can ensure that there are additional protections in place for remote access to data such as multi-factor authentication, automatic log-off, encryption, etc.
9. All other physicians outside of the laboratory are legally able to order tests, review charts, and render clinical diagnoses on patients from outside their healthcare organization.

POTENTIAL RISKS OF ALLOWING REMOTE SIGN-OUT

1. Technical failure (e.g., downtime, poor network connection, digital slides with areas of suboptimal focus), however these can be addressed by troubleshooting with appropriate information technology (IT) support (e.g., reboot system, re-scan slides) and attention to histologic processing.
2. Minor delays in turnaround time (e.g., slides will need to be scanned), however remote digital sign out would likely be safer (e.g. no loss/breakage of patient slides, no viral contamination, etc.) and may be faster than physical delivery of glass slides by couriers to pathologists at remote facilities.
3. Compromised information security for a limited number of patient specimens if established VPN and other secure remote access strategies are not used correctly.
4. Potential unintentional exposure of protected health information (PHI) at the remote facility.

POTENTIAL RISKS OF NOT ALLOWING REMOTE READ-OUTS

Immediate risks

1. Unnecessarily delaying diagnoses arising from a lack of in-house pathologists such as:
    a. those who are under a 14-day quarantine due to testing positive for SARS-CoV-2, but who are asymptomatic
    b. those who return from a country where the infection is more widespread or who have known significant exposure
    c. pathologists who must remain home to supervise children who cannot be in school or day care

    All of these pathologists would still be able to remotely sign-out cases thereby ensuring continuity of patient care.

2. Overburdening remaining pathologists with excess work due to staffing shortages, thereby increasing the risk of burnout, medical error and further shortages in staffing due to exposure.
3. Exposing pathologists with chronic medical conditions (e.g. elderly, low immunity, diabetes) to busy hospitals where there is a concentration of patients, specimens and surfaces harboring SARS-CoV-2. Twenty-five percent (25%) of pathologists are 60 years old or older, and nearly 40% are over 50 years-of-age. The demand for the

physical presence of pathologists under CLIA potentially jeopardizes a significant proportion of this country's pathologist workforce.

4. For pathologists who become infected but are asymptomatic, keeping them at home to perform sign-outs reduces the risk of other physicians and critical laboratory staff such as medical technologists, specimen processors, phlebotomists and histologists becoming infected.
5. The number of COVID-19 cases will increase and peak over the next two months and will stretch existing healthcare systems to their limits. Pathologists are critical to the ability of the United States to succeed in slowing the spread of the pandemic by ensuring accurate and safe testing for all patients. To dramatically underscore the risks, at least one pathologist, at the University of Washington, has died of COVID-19. Prior to the pandemic, there was already a projected shortage of pathologists [5]. If more pathologists and laboratory professionals become ill, then the COVID-19 public health dilemma will escalate due to lack of access to needed services and delayed care, making an already looming future public health dilemma potentially worse.

Longer term risks

6. Denying remote access to expert pathologists to provide patients with the most accurate diagnosis may have serious repercussions long after the current crisis subsides. Urgent biopsies can be directed to the most experienced subspecialized pathologist(s) to remotely report a diagnosis resulting in optimal and timely care, preventing a misdiagnosis, avoiding having less qualified/less experienced pathologists report diagnoses for difficult cases, and avoiding potentially serious medico-legal consequences arising from adverse outcomes.

CONCLUSION

Pathology and laboratory medicine departments in the United States have the infrastructure for remote sign-out. This includes, but is not limited to, the use of validated digital pathology systems and remote access to electrophetograms, dot plots, FISH images and charts. The benefits of remote sign-out during this COVID-19 pandemic far outweigh the risks. We urge CMS to temporarily waive the regulatory requirement to sign-out cases and tests from CLIA-licensed facilities where there are validated standard operating procedures approved by the Laboratory Medical Director for the specific use cases in his/her laboratory. This action will decrease risks to patient care and to healthcare workers during the pandemic, and it will help ensure that pathologists' professional interpretations and diagnoses continue during this unprecedented crisis.

REFERENCES

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