MITA Urges FDA Flexibility For COVID-19 Imaging

The Medical Imaging and Technology Alliance (MITA) has sent a letter to the U.S. Food and Drug Administration (FDA) recommending loosening restrictions on mobile imaging equipment to help combat COVID-19. “Mobile imaging is a key component in responding to where the crisis is most acute, and imaging manufacturers are working with the FDA and other key agencies to increase the availability of medical imaging equipment where it is most needed,” said Dennis Durmis, chair of the MITA’s board of directors and senior vice president and head of radiology of the Americas Region for Bayer HealthCare. MITA is asking the FDA to take the following steps:

• Temporarily prioritize review and clearance of medical imaging devices, such as mobile x-ray systems, CT scanners, and portable ultrasound systems.
• Expedite third-party review recommendations for current imaging device submissions and the issuance of accession numbers for 510(k)-cleared products being imported to address the COVID-19 pandemic.
• Temporarily grant greater flexibility for static-to-mobile conversions for 510(k)-cleared medical imaging systems.
• Grant temporary flexibility for the use of alternate components and supplier qualification in order to meet increased demand.
• Work with the U.S. Department of Homeland Security and other agencies to meet the growing demand for medical imaging devices in severely affected areas and facilitate movement of personnel servicing these medical devices.

The alliance added that its recommendations would not adversely affect the safety and efficacy of imaging devices and would help in the timely delivery of imaging equipment during the COVID-19 pandemic.

COVID-19 Is Changing The Delivery of Healthcare

Telehealth is becoming the lifeblood of many practices as most Americans abide by social distancing. If you are not already using this option, you are frankly, behind the curve. In a recent Advisory Board webinar, a statistic was given that really resonated with me: one health system saw 1,400 total telehealth visits in all of 2019. That total was matched in only 3 days during the week of March 9, 2020. Medicare has relaxed their regulations to allow both new and established OP visits to be performed via telehealth. The requirement for HIPAA-compliant media has also been relaxed, meaning that Facetime and Skype are eligible mediums for synchronous communication. If you have telehealth options established at your health system, now is the time to communicate that to your patients.

Telehealth not only protects your patients but also protects you and your staff. Use it as a screening tool to see only the patients that really require immediate care. Follow-up with your patients using telehealth for those who are self-quarantined to determine if they need further care. This is not only a primary care concept. I have seen several virtual follow-up visits submitted for patients who are status post saphenous vein ablations, for example.

With some practices across the country reporting a 30% or more decrease in volume, leveraging telehealth where you can for consults and follow-up visits could be beneficial. Even self-quarantined doctors can practice telemedicine!

Lori Shore
3 Ways Imaging Leaders Can Prepare For Increased Volumes During The Coronavirus Pandemic

12:00 PM on March 20, 2020 by Ty Aderhold, edited by Marisa Deline. The Advisory Board Company is the owner and publisher of this article.

The American College of Radiology (ACR), and the Royal College of Radiology continue to discourage the use of CT as a front-line screening tool for COVID-19. But imaging teams should be preparing for increased volumes regardless. There remains a possibility that CT scans may be used for diagnoses if the shortages of viral tests and/or testing supplies continue, as occurred in China last month. More immediately, imaging departments are likely to see imaging orders for COVID-19 patients as part of staging and treatment planning. The ACR recommends that clinicians order images only when it will potentially change the management of the disease. While this guidance will hopefully limit the inappropriate use of imaging, we still anticipate growing numbers of imaging exams ordered for COVID-19 patients. With that in mind, here are three steps that these departments should take to prepare:

1. Understand and follow infection control protocols

   CDC currently recommends that all transport and radiology staff wear all recommended personal protective equipment (PPE) and practice hand hygiene when transporting patients for imaging and conducting scans. After imaging a patient with suspected or confirmed COVID-19, all surfaces within the imaging room, including equipment, must be cleaned and decontaminated by staff wearing proper protective equipment. Furthermore, facilities must consider the air-flow within the imaging room in order to prevent against airborne transmission. Based on CDC guidelines on ventilation, rooms may need to sit idle for a period of time depending on the HVAC system, filtration levels, and air exchange rates of the facility. ACR's latest position statement on the use of CT and COVID-19 notes this could be up to an hour. If possible, facilities should take advantage of mobile imaging equipment to avoid the additional infection measures that must be taken when COVID-19 patients are transported. For more detailed guidance on safety steps imaging departments can take, including how University of Washington Medicine and NYU Langone Health are protecting their staff and patients, we recommend this expert panel published in Radiology on March 16th.

2. Consider postponing elective imaging procedures

   CDC has recommended that health care facilities reschedule non-urgent patient visits and process high-priority visits as rapidly as possible to prepare for the coming influx of COVID-19 patients. As COVID-19 cases continue to ramp up, here are steps to consider:

   a. Evaluate current volume of pre-operative imaging scans. These scans are almost certain to fall off the calendar, given that hospitals and surgeons are currently rescheduling and postponing elective surgeries. Imaging leaders can develop a better sense of true future capacity in upcoming capacity by identifying these “likely rescheduled” exams. Furthermore, leaders can use this list of upcoming exams to proactively reach out to their top referring providers with a full list of upcoming exams for their patients and have one consolidated conversation.

   b. Evaluate preventative screening volumes, as these exams can be postponed with relatively low risk and patient impact. Given social distancing recommendations, many patients will appreciate a proactive approach to offering other appointment options for these screenings.

   c. Evaluate all other scheduled diagnostic or interventional procedures to determine urgency. For any that are non-urgent or elective, such as varicose vein treatment, providers should proactively reach out to referring providers to have a conversation about rescheduling.

   d. Frontload high-priority exams. Taking the steps above will free short-term capacity. Imaging leaders should work with referring providers and patients to attempt to move time-sensitive exams forward.

Read full article here.