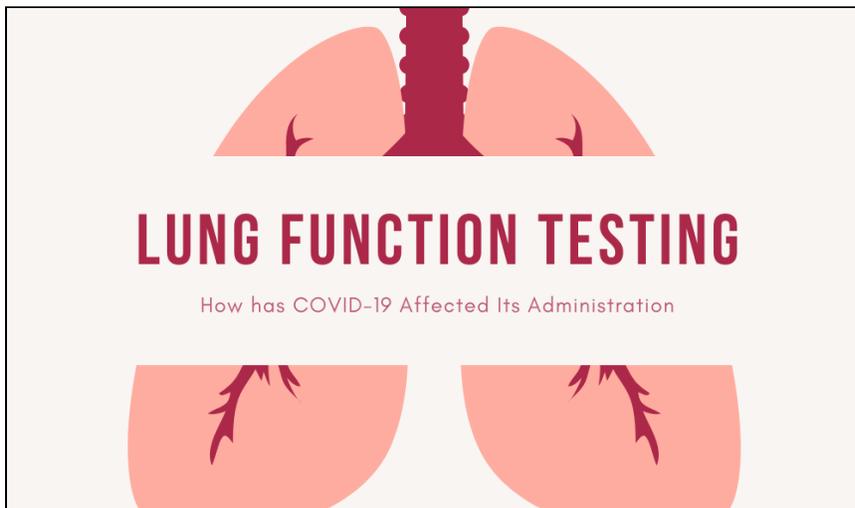




Delays During COVID-19 in Respiratory Diagnosis Highlight Need for Safer Pulmonary Lung Function Testing

Patients with chronic obstructive pulmonary disease (COPD) and other respiratory illnesses are more [at risk](#) of getting COVID-19. Lung function tests, such as spirometry and plethysmography, are often used to determine how well the lungs are working. These tests measure lung volume, capacity, rates of flow, and gas exchange. Information from these tests is helpful to clinicians to diagnose and determine the appropriate treatment for patients suffering from lung disorders.

However, to take a spirometry test, for example, the patient sits and breathes into a small machine. The spirometer records the amount of air the patient breathes in and out and the speed of the patient's breath. Because of the possibility of patients spreading COVID-19 when undergoing such tests, the Physician-Patient Alliance for Health & Safety (PPAHS) wanted to know how often lung function testing is being conducted during the COVID pandemic. Delays in or rescheduling of such tests could result in delays in diagnosis and treatment, which may have patient health and safety implications.



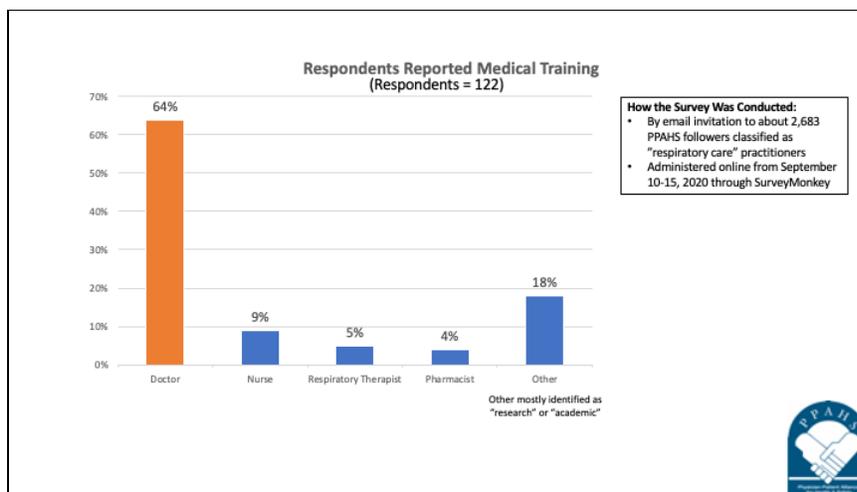
Moreover, if the patient suffers harm because of a delay in diagnosis, such a delay could result in a malpractice claim and a finding of negligence and damages awarded to the patient.

In their analysis of a claims database comprising more than 300,000 open and closed medical malpractice cases representing more than 400 hospitals and more than 165,000 physicians from both commercial and captive insurers, Crico, the Risk Management Foundation of the Harvard Medical Institutions, concluded that about 20% of the more than 23,000 malpractice claims filed from 2008-2012 alleged failure in diagnosis.

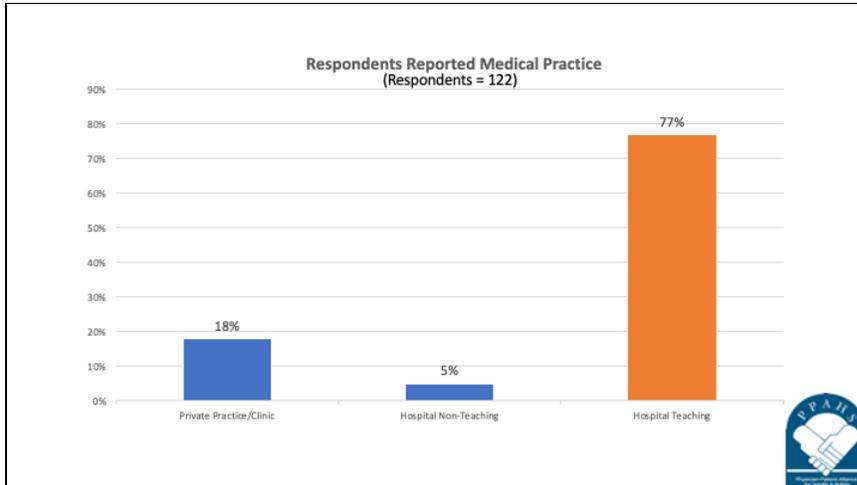
This failure or delay to diagnosis occurs most of the time in the ambulatory setting, which would include a patient's visit to a doctor's office. This occurred 57% of the time. Moreover, 31% of cases were because of a failure to or delay in ordering a diagnostic test - such as, not ordering, canceling, or rescheduling a lung function test.

Survey Respondents

The survey was conducted online through SurveyMonkey from September 10-15, 2020 among respiratory clinicians who follow PPAHS. There were 122 respondents to our survey. The medical training of the 122 respondents to the survey was primarily doctors (64%), followed by nurses (9%), respiratory therapists (5%), and pharmacists (4%) - 18% of the respondents indicated "other," who for the most part self-identified themselves as researchers or academics:



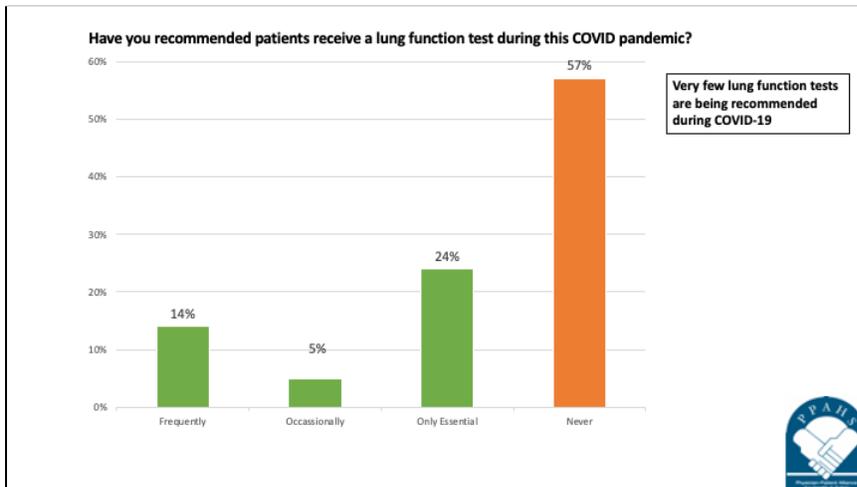
The overwhelming majority of the respondents were from teaching hospitals (77%), with 18% in private practice or in a clinic setting and 5% in a non-teaching hospital:



Question: Have you recommended patients receive a lung function test during this COVID pandemic?

The survey found that clinicians are not recommending lung function tests during the COVID-19 pandemic, with about one 1 out 4 respondents (24%) conducting only essential lung function testing (for example, for patients for a lung transplant, surveillance for side effects of chemotherapy, surgical candidates, etc.).

Most of the respondents said that they “never” recommended lung function tests (57%) and 5% occasionally recommended such testing:

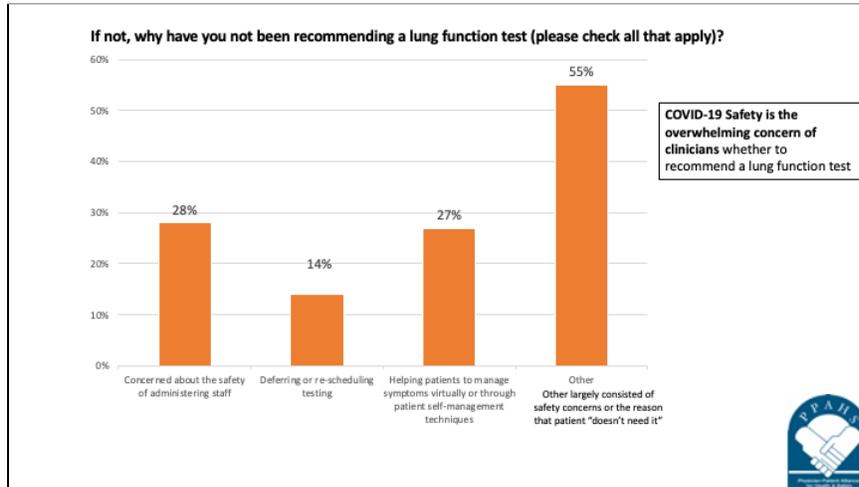


Question - Why have you not been recommending a lung function test?

Fear of COVID-19 was the overwhelming reason for not conducting lung function tests, with almost 1 out of 3 (28%) of respondents concerned about the safety of the administering staff.

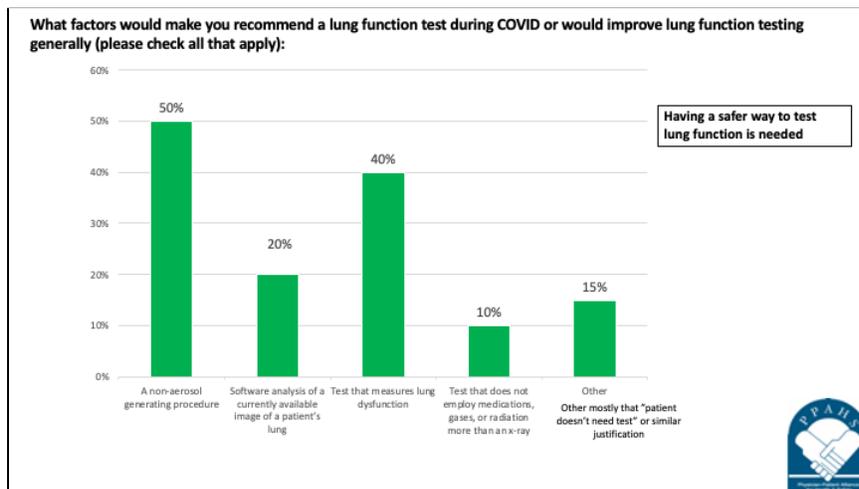
Most of those who checked “other” (55%) provided in their comments that the “other” reason was safety from COVID-19.

Consequently, 14% of the respondents said that they had deferred or rescheduled lung function testing and 27% of the respondents said that they were helping their patients through self-management techniques.



Question - What factors would make you recommend a lung function test during COVID or would improve lung function testing generally?

Having a safer way to test lung function is needed. Half of the survey respondents (50%) said that they would like a non-aerosol procedure. Having such a procedure would alleviate concerns about the safety of the administering staff (28%), a percentage which may have been substantially higher given that more than half of the respondents (55%) largely included comments about keeping safe from COVID-19.



Respondents to the survey also indicated that easier identification of lung disorders would be helpful. 2 out of 5 respondents (40%) would like a test that measures lung dysfunction. A determination of lung dysfunction is of course a conclusion about the state of the patient's lungs, which may be caused by any number of lung diseases, such as COPD, lung cancer, or asthma.

Additionally, 1 in 5 respondents (20%) would like software that would provide an analysis of lung function. The benefits of using software in making a determination of lung function are accuracy and certainty. Such use of software could be compared to using a map versus using GPS. While both are means of getting to a destination, using GPS facilitates that process.

Current modalities for both diagnosis and lung disease monitoring can be categorised broadly into two categories - pulmonary function tests (PFTs) to measure functional aspects of the lung, and imaging techniques for organ structure visualisation.

PFTs

PFTs are a group of tests that measure how well the lungs are functioning. They measure how much air is taken in and released by the lungs and how well the lungs move gases, such as oxygen, from the atmosphere into the body's circulation. Spirometry is a common functional test of the lung, measuring the volume and flow speed of air that can be inhaled and exhaled through sustained deep breaths into the spirometer device. Plotted graphs, called spirograms, of volume and flow are output and used to assess conditions of the lung. Although PFTs are not an imaging technique, and therefore have no radiation dose associated with their use, they are global measures of the lung, and do not pinpoint the presence or location of functional deficits, nor can they measure for compensation of different areas of lung returning regular results – a significant drop in overall lung function must be present to be detected via PFTs.

Imaging Techniques

Imaging techniques fall into three categories:

- Computed Tomography
- PET Scan
- X-Ray
- X-Ray Velocimetry

Computed Tomography (CT)

X-ray Computed Tomography (CT) or Computed Axial Tomography (CAT scan) uses tomography of X-rays to construct a 3-dimensional image of internal body structures. Tomography involves taking a succession of 2-dimensional images of the same object, around a single axis of rotation. Once complete, the large volume of data is manipulated in various planes to create a volumetric representation of much higher sensitivity than standalone X-ray. The high doses of radiation received by the patient during CT use limits the frequency with which it can

be used. Additionally, the quality of the scan is highly dependent on restriction of patient movement, hence regularly requiring patient sedation, especially for young patients. Magnetic Resonance Imaging (MRI) uses the property of nuclear magnetic resonance (NMR) to image the nuclei of atoms inside the body to produce detailed images of internal structures. An MRI machine uses a powerful magnetic field to align the magnetisation of select atoms in the body. Radio frequency fields are then used to systematically alter the alignment. The nuclei rotate accordingly, producing a detectable rotating magnetic field that is then detected by the scanner and used to construct images of the body. Unlike X-rays and CT, MRI provides contrast between different soft tissues, making it suitable for imaging of the brain, muscles, heart, and cancers. However, MRI has limitations in regard to the image resolution for application in lung imaging.

PET Scan

A PET scan detects pairs of gamma rays emitted indirectly by a positron-emitting radionuclide, a glucose-analogue tracer, which is introduced into the body. Dependent on the regions of glucose uptake within the body, three-dimensional images of tracer concentration are reconstructed with computer analysis. This imaging modality is relatively new for use with the lungs but is potentially suitable for certain types of lung function investigations where inflammation causes greater glucose uptake.

X-Ray

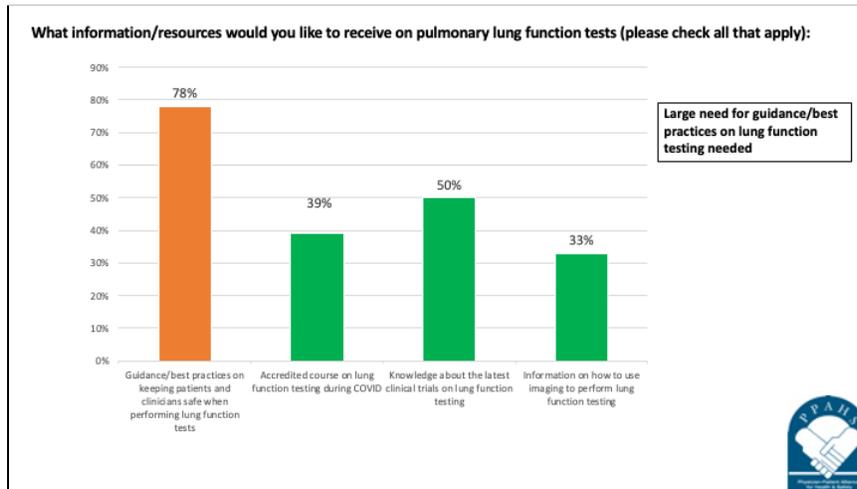
Projection radiography, commonly known as X-ray, is a widely utilised medical imaging method used to examine pathological changes in the lungs. A beam of X-rays is projected towards the body and according to the different composition and densities of the bodily materials along its path, the X-rays are absorbed at different rates. The transmitted X-rays are then captured on a detector plate behind the patient resulting in a 2-dimensional representation of the structures that form a superimposed image. A standalone chest X-ray lacks the sensitivity required to provide intricate detail of soft tissue structures and are therefore poor at detecting the early stages of lung disease.

X-Ray Velocimetry

One approach using cinefluoroscopy has shown promise according to Dr. Naresh Punjabi, in his recent presentation at the Crittenden Medical Conference. As discussed by Dr, Punjabi, 4D XV lung imaging technology looks at the way the lung functions by targeting the lungs' patterns of motion. It uses existing hospital imaging systems, X-ray images are taken simultaneously, from different acquisition angles. This innovative imaging technology precisely captures a breathing lung, without the use of contrast agents or and minimises levels of radiation. Novel functional measurements allow clinicians to measure and image the airflow in and out of each section of the lung.

Question - What information/resources would you like to receive on pulmonary lung function tests?

To help perform lung function testing, more than 3 out of 4 respondents would like guidance and best practices on keeping patients and clinicians safe when performing lung function tests:



Conclusion

Delays in diagnosis may result in worsening of the patient's condition and a resultant claim alleging malpractice. The COVID-19 pandemic has laid bare the dangers to both patients and their clinicians in testing and treating respiratory illnesses. This danger may occur when patients receive pulmonary lung function tests, such as spirometry which requires patients to exhale air out of their lungs. This recent survey conducted amongst our respiratory care clinicians found that very few lung function tests were being recommended during COVID-19, mostly because of safety concerns. Moreover, this survey also found that clinicians would like safer ways to measure their patients' lung function. Safer lung function testing would ensure that patients' lung conditions are diagnosed in a timely manner, as well as make sure that the safety of clinicians is maintained.

The results of the PPAHS survey on lung function testing shows that there is a need for improved technologies and procedures to measure lung dynamics and function that are outside of traditional pulmonary function testing (such as spirometry). Dr. Punjabi's use of 4D XV lung imaging technology or other such innovative approaches need to be explored and researched to determine its use in measuring lung function dynamics for clinical management and evaluation of treatment efficacy.