American College of Occupational and Environmental Medicine

ACOEM GUIDANCE STATEMENT

Occupational Spirometry and Fit Testing in the COVID-19 Era:

2021 Interim Recommendations from the American College of Occupational and Environmental Medicine

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BACKGROUND

Spirometry is an essential component of occupational health clinical practice, surveillance, and research. When indicated, spirometry should be performed if it can be done safely for the patient and the health care staff. The American College of Occupational and Environmental Medicine (ACOEM) has been an important voice in supporting safe spirometry testing during the coronavirus disease (COVID-19) pandemic.

On March 16, 2020, ACOEM recommended that routine spirometry be postponed due to COVID-19.[1] The U.S. Occupational Safety and Health Administration (OSHA) issued an Enforcement Memo on April 16, 2020, instructing its inspectors to avoid citing or fining employers who made good-faith efforts to obtain spirometry tests.[2] Reduced respirator fit-testing was also allowed by OSHA if National Institute for Occupational Safety and Health (NIOSH)-approved respirators and qualitative testing reagents were scarce.[2] ACOEM updated its recommendations on July 10, 2020.[3] At that time, the U.S. was in the midst of a surge. ACOEM recommended deferring spirometry except in unusual circumstances in which it was urgently necessary.

Since then, effective vaccines have become widely available, though rates of vaccination uptake vary, and there has been increasing return-to-work activity. Temporary OSHA relaxation of enforcement activity and U.S. Food and Drug Administration (FDA) relaxation of respirator certification criteria have been rescinded.[4,5] Though the pandemic persists and the impact of viral mutation-driven variants remains uncertain, ACOEM is updating its guidance for performing more widespread spirometry. The guidance remains interim due to the rapidly evolving understanding of how SARS-CoV-2 can be best controlled. In addition, experience during the COVID-19 pandemic may lead to long-term modification of some clinic practices for other seasonal and epidemic respiratory illnesses such as influenza. Furthermore, SARS-CoV-2 infection may become endemic at low levels rather than disappearing completely.

This statement is divided into two sections. First, tiers of COVID risk are discussed to help practitioners determine their tier of hazard and select appropriate protective measures. Second, recommended actions to make spirometry testing safer for patients and staff are presented.

RISK ASSESSMENT – TIERS OF COVID-19 RISK

The determination of whether and how to perform spirometry and fit testing must be based upon assessing the risk and the need for the test. The hazard level associated with testing varies considerably over time, by community, and according to the characteristics of the clinic and the worker population. The risk associated with the hazard may be characterized into 4 broad tiers as summarized in Table 1. The U.S. Centers for Disease Control and Prevention (CDC) has recently issued Guidance for Implementing COVID-19 Prevention Strategies in the Context of Varying Community Transmission Levels and Vaccination Coverage.[6] Table 1 extends the CDC classification scheme for occupational health programs, for which the risk may be higher or lower than the overall county rates upon which the CDC classifies areas.

Classification into tiers is dynamic, and clinic directors should regularly adjust the tier level and associated protective programs. This should be based upon best available information and should consider local as well as national trends. Employers should respect the expertise of a competent medical director for guiding programs.

Factors that determine a tier of risk include:

- *National and regional infection rates:* Current and short-term projected trends are generally available from sources such as CDC,[6] tracking websites,[7] and state health departments. CDC currently uses a 4-level summary measure, generally applicable at the countywide level.[8]

- *Community incidence:* Smaller geographic units may differ significantly from overall county or state trends.
- *Workforce prevalence:* The risk associated with specific workgroups is affected by workplace characteristics, workplace control measures, workplace surveillance processes, HR policies pertaining to isolation and quarantine, worker vaccine penetration, and community incidence. The quality of each employer's programs should also be considered since rates may differ from those in the general community.
- *Resources:* Community and workplace resources for managing patients with disease and efficiently instituting isolation and/or quarantine to protect other workers.
- *Clinic characteristics:* The availability of effective programs to protect both patients and clinic staff currently varies widely among clinics. A clinic serving many different employer clients may constitute greater risk than an in-house clinic serving a well-defined worker population with relatively low risk. For on-site services at non-health care workplaces, the characteristics of onsite clinical spaces must be considered.
- *Providers:* Availability of alternative service providers.

Tiers of Risk

Tier #1 – Low Risk: Per current CDC level classifications, the county is considered to be "low risk," and there is no indication that the local community and/or employer has greater than community risk. The clinic has a well-established program for limiting exposures.

Tier #2 – Probable Increased Risk Level: The county is designated as a moderate spread risk, the national trends are significantly increasing, the local community rates are elevated above the surrounding community rates, or the specific workplace has greater than county background rates or anticipated risk. A clinic without a well-defined control plan also falls in this tier.

Tier #3 – Significantly Elevated Risk: The county has "substantial" risk or projected incidence,[6] the employer/workplace includes higher risk activities (e.g., provision of inpatient health care services, prison, college/university with many residential facilities). Workplaces with many travelers to domestic or international areas with high prevalence also fall in this category. Clinics which otherwise would be considered within Tier #4, but which have excellent control measures in place may also fall into this category to permit meeting clinical needs of workers.

Tier #4 – High Risk: Very high national rates, county rates in the high range (CDC classification), or clinic servicing employer groups with significant outbreaks fall in this category. This also applies during early stages of developing epidemics, when the epidemic trend and/or the disease infectivity or virulence are unknown.

Table 1. Framework for Hazard Tiers

Tier	Rates (County,* Local)	Patient Group; Employer/Workplace	Clinic Hazard Level
0 – Background; no elevated risk	No unusual elevation	—	Standard precautions
1 – Low risk	Low	Low risk	Well-established comprehensive program
2 – Probable increased	Moderate	Higher rates than surrounding county	Program in place
3 – Significantly elevated risk	Substantial	Elevated risk activity or rates significantly above county rates	Limited program
4 – High risk	High or unknown but of very significant concern	High risk activity, extensive travel, or high consequence of infection	Minimal programmatic protection
This table provides a framework for classifying hazard level tiers (see accompanying text for details). It considers both the county rates and the characteristics of the worker population served. The clinic hazard level is based upon the clinic's protective measures in relation to the hazard level.			
*Adapted from CDC Community transmission criteria. (U.S. Centers for Disease Control and Prevention. COVID-19 Integrated County View. Available at: https://covid.cdc.gov/covid-data-tracker/#county-view. Accessed August 11, 2021.			

PROTECTIVE MEASURES

General guidance for selecting appropriate control measures: A framework for selecting appropriate control measures is summarized in Table 2 (see page 4). More restrictive or complex control measures are generally recommended only for the higher tier hazard categories. Protective measures are those summarized in Table 2. These include measures focused on case detection amongst potential patients, clinic environmental controls, testing procedures, clinic personnel, and interactions with employer and worker representatives. Several of these measures may become standard practice going forward. These recommendations are based upon the consensus judgment of experts since adequate scientific validation of the efficacy of these methods is currently very limited.

PATIENT EVALUATION AND DEFERRAL

Assess the need for testing: Decide whether to postpone the spirometry test based on several considerations: 1) does risk to patient and staff outweigh the risk to the patient of deferring testing; 2) is testing required by a government or employer standard; and 3) if a baseline test is required to qualify a new employee, can this information be obtained from other sources. The balance of risk and benefit will vary over time and by circumstances. If diagnostic testing is clinically indicated, necessary tests can be referred to a pulmonary function testing (PFT) lab, where testing can be done in a more controlled setting.

Links to OSHA standards which require spirometry are contained in the Appendix. Many employers also require periodic spirometry because of the additional exposures present in their workplaces. All applicable standards should be considered.

Prescreen patients: Patients should be prescreened to detect those who are infected, symptomatic, and capable of transmitting disease. The risk tier and the feasibility should guide selection among the several available approaches.

Symptom screening: Patients should be pre-screened with a questionnaire on the day of testing. The questionnaire should elicit any history of exposure to COVID-19 within the past 2 weeks, exhibiting any COVID-19 symptoms, and/or recent travel to high-risk areas. If positive, a spirometry test should not be performed then, but rescheduled. Passing the pre-screening test does not indicate that a patient is not infected since asymptomatic or pre-symptomatic patients can infect others. In most instances, it is advisable to ascertain vaccination status, preferably by reviewing written documentation rather than verbal report alone.

Testing for virus: Testing for presence of the SARS CoV-2 virus is generally appropriate in the higher risk settings:

- *Rapid, point-of-care tests:* These tests are increasingly available and may be used during the clinic visit or within the preceding few days. Only FDA-approved tests should be performed, and they should follow CDC guidelines.[9] This testing may be done at the time of visit or a few days before.
- *Nucleic acid amplification (NAAT) tests:* These tests are more complex, time demanding, and expensive. However, they are typically more sensitive than rapid point-of-care tests. They may be appropriate or necessary in particularly high-risk situations and should be selected carefully.[10] Reverse transcription polymerase chain reaction (RT-PCR) is an example of tests in this category.
- Antibody tests should generally not be used for patient screening.

CLINICAL FACILITY

Ventilation and air cleaning: Ventilation and air cleaning are key elements to control transmission of viruses that primarily spread through the air as droplets or aerosols. Preventive approaches for ventilation include:

- Ventilation of the test room
- Formal monitoring and special assessment of the test area
- Freestanding ventilation devices
- Air filtering and disinfection (e.g., ultraviolet germicidal irradiation [UVGI])

Table 2. Protective Measures by Risk Tier

This table indicates categories of preventive measures and suggests in which tiers of hazard they are recommended: Those shown in red are strongly recommended, and those shown in yellow cross-hatched should be seriously considered. More detailed descriptions of the methods are in the text (part 2). Column “0” refers to the future when there is no outbreak, pandemic, or epidemic.

Ventilation of the testing room: When feasible, the testing room should be at negative pressure relative to surrounding corridors so that air flows from clean to potentially contaminated areas and exhausts from the room to outside or through effective filters. Effective ventilation depends upon total ventilation, filtration, direction of air movement, and reducing recirculated air. Changes to ventilation in one room may disrupt air-flow patterns in other locations within a facility. Such adjustments likely require consultation with engineering or ventilation professionals.

Critical components to consider for effective ventilation are:

- *Air changes per hour (ACH):* ACH is the number of times the air volume of a given space is replaced by the ventilation system. For health care facilities, the American Institute of Architects (AIA) recommends 12 air changes per hour.[11]
- *Filtration:* Filters should have a minimum efficiency reporting value (MERV) rating of 13 or above.[12] A high-efficiency particulate absorbing (HEPA) unit, a higher standard of filtration, is preferred if feasible.
- *Portable:* Standalone HEPA filtration units can be used to substantially increase effective air changes per hour in the testing area.
- *Airflow pattern:* Dead spaces, where air flow is impeded in the testing area, and short-circuiting from supply to exhaust reduce the effectiveness of particulate removal.
- *Make-up air percentage:* Proportion of clean air introduced from outside the system to dilute any contaminants.

The time required for the ventilation system to adequately remove airborne particles depends on these factors and can affect the downtime between patients.[11] For example, with HEPA filtration, it would take 60 minutes to adequately clear respirable particles at 6 ACH and 30 minutes at 12 ACH (in ideal circumstances). If the building system utilizes a lower level of filtration, additional time will be required at a given ACH. Use of a portable HEPA filtration unit can increase the effective ACH substantially. Clearance time could be reduced if air can be drawn into the testing area with local exhaust ventilation to the outside (dilution). The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) has general and detailed guidance available.[13] Additional detailed guidance on using HEPA filters and portable air cleaners is also available from other sources.[11,14]

Ultraviolet Germicidal Irradiation (UVGI)

The concentration of infectious aerosols can also be reduced with ultraviolet germicidal irradiation (UVGI). These devices may be installed in the upper portion of a room within a facility's ductwork.[14] Both stand-alone HEPA filtration units and UVGI systems are advantageous in that they do not require changes to the parameters of the system facility. However, they require regular maintenance and consumable supplies.

TEST ROOM LOCATION

Dedicated room: Whenever possible, the room should be dedicated to spirometry testing and not used for other purposes. If the volume of spirometry is low, testing can be moved to the end of the workday. If test volume is high, the ventilation system and scheduling of patients should be adjusted to allow cleaning and sufficient air changes between patients.

Alternative test spaces: Some facilities have converted bathrooms with commercial exhaust fans into negative pressure spirometry rooms. For spirometry performed on-site in non-health care worksite embedded clinics or performed intermittently, low traffic spaces with high physical volumes and adequate ventilation may sometimes be used.

Outdoor testing: When other methods are not currently feasible in a high-risk area, outdoor testing in well-ventilated areas may be a temporary solution. Caution is needed because extreme heat and cold may change airway function and affect test results. Testing may be performed outdoors if care is taken to assure accuracy. A portable spirometer should be sheltered from the wind and excessive background air motion, which may interfere with accurate setting of the zero-flow baseline. Use of a tent or shelter can be considered. When testing outdoors, the calibration checks should be performed under the same conditions as the testing, ambient temperature and relative humidity settings on the spirometer should be adjusted as necessary to reflect outside conditions.

TEST PROCEDURE

Social distancing: Social distancing must be performed at all times to maintain distance between the technician and patient. Physical positioning should be carefully planned to keep a technician out of the direct plume of exhaled air.

Limit access to testing room: Only the patient to be tested and the technician should be present in the room. Depending on the hazard level and documented adequacy of the ventilation, testing should be scheduled with adequate time between patients to allow sufficient air changes and cleaning to occur.[15]

Room cleaning and disinfection: Room should be cleaned between patients and disinfected at end of the testing day.[15]

Spirometer BVF filters: A spirometer that has an in-line bacterial and viral filter (BVF) should be used to partially protect the testing space from virus contamination. Since bacterial viral filters may allow passage of some submicron particles, it is not safe to assume that they completely capture all infectious particles. Several spirometer manufacturers always use BVF filters to protect their pneumotach sensors, and two other spirometer manufacturers have placed such filters at the exit end of the spirometer flow tube. Many filters are now available, and their resistance varies widely, filters recommended by the spirometer manufacturer should be purchased. The filters are single use and are discarded after use by each patient.

Spirometer accuracy: The in-line BVF filter must not interfere with the accuracy or precision of the spirometer. Therefore, only spirometers which are designed for use with filters and have passed validation testing with the filter in place should be employed. Two spirometer manufacturers have evaluated accuracy with BVFs attached to the effluent end of the breathing tube and the filters were found to have minimal or no effect on expiratory measurements. Many spirometer filters currently used in occupational settings may not be adequate to prevent cross-contamination with SARS-CoV-2. If a generic filter is placed on one of those spirometers' mouthpiece/sensors, it may affect the accuracy of the test results.

Test procedures: To ensure accurate results, patients should receive careful instructions involving the testing procedures. Since technicians will be masked, they must verbally describe placing the mouthpiece on top of the tongue and with the lips sealed tightly around it. Pointing out that it is like putting a drinking straw in your mouth may be very helpful when a physical demonstration is not possible. Patients should wear nose clips or pinch their nostrils, and forcefully exhale through the filter, so that any virus particles in droplets from their lungs will not be blasted into the testing space. Patients should wear a mask in between maneuvers. Manufacturer instructions for cleaning the sensors during COVID-19 must be followed.

Technician certification: Under several standards, the person performing the testing must have successfully completed a course approved by NIOSH and maintain a valid certificate of course completion. NIOSH has extended the course certificates twice during the COVID pandemic, most recently extending for 1 year the certificates expiring in 2021.[16] Many NIOSH-approved courses have been postponed pending further notice and some are starting to teach live classes again.[17] Limited virtual courses are also available.[17]

CLINICAL OPERATIONS

Consistency with other clinical practice recommendations: Policies for spirometry testing should be consistent with other clinical policies of the institution. These include matters such as regular testing and monitoring of health care workers, limited access to the facility, maintaining a log of all persons entering and exiting, etc.

Staff PPE: Staff performing the testing should use appropriate respiratory protection (fit-tested N95 or higher level of filter efficiency, or PAPR). They should use disposable gloves and wash hands thoroughly before and after each test. Staff should also use a face shield or eye protection.

Staff vaccination: All staff members, including those with direct patient contact and those present in the common work areas, should have documented vaccination unless there is a clear religious or medical reason not to do so.

Reassign higher risk staff: On an individual basis, some staff with significantly elevated risks may be reassigned to other less potentially exposed jobs where possible. Clinics may consider limiting the number of staff members who will perform testing.

Written protection plan: A written, regularly updated protection plan should be available. Staff should be adequately trained initially and periodically to assure compliance with necessary safety procedures. Designate one individual with overall responsibility for implementing and monitoring the program to protect patients and staff.

Compliance with OSHA ETS: OSHA has recently promulgated an emergency temporary standard (ETS) for protecting health care workers in many facilities.[18] Occupational spirometry testing facilities are strongly encouraged to comply fully with appropriate provisions of OSHA ETS (even if not obligatory for some ambulatory or embedded clinical facilities).

Responsible oversight: The clinic medical director or designee should have a clear currently appropriate policy about when testing should be conducted or deferred based upon the current situation. As appropriate, this should be communicated to staff, clients, employers, worker representatives, and patients. The medical director should plan in advance for response if a transmissible patient inadvertently was tested.

FIT TESTING

Fit testing of workers assigned to tightfitting respirator use is required initially and annually by OSHA since respirators are fully protective only if there is minimal leakage around the sealing surface. Though postponement of annual fit testing and even some initial fit testing was permissible while NIOSH-approved respirators and qualitative fit-testing solutions were scarce earlier in the pandemic,[2] this is no longer the case.[4] In addition to initial and annual fit testing, fit testing should also be performed when: a) the type of respirator changes; b) user experiences difficulty with use; and/or c) weight loss or illness has occurred that may affect fit.

The 2020 ACOEM statement is updated to state:

1. Many respirators are equipped with exhalation valves. These may reduce resistance to exhalation and improve thermal comfort. However, there is concern that such respirators may allow unfiltered air from the user to enter the workspace. A NIOSH study assessed filtering facepiece devices with exhalation valves. This study showed that modifications to these respirators can further reduce particle emissions.[19] For respirator selection, occupational health experts may also recommend using a newer elastomeric-type respirator without exhalation valves.
2. Technicians performing fit testing should wear gloves, a fit-tested N95 or higher level of filter efficiency, or PAPR respirator, and eye protection or face shield.
3. Fit-testing hoods, adapters required for quantitative fit testing equipment, and shared elastomeric respirators, if used, should be disinfected per manufacturer recommendations and dried thoroughly between uses. This may require purchase of additional equipment to avoid delay between tests.

SUMMARY

As U.S. workplaces gradually reopen, this guidance will provide clinicians and managers with interim information on how to safely resume respirator fit testing and spirometry testing in situations where this testing is necessary. This document guides occupational health clinical service providers to help minimize risk to patients and health care personnel. Occupational medical specialists should also regularly assess local COVID-19 incidence rates as well as governmental recommendations and mandates when making decisions regarding the safe resumption of spirometry.

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Appendix – OSHA Standards Requiring Spirometry

Substance/Subject	Federal or Consensus Standard	Link
Asbestos – General Industry	1910.1001(l)	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1001
Asbestos – Construction	1926.1101(m)	https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1101
Asbestos – Maritime	1915.1001(m)	https://www.osha.gov/laws-regs/regulations/standardnumber/1915/1915.1001
Benzene	1910.1028(i); 1926.1128; 1915.1028	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1028
Beryllium – General Industry	1910.1024(k)	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1024
Beryllium – Construction	1926.1124(k)	https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1124
Beryllium – Maritime	1915.1024(k)	https://www.osha.gov/laws-regs/regulations/standardnumber/1915/1915.1024
Cadmium	1910.1027(l); 1926.1127; 1915.1027; 1928.1027	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1027
Coke Oven	1910.1029(j)	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1029
Cotton Dust	1910.1043(h)	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1043
Formaldehyde	1910.1048(l); 1926.1148; 1915.1048	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048
Silica – General Industry, Maritime	1910.1053(j)	https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1053
Silica – Construction	1926.1153	https://www.osha.gov/laws-regs/regulations/standardnumber/1926/1926.1153
Standard on Comprehensive Occupational Medical Program for Fire Departments	NFPA-1582	https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1582

Acknowledgements: The authors wish to acknowledge occupational medicine practitioners' practical suggestions on how to perform spirometry during the COVID-19 pandemic and the advice of their professional colleagues in government, corporate, and university settings.

This document was reviewed by the ACOEM Council on Scientific Affairs and approved by ACOEM on August 30, 2021.

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