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This guidance was developed in collaboration with the National Clinical Programme for Respiratory and in consultation with key stakeholders

Purpose

The purpose of this document is to provide interim guidance related to the performance of pulmonary function tests during the COVID-19 pandemic, in order to support delivery of this essential service with a high level of protection of patients and staff against the risk of disease transmission in the healthcare setting. This guidance should be applied according to local circumstances and in consideration of individual risk assessment for each patient.

Scope

This guidance document is intended to support healthcare professionals involved in the provision of pulmonary function tests.

For the purposes of this guidance pulmonary function tests include spirometry, peak flow measurement, Diffusion capacity (DLCO), Lung volume testing - body plethysmography, dilutional gas washout, cardiopulmonary exercise test (CPET), maximal inspiratory pressure (MIP), maximal expiratory pressure (MEP), sniff nasal inspiratory pressure (SNIP) and bronchial provocation tests (including mannitol, methacholine, histamine, inhaled allergen challenges and exercise provocation).

Introduction

The virus, which causes COVID-19 infection, is called SARS-CoV-2 and belongs to the broad family of viruses known as coronaviruses. It was first identified in the Wuhan province in China in December 2019 and a global pandemic event was declared in March 2020.

Transmission

Like other respiratory viruses, the transmission of SARS-CoV-2 occurs mainly through respiratory droplets generated from the mouth and nose of an infected person during activities such as coughing, sneezing, talking or laughing. The droplets may carry virus directly to the mouth, nose and eyes of person standing nearby or may land on a nearby surface. A recent scientific brief from the World Health Organization (09 July 2020) entitled Transmission of SARS-CoV-2: implications for infection prevention precautions – outlines new scientific evidence available on the virus that causes

COVID-19. The conclusion of this report is that the virus is primarily spread through contact and respiratory droplets, but that under certain circumstances airborne transmission may occur (such as when aerosol generating procedures are conducted in health care settings or potentially, in indoor crowded poorly ventilated settings elsewhere).

In general, higher levels of virus are present around the time of first onset of symptoms. Some people who never notice any symptoms may be infectious to others (asymptomatic transmission).

Virus can remain on the surface for some time and be transferred to the mouth, nose and eyes of another person on their hands after they touch the contaminated surface. The virus does not penetrate through the skin.

Survival in the environment

The SARS-CoV-2 virus has an outer coating called a lipid envelope. The presence of the lipid envelope means that virus is likely to survive for shorter periods outside the human body compared to a non-enveloped virus like Norovirus (Winter-vomiting virus).

The virus is easily killed by common household cleaning products, including bleach and disinfectants.

Survival on environmental surfaces depends on the type of surface and the environmental conditions. One study using a SARS-CoV-2 strain showed that it can survive on plastic for up to 72 hours, for 48 hours on stainless steel and up to eight hours on copper when no cleaning is performed. However, the levels of virus declined very quickly over the time period.

Duration of Infectivity

People may be infectious for up to two days before they develop symptoms (presymptomatic transmission).

In Ireland, people with COVID-19 are considered infectious for up to 14 days after the date of onset of symptoms or for 14 days after the date, the initial test was taken if the date of onset is not clear. After 14 days, the person is no longer considered infectious if they have been free of fever for 5 days and clinically recovered. Wolfel and colleagues (https://www.nature.com/articles/s41586-020-2196-x) reported that live virus was not found in the nasopharynx after 8 days.

We know that some patients who have COVID-19 may have positive (SARS CoV2 Detected) tests for a much longer than 14 days some will still have positive tests for weeks/months but this does not mean that they can pass on the infection to others.

Aerosol Generating Procedures associated with an increased risk of infection (AGPs)

There are a number of infectious diseases of the respiratory tract that are normally transmitted by droplets (larger respiratory liquid particles). Droplet transmitted infections include Influenza virus and SARS-CoV-2 virus (associated with COVID-19). Droplet transmitted infection may be associated with transmission by aerosols (very fine respiratory liquid particles) in the context of certain medical procedures that generate aerosols from the respiratory tract. The evidence of increased risk is strongest for endotracheal intubation. Vigorous respiratory effort or coughing as may be required for many PFTs are not considered AGPs. However, sputum induction using nebulised hypertonic saline or inhaled mannitol is considered an AGP; therefore, PFTs that involve inhalation of substances to potentially evoke a bronchoconstrictive response and which may also potentiate sputum production should be considered as AGPs.

Standard precautions

The foundation for managing the risks of spread of infection in every situation is Standard Precautions. Details of Standard Precautions are provided in Interim Guidance on Infection Prevention and Control for the Health Service Executive at the link below.

https://www.hpsc.ie/a-

z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/

Standard Precautions must be implemented scrupulously with all patients in all settings all of the time. Standard Precautions include hand hygiene, cough etiquette, appropriate use of PPE (based on risk associated with the task), environmental cleaning and cleaning and decontamination of reusable instruments. In addition to Standard Precautions all healthcare workers are advised to wear a surgical mask for all patient care activities where a distance of 2m cannot be maintained. Other than a

mask, personal protective equipment should be used in accordance with standard precautions based on a risk assessment. If there is a risk of contact with blood or body fluids (other than sweat) gloves and apron may be required. If there is a risk of splashing eye protection is required. Gowns are generally not required.

Transmission based precautions

Transmission based precautions (TBPs) are IPC measures which are implemented in addition to standard precautions when standard precautions alone are insufficient to prevent the transmission of specific infectious diseases for example, in patients with suspected/confirmed COVID-19 contact and droplet precautions are indicated. Details of Standard Precautions are provided in Interim Guidance on Infection Prevention and Control for the Health Service Executive.

Measures to minimise the risk of transmission of COVID-19 in the setting of pulmonary function tests

The single most important element of managing the risk of transmission of COVID-19 in all healthcare settings is the differentiation as early as possible in the healthcare delivery process between those people likely to be infectious and those who are not. Those likely to be infectious are those with clinical features suggestive of COVID-19 who require further evaluation, those with a diagnosis of COVID-19 who are still in the infectious period and those who are Contacts of COVID-19 still in the period of self-isolation. These people can generally be identified by appropriate clinical assessment. Staff members who are likely to be infectious should absent themselves from work. Pulmonary function tests can generally be deferred for patients until the infectious period has passed or in an exceptional circumstance where testing is deemed necessary the procedure should be performed with specific infection prevention and control precautions (Contact and Droplet Precautions).

If a rigorous process for pre-test assessment is in place, the residual risk relates to patients with clinically unrecognisable infectious COVID-19 infection. The risk in this group of patients is generally managed by scrupulous attention to Standard Precautions, maintaining as much distance as possible and the wearing of a surgical mask in accordance with NPHET guidance.

It is acknowledged that there is a body of opinion reflected by a number of professional societies both nationally and internationally that additional measures are required to manage the risk of infection however the experience to date in relation to COVID-19 is that good infection control practice based on identifying potentially infectious people and the application of Contact and Droplet precautions is effective in protecting patients and healthcare workers.

Risk of infection associated with Pulmonary function tests

Contact Transmission

The surface of equipment used in performing PFTs may become contaminated with respiratory secretions that may contain infectious organisms such as SARS-CoV-2. The patient or respiratory physiologist may then touch contaminated surfaces and transmit the infectious organisms to their eyes, nose or mouth.

Droplet Transmission

The patient and the respiratory physiologist may be in close proximity as it is not possible to maintain social distance for all steps of the process. Respiratory droplets are generated when talking, sneezing or coughing or during expiration for PFTs. There is therefore potential for droplet transmission to the other person if either the patient or the operator has an infectious respiratory disease transmitted by droplets including COVID-19.

Airborne Transmission

As the patient and the respiratory physiologist performing the test share the same air space for a period of time there is potential for airborne transmission if either the patient or the physiologist ha an infection transmitted by the airborne route such as tuberculosis, measles or chickenpox. COVID-19 is not generally considered an airborne infectious disease although there is concern regarding potential for airborne transmission in the context of Aerosol Generating Procedures associated with an increased risk of infection.

A review of each step of the patient pathway appropriate to the setting where PFTs are performed should take place as part of return to service planning.

Ensure regular reminders about hand hygiene and respiratory etiquette for patients and staff are visible along the patient pathway (e.g. posters/stickers).

Staff

Staff should not be at work if they have symptoms of COVID-19 infection. If symptoms develop during a shift, staff should immediately report to their line manager/person in charge. A local pathway should be established for management (including testing) of staff who develop symptoms while either on or off duty.

Early Identification of patients at high risk of COVID-19

It is the responsibility of every healthcare worker in every situation to continually assess and manage the risks to the patient, to themselves and to their colleagues related to the care they deliver.

Patients should have a pre-procedural assessment to establish

- Do they have symptoms or signs that are consistent with COVID-19
- Are they a close contact of someone with COVID-19
- Suffering from acute communicable infectious disease

If the patient has any such clinical features, they should be assessed for COVID-19 before PFTs are performed.

Based on the above, patients for PFTs can be categorised into two groups;

High Risk

 Known SARS-CoV-2 patients or patients who have new onset symptoms which may be consistent with SARS coV-2 infection or COVID-19 contacts

Standard Risk

 Patients with no clinical features suggestive of COVID-19 and who are not COVID-19 Contacts

High Risk

PFTs can rarely be justified until 14 days after onset of COVID-19 (with last 5 days fever free) **or** in the case of COVID-19 Contacts until the 14 day self-isolation period is expired **or** in the case of suspect cases until assessment is complete and their status

is determined. In very exceptional circumstances if PFTs are considered essential for clinical management in such patients, a risk assessment should be performed and all appropriate precautions should be applied.

Standard risk

There is generally no requirement for patients at standard risk to undergo testing for SARS-CoV-2 prior to having PFTs. Routine testing in low risk populations can cause delays and may generate non-clinically significant results. However, if the patient is having a PFT that is considered an AGP as above (bronchial challenge test) or cardiopulmonary exercise testing, or there are other specific identified concerns testing for SARS-CoV-2 within the 3 days prior to the test may be appropriate if the hospital is applying this approach to other AGPs or similar procedures based on their institutional risk assessment or current national guidance. Testing for SARS-CoV-2 is not required for assessing for a bronchodilator response.

Implement Physical Distancing

Pre-procedure

Consider how to implement social distancing in waiting areas e.g. Lay out of the appointments should be carefully staggered to avoid multiple patients arriving at the same time. Patients should be encouraged to wait remotely (for example in their car/vehicle) to be admitted directly to the patient assessment area to minimise patient numbers in the designated waiting area. The designated waiting area should be adapted (either by removing or marking seating) to ensure physical distancing of is maintained where possible in keeping with guidance relevant to the context. Develop contingencies in the event of unexpected congestion – identify sub-wait areas that can be used for overflow. Steps should be taken to minimise any staff or other footfall through the waiting area that is not essential to the operation of the service

Patients identified as High Risk should be brought directly to the procedure room and avoid waiting in public areas

During the procedure

As a general principle increasing the distance between the respiratory physiologist and the patient during the examination reduces the exposure to droplets from either party.

Persons accompanying the patient should not enter the testing room unless they are essential for performing the test, such as in interpreter, parent, guardian or carer. If they are accompanying the person, they should be assessed for symptoms of COVID-19. They should wear a face covering or mask and maintain a safe distance from the procedure unless they need to be close to the person for a specific reason.

If a pause is required between elements of testing (for example when assessing response to bronchodilator) patients should remain in the room until testing is complete.

Face Coverings

All patients at standard risk and any accompanying persons are required to wear their own cloth face covering or a surgical mask in waiting areas or other areas where they are in contact with other members of the public unless their condition is such that they cannot tolerate a mask. If the patient does not have a cloth face covering or mask or if there is any concern regarding the adequacy of the cloth face covering a surgical mask should be provided. The mask should be worn other than when at removed to perform the PFTs.

Personal Protective Equipment

The requirement for PPE is based on an individual assessment of risk for each procedure (examining factors relating to patient, procedure and staff). The exact level of PPE can be guided by the risk categorisation.

High Risk

- Hand hygiene
- Disposable single use gloves
- Long sleeved disposable gown
- Fluid Resistant Surgical facemask is sufficient however FFP2 mask may be considered

Eye protection

Standard Risk

- Hand hygiene
- Fluid Resistant Surgical facemask
- Other items of PPE as per Standard Precautions (see above)

Based on an individual risk assessment the respiratory physiologist may consider use of a respirator mask (FFP2) in preference to a surgical face mask for some procedures although this is not strictly required other than when performing AGPs on patients with suspected or confirmed infectious disease.

Gloves are not appropriate if the operator has contact only with the patients intact skin and equipment however if the operator expects to have hand contact with blood or body fluids (including respiratory secretions) gloves are appropriate in addition to hand hygiene as per Standard Precautions. Contact only with skin and equipment is expected to be the case when performing many PFT manoeuvres.

Additional PPE (eye protection and apron) should be utilised where there is a risk of splashing to face or body, as per Standard Precautions. This may arise when performing certain forced manoeuvres.

Surgical scrubs are not personal protective equipment but the respiratory physiologist should consider wearing surgical scrubs if working in areas of high activity with direct contact with patients for these procedures

Proper hand hygiene and safe donning, doffing and disposal of PPE should be standard practice.

Environment

Ensure area is free of clutter and non-essential equipment to facilitate adequate cleaning.

Alcohol Based Hand Rub (ABHR) and tissues should be made available for patient use in particular in the procedure room where there is a risk of coughing/sneezing. Patients should be encouraged to use ABHR after discarding tissues.

PFTs should be performed in a quiet and comfortable room. The room should be separate from the waiting room and from other patients being tested. The room should

have adequate space and ventilation. In the absence of any generally accepted specifications, the testing room in relation to space and ventilation should not be inferior to the minimum requirements for a single patient room in relation to size (22.5 to 26²) and ventilation.

Mechanical ventilation is not required but for rooms with mechanical ventilation, this should be deployed. In rooms without mechanical ventilation keeping windows open where possible will improve air circulation although it is recognised that this may impact the ambient air temperature and other parameters within the laboratory, which may need to be factored into result interpretation.

A pause is not required between procedures other than if an AGP is performed on a patient with suspected or confirmed infectious disease (such as COVID-19). However, adequate time should be left for cleaning surfaces/equipment as outlined below.

A negative pressure isolation room is not required for performing PFTs unless the negative pressure room is required because of their specific diagnosis.

Cleaning

All staff should be aware of their role and responsibility in relation to cleaning. An adequate supply of suitable cleaning products in line with local policy should be available in the procedure room.

After the procedure cleaning of surfaces which have been in direct contact with the patient should be performed using cleaning product in line with local policy (detergent wipes/sprays). Where coughing or throat clearing has been provoked with potential for droplet contamination of the environment then the surfaces in the immediate space surrounding the patients should be wiped clean using detergent wipe/spray. Cleaning of the floor between patients is not required.

Equipment

Disposable mouth pieces and in-line microbial filters should be used.

Cleaning, decontamination and maintenance of equipment - used for PFTs should conform to the manufacturer's specifications. Reusable equipment that has no contact with blood/body fluids, mucus membranes or non -intact skin may be cleaned with a detergent and allowed to dry.

Reusable equipment that is in direct contact with blood/body fluids, mucus membranes or non -intact skin of a patient must be contaminated, that is cleaned then disinfected using a 1 step or 2 step cleaning method.

Useful References

Covid-19 critical evidence review, NSW - Spirometry as an AGP

https://www.aci.health.nsw.gov.au/__data/assets/pdf_file/0009/579492/20200406-Evidence-Check-Spirometry.pdf

Aerosol Generating Procedures and Risk of Transmission of Acute Respiratory Infections to Healthcare Workers: A Systematic Review Tran *et al*

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338532/#!po=72.2222

CDC FAQ COVID-19 AGP list

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-fag.html

PHE list of AGPs

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe

HPSC list of AGPs

https://www.hpsc.ie/a-

z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolgu idance/aerosolgeneratingprocedures/

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