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Risk minimisation in spirometry re-start

Introduction

Restoration of spirometry is a key step in managing respiratory disease, ensuring the correct diagnosis and therapeutic / referral interventions. Regrettably due to COVID provision of spirometry in primary / community settings has greatly reduced or ceased. This needs to be addressed with a matter of urgency to limit patient harm, whilst taking opportunities learnt from COVID to deliver better care.

Attached are two documents, one from the Association for Respiratory Technology and Physiology (ARTP) and one from the Primary Care Respiratory Society (PCRS) to aid restoration of spirometry services by mitigating risk to both staff and patients. These were developed from a Task and Finish group established by the NHS England and NHS Improvement Clinical Policy Unit and have been reviewed by:

- Association of Respiratory Nurse Specialists
- Association for Respiratory Technology and Physiology
- British Lung Foundation / Asthma UK Partnership
- British Thoracic Society
- Royal College of Nursing
- Primary Care Respiratory Society

Feedback from colleagues has highlighted the importance of checking with manufacturers the impact of filters when using hand held devices and the opportunity to use the highest value from either relaxed or forced vital capacity to calculate the FEV₁:FVC ratio, something advocated by ARTP.

The major issue raised has been the infection and prevention control (IPC) measures and while clearly important it is not the position of the Task and Finish group to make such recommendations. Due consideration needs to be given to: room air changes, the choice of personal protective equipment (PPE), cleaning of room and equipment, the opportunities to reduce risk by considering vaccination status of staff and patients and the use of lateral flow tests. Local IPC advice on these measures must be obtained. Those responsible for providing spirometry are required to have risk assessed the process and ensured that all aspects are safe for both staff undertaking and patients attending the testing, including supply of appropriate PPE. If there is any doubt further advice should be sought from IPC leads.

The COVID pandemic has given us the opportunity to consider how we deliver services in primary care and spirometry is an excellent example. Previously delivered mainly in GP surgeries, there is the potential to consider restoration at Primary Care Network (PCN) level, possibly acting as a spoke for the new Community Diagnostic Hubs (CDHs) that will be starting in the near future. Such economies of scale will help with workforce issues and

training to ensure spirometry is quality assured and offers the chance to incorporate the use of other appropriate measurements such as exhaled carbon monoxide for assessing smoking and nitric oxide (FeNO) to aid asthma diagnosis, the latter being part of an Accelerated Access Collaborative.

We must recognise that restoring services will help with the current patients who need spirometry for confirmation of diagnosis as part of the Quality Outcomes Framework (QOF) that has restarted in April 2021. However, given that spirometry services have been disrupted for over one year, we must also consider how we address the backlog of patients requiring spirometry. This will require focused work at PCN, Clinical Commissioning Group and Integrated Care System level and may be an emergent role for the forthcoming CDHs.

Martin Allen – Spirometry Task and Finish Group Chair

Task and Finish Group Membership

| Name | Organisation / role representing |
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Spirometry in Primary Care
Guidance on reinstating spirometry in England

The current situation

The provision for diagnostic spirometry in primary care was severely disrupted by the COVID-19 pandemic. Whilst there may have been brief intervals when spirometry has been performed, in a limited way, on the whole there has been little activity in primary care since March 2020. There has been a resulting impact on patients with respiratory symptoms, many of whom have been given a provisional diagnosis and await diagnostic spirometry for confirmation of this. Worryingly, some provisional diagnoses will have resulted in patients being prescribed medications they may not need whilst they wait for spirometry testing and results. The exact number of patients caught in the backlog for diagnostic spirometry is unknown but is estimated to be around 200–250 patients per 500,000 population (based on estimates from a CCG database of patients newly prescribed inhaled bronchodilators in the absence of systematic evidence). The actual number of patients may be considerably higher, especially in areas with higher underlying levels of respiratory disease due to local social and industrial factors.

As we enter a potentially more stable period in the pandemic with many of the population and most health care providers receiving vaccination against COVID-19, we need to consider how we can safely restart diagnostic spirometry in primary care and manage the risks involved. The service needs to continue to develop from where it was as we entered the pandemic. Spirometry should only be provided by appropriately trained health care practitioners who are certified and who are competent and confident in their role. Spirometry should be reinstated as a part of the diagnostic pathway for breathlessness, which may be at a Primary Care Network (PCN)-based local diagnostic 'hublet' (or spoke as referred to in the London model) as a PCN delivered spirometry service, or at practice level with a view to moving towards a PCN model in the future. Whichever model is followed, the priority remains to reinstate diagnostic spirometry and there must be a clear assignment of responsibility for ensuring this happens. Spirometry as a stand-alone test is insufficient to make an informed respiratory diagnosis.

This document has not been written to give clarity on how to perform or interpret quality assured diagnostic spirometry – those trained to do so will have completed the required assessment and achieved the required level of competency to deliver the service.¹ Rather, this document provides guidance on reinstating spirometry in the primary care setting and the management of the ongoing risk that will remain as a legacy of the COVID-19 pandemic.

What good looks like

There are good examples of network-based respiratory symptom diagnostic service specifications available from the Primary Care Respiratory Society² and The London

¹ Lawlor R. Fit to care: key knowledge skills and training for clinicians providing respiratory care. Available at: <https://www.pcrs-uk.org/sites/pcrs-uk.org/files/resources/2019-FitToCare.pdf>

² <https://www.pcrs-uk.org/resource/pcrs-diagnostic-service-specification>

Network (2020)³ which present the case for a full diagnostic service, include full protocols for individual procedures of the service and data tracking for evaluation.

Recommencing spirometry in primary care needs extra consideration than would have previously been required. Intermediate guidance offered from the South West Respiratory Network gave advice around performing spirometry in a safe but limited way, responsive to the fluctuating infection levels in the community based on the Association for Respiratory Technology & Physiology (ARTP) advice pre-vaccination.⁴ This advice has considered the changing situation with increasing vaccination uptake.

Who should perform spirometry?

Spirometry should be performed by an appropriately trained health care professional who is certified and registered as competent with the ARTP.⁵ The register defines competence in performing spirometry, interpretation of results, or full (performance and interpretation). It does not include competence in making a diagnosis.⁶

When should spirometry be performed?

Spirometry is performed as part of the diagnostic pathway. Adult patients presenting with symptoms indicative of a respiratory diagnosis should have a full clinical assessment performed, including history and examination, by an appropriately qualified clinician. Spirometry may be performed as one of the tests to help confirm a diagnosis, if appropriate.

There is a recognised list of relative and absolute contraindications to performing spirometry that trained operators will be familiar with.⁷ In addition, spirometry should not be performed if the patient has any symptoms of COVID-19 infection at the time of the test, or if they are known to have recently been in contact (within previous 10 days) with a confirmed case.

Infection control measures

Spirometry is not considered to be an aerosol generating procedure (AGP).⁸ However, spirometry-associated cough has the potential to generate aerosol droplets necessitating a mitigation strategy which may include:

- All tests must be performed using a single use antibacterial antiviral filter.

³ Available via the NHSFutures website

⁴ <https://rms.kernowccg.nhs.uk/content/SW%20Respiratory%20Network%20ARTP%20Guidelines%20for%20Lung%20Function%20Testing%20V1.1.pdf>

⁵ <https://www.artp.org.uk/Resources/b92ec02d-d681-461d-bdfa-7ef6674cddb7>

⁶ (<https://www.artp.org.uk/Spirometry-Register>
⁷ [file:///C:/Users/trace/Downloads/ARTP_Standards_Committee_General_Testing_Considerations_PJM_05.11.2020%20\(1\).pdf](file:///C:/Users/trace/Downloads/ARTP_Standards_Committee_General_Testing_Considerations_PJM_05.11.2020%20(1).pdf)

⁸ https://www.artp.org.uk/write/MediaUploads/Standards/COVID19/ARTP_COVID-19_endemic_guidance_Vers_5.6_final.pdf

- The spirometer must be cleaned between patients per manufacturer’s COVID-specific instructions. As a minimum this should involve cleaning the outer casing of the transducer and the outer part of the spirometer itself with alcohol wipes.
- Unless the patient is considered high risk for any reason, operators will need Personal Protective Equipment (PPE) consisting of gloves, apron, visor and Type IIR (surgical) mask.
- A Perspex screen between patient and operator offers an additional physical barrier for protection.
- If available, use a room with mechanical air circulation or ventilate as able (e.g. open windows).⁹ Ideally this should be in the region of 6 room air changes per hour.

Other options that may be considered depending on the local situation include a drive through service or virtual spirometry.

Where to start with the backlog?

With such a backlog there needs to be a strategy to tackle the waiting list. How has the list been maintained – is it a manual list of patients or will the list be generated by computer search? If so, be clear on search criteria – suspected Chronic Obstructive Pulmonary Disease (COPD), unexplained breathlessness, intermediate probability of asthma, new initiation of inhaled medication, new documentation of respiratory symptoms, coded ‘awaiting spirometry’ etc.

Prioritise groups of patients for whom diagnostic spirometry will potentially impact their treatment pathway or determine their onward care. Consider spirometry for those patients with a provisional diagnosis but poor response to treatment (although one hopes further investigation would have already been considered).

Spirometry to confirm diagnosis is valuable but not an immediate priority. If a patient’s history and clinical picture fits with the provisional diagnosis and they respond well to treatment it is important to confirm diagnosis but not at the expense of patients in whom spirometry might alter the diagnosis or treatment.

Routine spirometry is of low priority. Annual spirometry is no longer a Quality Outcomes Framework (QOF) requirement and the evidence shows little clinical value but if you still regularly perform spirometry on stable patients (e.g. those with pulmonary fibrosis) these should be at the back of the queue.

⁹https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/945754/S0_973_Ventilation_Actions_Summary_16122020_V2.pdf

Practice or PCN delivery?

There are pros and cons to both practice and PCN delivery of care. Working through the pandemic has enabled us to work quickly as networks and has demonstrated to patients that care does not necessarily need to be delivered by their own practice to be good as they have seen with COVID hubs and delivery of vaccine programmes.

Individual areas need to decide what is best for their way of working to restart spirometry. Delivery at network level has the benefit of needing fewer trained staff to deliver the service whilst ensuring the competence of the staff as they will be undertaking spirometry on a very regular basis. It may happen as part of an established bigger diagnostic service or might be a step towards PCNs being able to develop from a spirometry service into a broader diagnostic 'hublet'.



**Statement for the NHS NATIONAL RESPIRATORY PROGRAMME
Task and Finish Group**

Recommendations for undertaking risk-managed spirometry

Context

The COVID-19 pandemic has significantly affected capacity to perform respiratory physiology measurements in both primary and secondary care; it continues to constrain capability to deliver this important diagnostic service.

Spirometry has an established role in the diagnosis and surveillance of most respiratory diseases. The exact number of patients caught in the backlog for diagnostic spirometry is unknown but is estimated to be around 200–250 patients per 500,000 population (based on estimates from a CCG database of patients newly prescribed inhaled bronchodilators in the absence of systematic evidence). The actual number of patients may be considerably higher, especially in areas with higher underlying levels of respiratory disease due to local social and industrial factors. In many clinical scenarios, the risk of not undertaking spirometry (e.g. missed diagnosis, lack of surveillance response to treatment) is often not considered in risk vs benefit assessment.

This statement supports the larger task and finish group NHS England & Improvement statement and specifically provides advice and guidance regarding the safety of performing spirometry, during the COVID 'endemic phase'; i.e. a situation where a low-level background prevalence of COVID-19 related illness persists in the community.

The statement addresses spirometry measurement performed in both primary and secondary care settings and complements the suite of COVID-19 information, developed by the ARTP, BTS and other international organisations, with respect to the safety of performing lung function (see [COVID19 \(artp.org.uk\)](https://www.artp.org.uk/covid19)).

The statement acknowledges that there are still unanswered questions regarding 'absolute cross-infection risk' from spirometry, but uses the best available published evidence to date, to assist clinical teams and should complement local standard infection and prevention control (IPC) advice.

Safe delivery of spirometry in clinical settings – important background considerations

There is a long history of spirometry being successfully and safely performed in both hospital and community settings. Robust guidelines and governance structures are established in most Trusts and primary care settings to ensure patient and staff safety when performing this test. High quality standard operating procedures (SOPs) are the cornerstone of mitigating risk and reducing cross infection between staff and patients undergoing spirometry. Indeed, whilst SARS-CoV-2 infection presents a new challenge with respect to IPC, other airborne or contact transmitted pathogens (e.g. influenza, tuberculosis, HIV) have long presented a similar challenge, both in hospital and community settings.

In this context, spirometry SOPs are in place to minimize and 'manage overall risk'. This includes a need for rigorous enforcement of IPC cleaning policies, and recommendations regarding the use of specialist viral and bacterial filters during expiratory measurements.

Irrespective of the COVID-19 endemic phase, these steps continue to be essential to reduce infection risk from not only a potential SARS-CoV-2 infection but also from other infective pathogens. Accordingly, staff undertaking spirometry are aware that, in this context, risk cannot be completely abolished; the strategies set out below should act to minimise risk

to both staff and patients.

Risk of airborne particle transmission from spirometry

Several studies have now evaluated the expiratory output and particle generation patterns whilst performing spirometric manoeuvres (Table 1). A key finding from these studies, in line with other evaluations (e.g. with the use of some forms of positive pressure ventilation), is that the risk of aerosol generation (AGP) appears to be most likely associated with coughing. Indeed, it appears that spirometry when performed on a closed circuit, with an appropriate filter in situ, generates few aerosolized particles further than a few centimetres from the device. In contrast, coughing off a filter does confer a risk of particle dissemination and thus, individuals who perform expiratory manoeuvres and then cough vigorously after a deep or forced airway manoeuvre, are likely to expose any individual in immediate proximity (i.e. the clinician performing the test) to a greater degree of risk.

This is relevant, because spirometry is associated with cough in a significant proportion of patients. Kimberley et al. (data presented at the 2021 Winter BTS meeting) reported that of 122 individuals with various chronic respiratory illnesses (e.g. bronchiectasis, asthma, ILD), 63 (51%) coughed following spirometry. In a subgroup of patients with no prior history of coughing (n=78), approximately a third coughed following the procedure. Data from a recent audit of patients at Royal Brompton Hospital indicate a similar prevalence of post-spirometry cough (n=80), but with half of those coughing 1-5 times (personal communication, S Thomas). Thus, there is an apparent risk of cough associated with spirometry, which is likely to be associated with particle dissemination in the immediate vicinity. This forms the basis of the recommendations below to reduce risk.

Recommendations and steps to facilitate risk-managed spirometry:

- Pre-screening considerations should always be undertaken to reduce risk i.e. to rule out patients arriving for testing with active COVID-19 related symptoms. Pre-screening precautions will vary, based on local IPC policies, but should align with national guidance and at the very minimum, include the use of a pre-attendance questionnaire. As lateral flow testing becomes more widely available, this should be considered as part of routine pre-screening
- Spirometry should only be performed in patients where there is a clinical question to be addressed i.e. where there is a clear clinical indication. Several evidence-based and established diagnostic pathways for respiratory disease (e.g. NICE guideline on diagnosis of asthma) have spirometry measurement as key part of a robust assessment process; this should not be altered based on IPC risk from spirometry.
- Procedures in which spirometry is repeatedly undertaken (e.g. as part of bronchoprovocation testing), or those that transmit high volumes of aerosols (e.g. exercise testing), are intuitively more likely to increase the risk of coughing. Likewise, spirometry conducted in facilities with poor air circulation are, again, likely to be associated with a heightened risk for staff and any subsequent patients using that facility.
- Spirometry should be performed with a single use bacterial/viral filter in the circuit that meets ATS/ERS standards. The cost of these has reduced significantly and can be purchased for < £0.50 per unit. Surface cleaning materials should be used and all areas that have come in to contact with the patient (flow head, spirometer orifice etc.) should be cleaned in line with manufacturer and local IPC recommendations.
- Coughing is likely to be the foremost risk for disseminating airborne particles with any lung function test measurement. Therefore, policies to manage IPC risk from coughing in this setting should align with local IPC procedures and policies i.e. how a clinical facility manages risk with a patient with a cough in a clinical setting.
- Staff and the centres performing spirometry should be aware of and utilize strategies to reduce cough and thus transmission of particles. These include but are not limited to
 - Prior to testing, ensuring that patients are pre-counselled about what actions to take if they start to cough (see below)
 - Staff being made aware of a patient who has a history of cough / cough related condition.
- Coughing associated with spirometry occurs predominantly following a forced and prolonged expiratory manoeuvre. To circumvent the need for this type of manoeuvre, in individuals where clinicians are concerned there is likely to be a heightened risk of infective cough, it is suggested to undertake a relaxed or slow vital capacity manoeuvre followed by a 1-2 second expiratory manoeuvre to obtain the forced expiratory volume in one second (FEV₁).

- To reduce immediate risk from coughing, it is highly recommended that patients are pre-counselled about what actions to take if they need to cough. Firstly, they should try to stay on the mouthpiece / testing device if possible and cough in to the bacterial/viral filter. If they feel they need to come off the device to cough, they should have a surgical facemask in immediate proximity that is placed over the mouth immediately following completion of the manoeuvre (e.g. simple surgical mask is lowered to the chin to allow a mouthpiece to be used and then replaced at end of procedure). This will allow capture of any airborne particles on coughing. Local services may wish to adapt the approach used in this context and in some cases use of a face shield that is lifted during the manoeuvre may be appropriate / easier for the patient. Other services may wish to use adapted screens or masks to undertake these procedures.
- Patients with profound immune vulnerability (e.g. post-transplant or immunosuppressed) should be considered at increased risk. Procedures to protect them should be discussed with local clinical leads (e.g. local transplant team) and may include testing them at the start of a day or using a 'cold' testing room if possible.
- Low effort procedures that are not likely to cause coughing with deep expectoration (e.g. rate control exhalation during FeNO) and should not be considered to be high risk.
- General IPC considerations for clinical areas (i.e. that might have patients who attend and whom cough) should be considered and include ensuring good air circulation e.g. testing in a room with an opening window; ensuring the door is closed during testing).
- The use of extraction fans placed in windows to exhaust room air to the outdoors may be considered. This will help draw fresh air into room via other open windows and doors without generating strong room air currents. Care must be taken to avoid causing contaminated air to flow directly from one person over another.
- Consider portable high-efficiency particulate air (HEPA) fan/filtration systems to help enhance air cleaning in areas frequently inhabited by persons with higher likelihood of COVID-19 and/or increased risk of getting COVID-19 (Cost <£500) Schoen .2020.
- The risk for an individual clinician undertaking spirometry should be assessed by the local service lead and all efforts made to assess and reduce exposure risk.
- Operators will need Personal Protective Equipment (PPE) consisting of gloves, apron, visor and Type IIR (surgical) mask but may be modified in line with local IPC policy.

- In most cases, staff undertaking spirometry will have been vaccinated. Individuals deemed to be at heightened risk of developing severe COVID-19 infection should receive an individual risk assessment in conjunction with the local Occupational Health team before undertaking frontline clinical measurements.

Studies evaluating spirometry during COVID-19 pandemic

| Authors | Title | Aims | Study population | Methodology | Results | Conclusions (authors) | Comments / considerations |
|-----------------------|---|---|--|---|---|--|---|
| Greening et al., 2020 | LETTER: Small droplet emission in exhaled breath during different breathing manoeuvres: Implications for clinical lung function testing during COVID-19 | To determine small droplet production of varying flow rates during different breathing manoeuvres | Healthy population (n=33), FEV1 101.8±11% predicted. Age 46. | Particles in exhaled air (PExA) No expiratory particle filter. Breathing manoeuvres: Vt, FEV, slow VC from FRC and RV, coughs at TLC. | No significant difference in particle mass when comparing Vt to slow VC from FRC and FEV. Significant difference seen in particle mass with slow VC from RV and during coughing. No difference in particle mass and peak expiratory flow. Coughing resulted in highest mass | Coughing is associated significant increase in particles due to involuntary and uncoordinated airway spasm, resulting in greater RTLf film rupture, as well as upper airways shearing. This is likely to confer significant risk during PFTs, and procedures such as sputum induction or physiotherapy, for example using hypertonic saline. For measures in confirmed airways disease, such as asthma and COPD, these data suggest | No particle filter used. Healthy subjects only. PExA system only evaluates smaller airway output. |

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| | | | | | of particles (640% >sVC to FRC) | that fewer droplets would be produced, potentially reducing risk, if a FEV manoeuvre was stopped once achieved and before exhalation to RV. Our data suggest that first few breaths immediately following the measurement should also exhaled into a filter before letting go of the mouthpiece, ensuring particles continue to be exhaled into filters. | |
| Helgeson et al., 2020 | LETTER: Aerosol Generation during Spirometry | To evaluate particle distribution and particle size during PFTs. | Healthy population (n=5) | Performed Vt, FVC, MVV manoeuvres and any coughs were discarded from | Proximity to the source was associated with significant | PFTs and normal breathing all generate aerosols rather than just droplets. The room air exchange, room | Small number of healthy subjects. Underpowered for multiple comparisons. |

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| | | | | <p>data collection. Air will be sampled at 0ft, 1.5ft and 3ft from the exhalation port.</p> <p>A light-scattering particle counter (FLUKE 983) was used to simultaneously measure six channels of particle size distribution (0.3, 0.5, 1, 2, 5, and 10 mm), temperature, and humidity while each manoeuvre was being performed at each measured</p> | <p>increases in particle generation. With normal speaking, there was not an increase of generated 0.3-mm particles at 12 inches. When sampled close to the exhalation port position, all the manoeuvres generated an increase in respirable 0.3-mm particles when compared with baseline (Figure 1). Other aerosol-sized particles measured at 0.5 mm were</p> | <p>turnaround time between testing, and distance between the patient and technician in the testing room are important. Particle generation close to the exhalation port warrants using a single-use plastic covering over the device, with the mouthpiece port and the exhalation port exposed, to avoid equipment contamination.</p> | |
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| | | | | <p>location.</p> <p>A Microgard II filter (Vyair Medical) was interposed between the mouthpiece and intake port for all manoeuvres, as per manufacturer.</p> | <p>also increased at this close position.</p> <p>At 1.5 ft and 3 ft distance from the exhalation port, there was no increase in particle generation for any of the trialled manoeuvres.</p> | | |
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