



Northern Ireland
Assembly

Research and Information Service Briefing Note

Paper No. 14/20

1st April 2020

NIAR 99-2020

Sinéad McMurray and Janice Thompson

COVID-19: The use of Personal Protective Equipment and Ventilators

This Briefing Paper has been prepared to support the NI Assembly Ad-Hoc COVID-19 Committee. It provides information on the role of Personal Protection Equipment (PPE) in infection control measures including an overview of current guidelines relating to their use. The paper will also look at the use of ventilators in supportive therapies to treat COVID-19 patients.

Lastly, the paper will explore how shortages of PPE and Ventilators are a major global issue of the ongoing pandemic and will examine actions taken by the UK government to increase supplies in the face of these shortages.

Coronavirus disease 2019 (COVID-19) is the infectious disease caused by the coronavirus - 'severe acute respiratory syndrome coronavirus 2' (SARS-CoV-2).

1. Personal Protection Equipment and COVID-19

1.1 Introduction – Personal Protective Equipment

Personal protective equipment (PPE) refers to protective clothing, helmets, gloves, face shields, goggles, facemasks and/or respirators designed to protect the wearer from injury or the spread of infection or illness.

PPE is commonly used in health care settings such as hospitals, doctor's offices and in social care settings. When used properly, PPE acts as a barrier between infectious materials such as viral and bacterial contaminants and healthcare workers skin, mouth, nose, or eyes. The barrier has the potential to block transmission of contaminants from blood, body fluids, or respiratory secretions. When used with other infection control practices such as hand-washing, use of alcohol-based hand sanitizers, and covering coughs and sneezes, it minimizes the spread of infection from one person to another.¹

The selection of PPE is based on an assessment of the risk of transmission of contaminants to the healthcare worker, and the risk of contamination of the healthcare workers clothing and skin by patients' blood, body fluids, secretions or excretions.²

1.2 Rational Use of PPE in the face of global shortages

The supply and appropriate use of PPE for frontline workers has been a contentious issue across the globe since the emergence of COVID-19. Government and public health agencies are struggling to meet demand and current estimates by the WHO indicate that industry would need to increase manufacturing capacity by 40 per cent to meet this demand.³ In recent days the EU has moved to protect its supply of PPE by limiting the amount its own manufacturers are able to export to other Non EU Countries.⁴ Quality issues with PPE coming from China, one of the world's main suppliers of PPE, have also been identified and have led to some countries such as Turkey, Spain and Italy rejecting batches of ordered supplies.⁵

¹U.S Drug and Food Administration (2020) personal-protective-equipment-infection-control October 20th 2020

<https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/personal-protective-equipment-infection-control>

² NHS Education for Scotland (2019) Promoting the Prevention & Control of Infection. UNIT4 Personal Protective Equipment (PPE). https://www.nes.scot.nhs.uk/media/4011312/ccp_unit_4.pdf

³Fadela, C (2020) Shortage of personal protective equipment endangering health workers worldwide World Health Organisation <https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>

⁴ European Commission (2020) Commission moves to ensure supply of personal protective equipment in the European Union March 15th 2020 <https://trade.ec.europa.eu/doclib/press/index.cfm?id=2122> ,

⁵Peel, M (2020) Countries reject China pandemic product batches Financial Times march 29th 2020 <https://www.ft.com/content/f3435779-a706-45c7-a7e2-43efbdd7777b>

The WHO has called on countries to ensure that PPE use is rationalised and appropriate and have developed a set recommendations to minimise the unnecessary use of PPE and ensure optimal availability for those who really need it.⁶ Governments and health agencies across the world including the UK are struggling to find a balance between ensuring that frontline healthcare workers are afforded the utmost protection to treat the public while also rationing supplies to ensure availability over the course of the pandemic.

1.3 UK efforts to increase PPE stock and refine PPE guidelines

1.3.1 Improving PPE stocks in the UK

In order to meet the increased demand for PPE in the face of global shortages, the UK government has put out a call to domestic manufacturers who could potentially produce PPE. Similar to the approach it is taking with ventilator procurement, the government has issued a set of high level specifications that any manufacturer must meet to be granted approval to produce PPE. The guidelines are set out in Specification for Examination Gloves and Specification for Gowns Surgical Face mask, Respirator masks and Eye Protection (PPE).⁷ The Business Secretary has also announced a range of measures to ease the administrative requirements that are currently in place to bring PPE and hand sanitiser to market⁸. These include

In addition to producing new PPE stock, the government acknowledged that there have been issues with local supply chains and the distribution of stocks that are currently available. In response to these issues the government mobilised a large scale effort including use of the army to distribute supplies and also put further measures in place to increase effectiveness of the supply chains⁹.

1.3.2 Concerns expressed regarding the availability of PPE in Northern Ireland

Reflecting the situation in the rest of the UK, a document seen by the media entitled “Covid-19 product shortages” indicates that the levels of PPE stock in Northern Ireland (NI) are very low.¹⁰ There are fears that commercial suppliers are struggling

⁶ WHO (2020) Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19), Interim Guidance 27th February 2020

https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPE_use-2020.1-eng.pdf

⁷ UK Government Health and Social Care (2020) Technical Specifications for Personal Protective Equipment (PPE) 30th March 2020 https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe?utm_source=c3891cb9-cda6-4824-900b-8ce507fbf9e5&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

⁸ UK Government (2020) Business and Industry. Regulations temporarily suspended to fast-track supplies of PPE to NHS staff and protect companies hit by COVID-19 <https://www.gov.uk/government/news/regulations-temporarily-suspended-to-fast-track-supplies-of-ppe-to-nhs-staff-and-protect-companies-hit-by-covid-19>

⁹ <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/personal-protection-equipment-letter-28-march-2020.pdf>

¹⁰ Davis, H (2020) Leak reveals shortage of coronavirus PPE in Northern Ireland, The Guardian 30th March 2020 <https://www.theguardian.com/world/2020/mar/30/leak-reveals-shortage-of-coronavirus-ppe-in-northern-ireland>

the meet the increase demand for stock in NI in the face of rising numbers of cases.¹¹ The Department of Health (DoH) has said that this document does not reflect the true picture of available supply in the country and it has only recently released 30% of its pandemic stock to meet current shortages. To further ensure continued supply, Stormont is also engaging in a joint initiative with the Republic of Ireland to import additional stocks of PPE from China.¹²

1.3.3 Improving current UK PPE guidelines

With ongoing improvements to the supply chain for PPE in the UK, efforts have moved towards resolving confusion that exists around what equipment should be used by different types of workers in different healthcare settings. In particular, The Royal College of General Practitioners (RCGP) have continually called on the government to provide clarity as to whether GP's should use PPE when treating asymptomatic patients.¹³

To this end the government is updating its PPE guidelines using a 'place-based' approach, setting out the level of appropriate PPE needed in various healthcare settings for different medical procedures and levels of contact with COVID patients¹⁴. The guidelines are expected that to be published in the week beginning the 30th March 2020.

1.4 Current UK guidelines for use of PPE in healthcare settings

1.4.1 Introduction

All four UK countries have adopted the same guidelines on infection prevention and control in healthcare settings when treating patients with suspected or confirmed COVID-19. The guidelines are set out in the Public Health England (PHE) document [COVID-19 guidance for infection prevention and control in healthcare settings](#) and include best practice with regard to the use of PPE.¹⁵ The guidelines are consistent

¹¹Davis, H (2020) Leak reveals shortage of coronavirus PPE in Northern Ireland, The Guardian 30th March 2020

<https://www.theguardian.com/world/2020/mar/30/leak-reveals-shortage-of-coronavirus-ppe-in-northern-ireland>

¹²BBC (2020) Coronavirus: 'Significant order' of PPE from China 2th March 2020 <https://www.bbc.co.uk/news/uk-northern-ireland-52070533>

¹³ The Royal College of General Practitioners Letter to the Secretary of State on PPE 25 March 2020

<https://www.rcgp.org.uk/covid-19/-/media/DF275B7640AC44AE8A90BB7C4D1CCAE4.ashx>

¹⁴NHS (2020) Personal Protection Equipment: letter from Professor Stephen Powis, Yvonne Doyle CB MD and Carrie MacEwen - 28 March 2020 <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/personal-protection-equipment-letter-28-march-2020.pdf>

¹⁵ COVID-19 guidance for infection prevention and control in healthcare settings. Available from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

with WHO best practice and also meet the standard measures set out by the European Centre for Disease Control (ECDC).^{16 17}

1.4.2 PPE use in healthcare settings – Task Specific

The guidelines indicate that the level of PPE required in healthcare settings is task specific. The greater the risk of transmission associated with the task, the greater the level of protection that needs to be afforded to the person performing it¹⁸. For example, a healthcare worker performing an aerosol generating procedure (AGP) such as intubation will require more comprehensive protection than someone who is working closely with a COVID-19 patient providing care such as physiotherapy or phlebotomy services. The appropriate uses of PPE equipment in healthcare settings are described in Table 1 as extracted from the official guidance.

	Entry to cohort area (only if necessary) no patient contact*	Within 1 metre of a patient with possible/confirmed COVID-19*	High risk units where AGPs are being conducted eg: ICU/ITU/HDU	Aerosol generating procedures (any setting)
Disposable Gloves	No	Yes	Yes	Yes
Disposable Plastic Apron	No	Yes	Yes	No
Disposable Gown	No	No	No	Yes
Fluid-resistant (Type IIR) surgical mask (FRSM)	Yes	Yes	No	No
Filtering face piece (class 3) (FFP3) respirator	No	No	Yes	Yes
Disposable Eye protection	No	Risk assessment	Yes	Yes

Table 1 Personal protective equipment (PPE) for healthcare staff¹⁹

¹⁶ NHS (2020) Personal Protection Equipment: letter from Professor Stephen Powis, Yvonne Doyle CB MD and Carrie MacEwen - 28 March 2020 <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/personal-protection-equipment-letter-28-march-2020.pdf>

¹⁷ ECDC TECHNICAL REPORT (2020) Infection prevention and control for COVID-19 in healthcare settings March 2020 <https://www.ecdc.europa.eu/sites/default/files/documents/COVID-19-infection-prevention-and-control-healthcare-settings-march-2020.pdf>

¹⁸ The Royal College of General Practitioners COVID-19 - GP guide personal protective equipment 28th March 2020 <https://www.rcgp.org.uk/about-us/rcgp-blog/covid-19-gp-guide-personal-protective-equipment.aspx>

¹⁹ COVID-19 guidance for infection prevention and control in healthcare settings. Page 24. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

1.4.3 Standard PPE use in healthcare settings for COVID 19 infection control

Standard PPE is designed to protect the hands, eyes, face and body against contamination from blood splashes and bodily fluids. It should be used in all incidences where a healthcare professional is providing direct care to a suspected or confirmed case of COVID-19. This type of equipment includes:

- Disposable gloves – to be worn by all staff providing direct care and when exposure to blood and/or other body fluids is anticipated/likely;
- Disposable aprons - to protect staff uniform or clothes from contamination;
- Fluid-resistant (Type IIR) surgical masks - provide a physical barrier against droplet transmission and should be worn by any worker who comes into contact (within 1 metre) with suspected or confirmed COVID-19 cases in the course of their work, whether providing direct care or not; and
- Eye protection/Face visor - should be worn when there is a risk of contamination to the eyes from splashing of secretions, blood, body fluids etc. – need for eye protection to be decided on a case by case basis

PPE to protect the face and eyes can include a:

- Surgical mask with integrated visor;
- Full face shield/visor; and
- Polycarbonate safety spectacles.²⁰

1.4.4 PPE use in healthcare settings during high risk medical procedures

It is recommended that a healthcare worker should use the **maximum** PPE that is available when undertaking or assisting with an AGP or working in high risk areas where AGPs are being conducted (e.g. ICU including in Intensive Care Units or the hot zone of an Emergency Department). This equipment includes:

- FFP3 respirator - When used correctly FFP3 respirators provide protection against airborne transmission and where there is an increased risk of aerosol spread of COVID-19. Unlike surgical face masks, respirators require a fit test by a health and safety professional to ensure they are being worn correctly;
- Long sleeved disposable gown instead of an apron;

²⁰Public Health England. COVID-19 guidance for infection prevention and control in healthcare settings. Page 16.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf

- Gloves; and
- Eye protection (disposable goggles or full-face visor).

Image 1 illustrates full protective PPE worn during a high risk procedure. In all instances care should be taken to ensure that PPE is put on (donned) and taken off (doffed) correctly to avoid inadvertent contamination. Public Health England has produced a number of specific guidelines to assist with this. The appropriate steps should also be taken to ensure that used PPE is disposed of in accordance with guidelines to minimise risk of contamination.

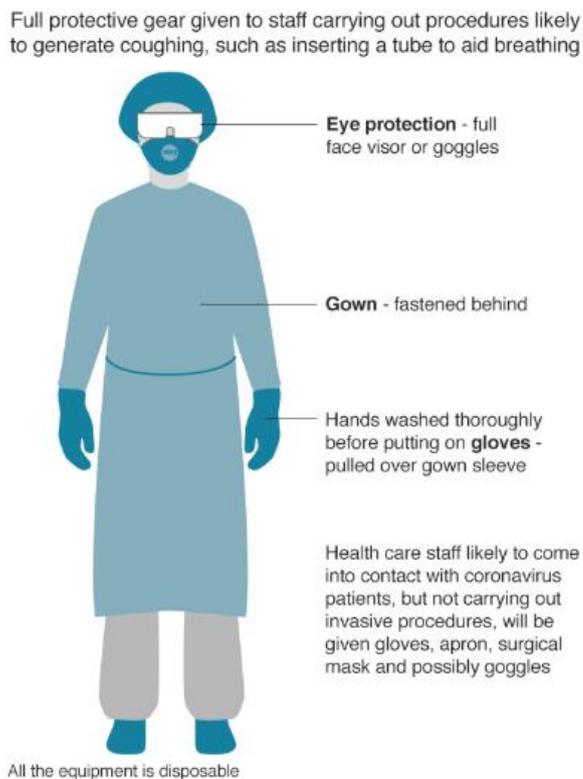


Image 1: Full PPE gear for high risk procedures²¹

1.5 PPE guidance for ambulance personnel

Guidelines for the use of PPE by ambulance trust personnel is the same as that for healthcare staff. The only exception to this is the recommendation of a fluid repellent overall in place of a gown. The overall will usually have a hood which covers the head, ears and neck.

²¹ Kirkland, F (2020) Coronavirus: Protective gear guidance 'to be updated' <https://www.bbc.co.uk/news/health-52057626> 27th March 2020

Table 2 lists the required level of PPE that is recommended for ambulance trust personnel for the care of all possible COVID-19 cases. Guidelines also recommend carrying out a risk assessment prior to engaging with any patient to determine if a higher level or additional PPE is required.²² Ambulance personnel are the only healthcare workers outside of a hospital setting who are likely to carry out AGP's and employ the use of FFP3's. The type of AGPs relevant to the ambulance service include intubation, suctioning, and procedures related to cardiopulmonary resuscitation.²³

PPE requirements	Close patient contact – possible or confirmed case	AGP – possible and confirmed cases
Hand hygiene	√	√
Gloves	√	√
Plastic apron	√	X
Fluid repellent coverall	X	√
Fluid repellent surgical facemask	√	X
FFP3 respirator	X	√
Eye protection	Risk assessment	√

Table 2: Personal protective equipment (PPE) for Ambulance personnel²⁴

1.6 PPE Guidance for social or community care and residential settings

Organisations representing the social care workforce have called on the government to provide clearer guidance on PPE use in social and community care settings and to increase the supply of PPE that is currently available to protect staff. The guidelines that are currently available are limited and have been designed to be applied consistently across the various social and community settings.

The guidelines state that where an individual is suspected or confirmed as having COVID-19, staff should use PPE for any activities that bring them into close personal contact (1 metre) with that individual. This includes washing and bathing, personal

²² COVID 19: Guidance for ambulance trusts <https://www.gov.uk/government/publications/covid-19-guidance-for-ambulance-trusts/covid-19-guidance-for-ambulance-trusts#personal-protective-equipment-ppe>

²³ COVID 19: Guidance for ambulance trusts <https://www.gov.uk/government/publications/covid-19-guidance-for-ambulance-trusts/covid-19-guidance-for-ambulance-trusts#personal-protective-equipment-ppe>

hygiene and contact with bodily fluids. The type of PPE used in these situations include:

- Disposable plastic aprons;
- Gloves;
- Fluid repellent surgical masks and/or
- Eye protection.²⁵

If neither the staff nor the individual receiving care and support is symptomatic, then no personal protective equipment is required above and beyond normal good hygiene practices.

2. Ventilator Supply and use during COVID-19 Pandemic

2.1 Introduction – the vital role of oxygen therapy in COVID-19 treatment protocols

According to the World Health Organization (WHO) there are no medications or vaccines that have proven to be effective in the treatment or prevention of COVID-19.²⁶ In the absence of medication, treatment primarily involves managing the clinical symptoms of the infection and supplemental oxygen therapy represents the main intervention for severely affected patients.

Supplemental oxygen therapy for patients with COVID-19 is provided through the use of non-invasive or mechanical ventilation procedures with the choice dependent on the stage of illness a patient is at. The UK guidelines for the use of oxygen therapy are set out in 'Clinical management of persons admitted to hospital with suspected COVID-19 infection'.²⁷

²⁵ UK Government (2020) COVID-19: guidance for residential care, supported living and home care

<https://www.gov.uk/government/publications/covid-19-residential-care-supported-living-and-home-care-guidance>

²⁶ World Health Organization. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected. Interim Guidance 13 March 2020. [https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-\(ncov\)-infection-is-suspected](https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected)

²⁷ NHS (2020) Clinical management of persons admitted to hospital with suspected COVID-19 infection 19th March 2020 <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/clinical-management-of-persons-admitted-to-hospita-v1-19-march-2020.pdf>

2.2 Different types of Ventilation Support

2.2.1 Mechanical ventilation support

In the most advanced cases of COVID-19 a person can become seriously ill and develop severe breathing difficulties known as acute respiratory distress. In this instance they will usually be admitted to ICU and a mechanical ventilator will be used. A mechanical ventilator is a machine designed to mechanically move breathable air into and out of the lungs of a patient who is physically unable to breathe, or where breathing is insufficient²⁸.

The patient is intubated which involves inserting a tube through the mouth and into the windpipe and the ventilator is then used to push air, with increased levels of oxygen through the tube and into the lungs.²⁹ The ventilator also has a humidifier through which oxygen is warmed and its humidity artificially increased so as to avoid uncomfortable dryness for the patient.³⁰ Patients are given medication to relax the respiratory muscles so their breathing can be fully regulated by the machine. The process of mechanical ventilation is illustrated in Image 2.

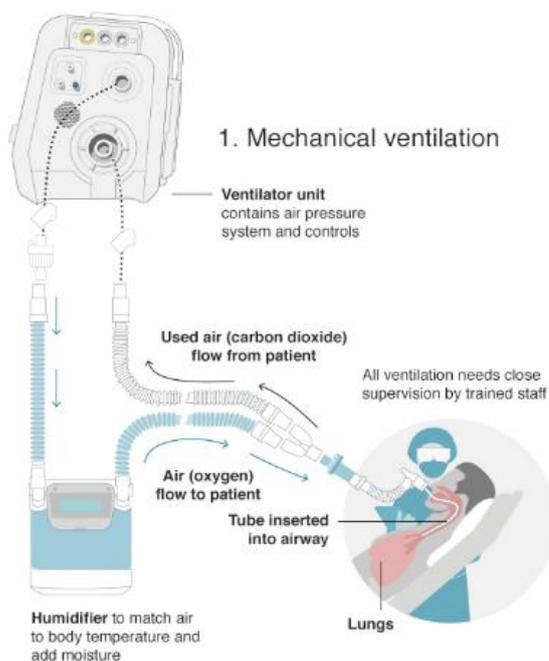


Image 2: The process of mechanical ventilation.³¹

²⁸ Anaesthesia UK (2005) Principles of ventilation 18th February 2005
<https://www.anaesthesiauk.com/article.aspx?articleid=100419>

²⁹ BBC News 2020 Coronavirus: What are ventilators and why are they important? 27th March 2020
<https://www.bbc.co.uk/news/amp/health-52036948>

³⁰ Wark, P (2020) How are the most serious COVID-19 cases treated, and does the coronavirus cause lasting damage? The Conversation March 3rd 2020 <https://theconversation.com/how-are-the-most-serious-covid-19-cases-treated-and-does-the-coronavirus-cause-lasting-damage-134398>

³¹ BBC News 2020 Coronavirus: What are ventilators and why are they important? 27th March 2020
<https://www.bbc.co.uk/news/amp/health-52036948>

2.2.2 Non Invasive Ventilation Support

Where individuals have milder symptoms of COVID-19 but still require breathing support, non-invasive ventilation techniques will be used. There are three different types currently being used in COVID-19 treatment protocols:

- Facemasks, nasal masks or mouthpieces;
- Non-invasive Hoods or helmets; and
- Continuous positive airway pressure (CPAP) devices.

Facemasks, nasal masks or mouthpieces

These types of devices allow pressurised air or mixtures of gases to be pushed into the lungs without the use of internal tubes.³² Image 3 illustrates non-invasive ventilation measures.

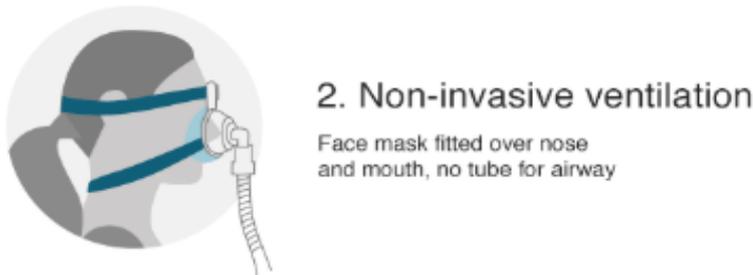


Image 3: The process of non-invasive ventilation.³³

Non-invasive Hoods or helmets

Non-invasive Hoods or helmets are also being commonly used to treat Covid-19 patients, partly because they reduce the risk of airborne transmission of the virus from droplets in the breath.³⁴ The helmet surrounds the patient's entire head to supply oxygen and is sealed with a soft, airtight collar that wraps around the neck.³⁵ Image 4 illustrates a non-invasive hood/helmet based ventilation system.

³² Anesthaesia UK (2010) Non-invasive ventilation 25th March 2010 <https://www.frca.co.uk/article.aspx?articleid=100430>

³³ BBC News 2020 Coronavirus: What are ventilators and why are they important? 27th March 2020 <https://www.bbc.co.uk/news/amp/health-52036948>

³⁴ Horgan-Jones, J and O'Leary, N (2020) Irish Times Coronavirus: Oxygen equipment meant for Ireland held back by Italy, <https://www.irishtimes.com/news/ireland/irish-news/coronavirus-oxygen-equipment-meant-for-ireland-held-back-by-italy-1.4214229>

³⁵ Easton, J (2020) Helmet-based ventilation is superior to face mask for patients with respiratory distress March 25th 2020 <https://www.uchicagomedicine.org/forefront/patient-care-articles/helmet-based-ventilation-is-superior-to-face-mask-for-patients-with-respiratory-distress>



Image 4 non-invasive hood/helmet based ventilation system.³⁶

Continuous Positive Airway Pressure (CPAP)

There is growing evidence that there is a more significant role for the use of CPAP in COVID-19 patients than initially first thought.³⁷ Based on reports from china it was first suggested that early intubation and ventilation was preferable to the use of CPAP. However, it is now clearer that CPAP may be of benefit to patients earlier on in the disease process and may even assist patients to the extent that they do not need to progress to invasive ventilation³⁸. Reports from Italy indicate that about 50 per cent of patients using these aids have not needed ventilation afterwards³⁹. NICE guidelines have been updated to include the use of CPAP in the early stages of the disease⁴⁰.

³⁶ Easton, J (2020) Helmet-based ventilation is superior to face mask for patients with respiratory distress March 25th 2020 <https://www.uchicagomedicine.org/forefront/patient-care-articles/helmet-based-ventilation-is-superior-to-face-mask-for-patients-with-respiratory-distress>

³⁷ Eddleston, J Use of Continuous Positive Airway Pressure (CPAP) for COVID-19 positive patients, the Faculty of Intensive Care Medicine 28th March 2020 <https://www.ficm.ac.uk/news-events-education/news/letter-regarding-use-continuous-positive-airway-pressure-cpap-covid-19>

³⁸ Eddleston, J Use of Continuous Positive Airway Pressure (CPAP) for COVID-19 positive patients, the Faculty of Intensive Care Medicine 28th March 2020 <https://www.ficm.ac.uk/news-events-education/news/letter-regarding-use-continuous-positive-airway-pressure-cpap-covid-19>

³⁹ Gross, A (2020) Mercedes, F1 and London university develop life-saving device for NHS, The Financial Times, 30th March 2020 <https://www.ft.com/content/f003aebe-3804-4e1e-87c4-4fff4a965326>

⁴⁰ NICE guideline NG159 2020 COVID-19 rapid guideline: critical care in adults National Institute for Health and Care Excellence March 2020 <https://www.nice.org.uk/guidance/NG159>



Image 5: shows a patient trialing the new CPAP device at UCHL⁴¹

2.3 Supplying Ventilators in the face of International shortages

The United States, Europe and Asian countries are facing critical shortages of the lifesaving machines with no easy solutions to lift production. Governments and healthcare agencies across the globe have been trying to source machines in three key ways:

- Through existing domestic ventilator producers;
- Engaging overseas suppliers; and
- Through the development of new prototypes by manufacturers new the medical device market.⁴²

The UK government is facing a similar supply problem with current stocks of 8,175 ventilators falling far short of the 30,000 that could be needed to treat Covid-19 patients at the peak of the pandemic.

2.4 How is the UK Government going to meet the increased demand for ventilators?

2.4.1 Multiple procurement strategies to meet demand and ensure supply

The government is employing three separate strategies to source the additional ventilators required, namely:

- Ordering newly designed models;

⁴¹

⁴²Scientists and industry are dashing to make more ventilators The economist March 26th 2020
<https://www.economist.com/international/2020/03/26/scientists-and-industry-are-dashing-to-make-more-ventilators>

- Scaling up production of existing UK devices; and
- Importing machines from overseas to meet immediate shortfall⁴³.

It is hoped that pursuing different strategies in parallel will mitigate the risk of failure of any one option. To this end, the government put out a call to UK and international businesses to assist with rapidly scaling up ventilator production⁴⁴. Businesses with capacity and skills in any part of the production process including design, procurement, assembly, testing and shipping were invited to submit proposals to support in the production and supply of ventilators⁴⁵.

2.4.2 New clinical specifications to guide ventilator and CPAP production

All ventilators whether newly designed, based on existing models or imported from other countries must meet the high level specifications set out in the UK Government document Specification for Rapidly Manufactured Ventilator System (RMVS).⁴⁶

The clinical guidelines which were developed by anaesthesia and intensive care medicine professionals as well as the Medicines and Healthcare Products Regulatory Agency (MHRA) are based on consensus of what is the 'minimally acceptable' performance for a medical ventilator.

Based on positive data emerging from other countries on the therapeutic benefit of CPAP, the government has also recently released a second document which details the minimal clinical specifications any CPAP machine must meet to warrant consideration for use in UK hospitals. The guidelines are set out in Specification for Rapidly Manufactured CPAP System (RMCPAPS).⁴⁷

Given the exceptionally tight timelines within which medical device manufacturers are working, the MHRA have produced regulations to assist with fast-track approval of medical devices and have indicated that they may authorise manufacturers to supply

⁴³ Goodley S (2020) UK government orders more ventilators for coronavirus crisis the Guardian March 30th 2020
<https://www.theguardian.com/world/2020/mar/30/uk-government-orders-more-ventilators-for-coronavirus-crisis>

⁴⁴ Hughes L et al. (2020) UK confident of delivering tens of thousands of ventilators, The Financial Times March 26th 2020
<https://amp-ft-com.cdn.ampproject.org/c/s/amp.ft.com/content/3a27f8f0-e0e7-4e5d-8760-b08669baee71>

⁴⁵ UK Government (2020) PM call with ventilator manufacturers and suppliers 27th March 2020
<https://www.gov.uk/government/news/pm-call-with-ventilator-manufacturers-and-suppliers-26-march-2020>

⁴⁶ UK Government Medicines and Healthcare products Regulatory Agency (2020) Specification for ventilators to be used in UK hospitals during the coronavirus (COVID-19) outbreak, March 26th 2020
<https://www.gov.uk/government/publications/specification-for-ventilators-to-be-used-in-uk-hospitals-during-the-coronavirus-covid-19-outbreak>

⁴⁷ Medicine and Healthcare Products Regulatory Agency (2020) Specification for Rapidly Manufactured CPAP System (RMCPAPS) 29th March 2020
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/876593/RMCPAPS001.pdf

non-CE marked machines.⁴⁸ The regulations can be found under regulations 12(5), 26(3) and 39(2) of the Medical Devices Regulations 2002.⁴⁹

2.4.3 Robust response by UK industry in response to government call

A consortium of 14 significant UK industrial, technology and engineering businesses was formed in response to government calls for businesses to support medical device production⁵⁰. The consortium named Ventilator Challenge UK (VCU) has paired a number of the UK's leading technology and engineering firms with smaller manufacturers to rapidly build existing, modified and newly designed ventilators⁵¹. Some of the initiatives of the VCU includes larger companies such as JCB changing their existing operations to accelerate the manufacture of device components for smaller UK companies and expert engineering firms providing technical expertise to assist with development of new designs⁵².

In addition to the efforts of the newly established VCU who are focusing on existing ventilator designs, a number of UK firms and collaborative groups are developing new prototypes of Ventilators and CPAP machines. Dyson and the collaboration between Mercedes-AMG-HPP group and University College London (UCL) are two of the most high profile developers of new prototypes.⁵³ While both types of producers have received government contracts for large numbers of machines, it is thought that the models being produced by the VCU consortium will be ready to move into production faster because it is working from existing models that do not require the same regulatory approval as new devices.

2.5 Scaling up production of existing UK Ventilator models

2.5.1 Penlon ES02 and Smiths Medical Group ParaPAC ventilator models

Two companies within the VCU consortium, Penlon and Smiths Medical have secured a formal order to produce 10,000 units of two existing ventilator models,

⁴⁸ Medicines and Healthcare products Regulatory Agency (2020) Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak 25th March 2020 <https://www.gov.uk/guidance/exemptions-from-devices-regulations-during-the-coronavirus-covid-19-outbreak>

⁴⁹ UK Government The Medical Devices Regulations 2002 <http://www.legislation.gov.uk/uksi/2002/618/regulation/12/made>

⁵⁰ Smiths Engineering (2020) Ventilator Challenge UK Consortium 30th March 2020 <https://www.smiths.com/news-and-media/2020/03/ventilatorchallengeuk-consortium>

⁵¹ UK Government (2020) PM call with ventilator manufacturers and suppliers 27th March 2020

<https://www.gov.uk/government/news/pm-call-with-ventilator-manufacturers-and-suppliers-26-march-2020>

⁵² Davis, R (2020) UK government sends ventilator blueprints to major manufacturers, 16th March 2020

<https://www.theguardian.com/business/2020/mar/16/vauxhall-owner-psa-car-shuts-european-plants-amid-coronavirus-fears>

⁵³ Gross, A (2020) Mercedes, F1 and London university develop life-saving device for NHS The Financial Times 30th March 2020 <https://www.ft.com/content/f003aebc-3804-4e1e-87c4-4fff4a965326>

which have been chosen by the UK government as their preferred designs⁵⁴. The VCU will assist Penlon and Smiths at all levels of production, including sourcing parts, component assembly through to testing and training for medical professionals. The first model produced by Smiths Medical is a portable ventilator called ParaPAC often found in ambulances and used by the NHS for over ten years⁵⁵. The second design is a slightly modified version of the ES02 Ventilator system manufactured by UK medical device company, Penlon⁵⁶. The ES02 system requires regulatory sign off as a result of the design modifications but is expected to be fast tracked by the MRHA who have had oversight of all stages of its development.⁵⁷ Image 6 illustrates the Penlon ES02 and SmithParaPAC ventilator models.



Image 6: The ES02 and ParaPAC ventilator models^{58 59}

2.6 Drawing on technology to develop new ventilator models

2.6.1 The Dyson CoVent

Dyson have been working with The Technology Partnership (TTP) to design a ventilator called the CoVent. The design leverages Dyson's existing technology meaning it can be

⁵⁴Davis, R (2020) March 29th 2020 Ventilator Challenge UK to start production in Covid-19 fight <https://www.theguardian.com/world/2020/mar/29/ventilator-challenge-uk-to-start-production-in-covid-19-fight>

⁵⁵Pooler, M (2020) UK steps up efforts to supply tens of thousands of ventilators Financial Times, 30th March 2020 <https://www.ft.com/content/8eca845b-56c8-4724-bd77-d7d83c005bfb>

⁵⁶ Pooler, M (2020) UK steps up efforts to supply tens of thousands of ventilators 30th March 2020 <https://www.ft.com/content/8eca845b-56c8-4724-bd77-d7d83c005bfb>

⁵⁷Goodley, S (2020) UK government orders more ventilators for coronavirus crisis, Moday 30th March 2020 <https://www.theguardian.com/world/2020/mar/30/uk-government-orders-more-ventilators-for-coronavirus-crisis>

⁵⁸ Smiths Medical ParaPAC® Ventilator <https://www.smiths-medical.com/products/ventilation/mechanical-ventilation/ventilators/pneupac-parapac-ventilator>

⁵⁹ <https://www.penlon.com/Product-Groups/Anaesthesia-Ventilators/Nuffield-200-Ventilator>

produced rapidly and in high volumes⁶⁰. The model is both bed-mounted and portable with a battery power supply, for flexible use across a variety of settings, including during patient transportation⁶¹. It is understood that the machine was designed in less than two weeks.

The company announced that it had received an order for 10,000 units from the UK government⁶². While the ventilator still needs to be tested and its production process approved, experts from both the UK government and the MRHA have been involved throughout its design process, which should help expedite approvals.⁶³ It is expected that the models will be available for distribution in April. Image 7 illustrates the new Dyson model.



Image 7: The Dyson CoVent model ⁶⁴

2.6.2 Continuous Positive Airway Pressure (CPAP) device

University College London (UCL) engineers have worked with clinicians at University College London Hospital (UCHL) and Mercedes-AMG High Performance Powertrains (Mercedes-AMG HPP) to build what is known as the Continuous Positive Airway Pressure (CPAP) device.⁶⁵ This breathing aid was produced within a rapid timeframe – it took fewer than 100 hours from the initial meeting to production of the first device and

⁶⁰Ethrington, D (2020) Dyson and Gtech answer UK call for ventilator design and production to support COVID-19 response March 26th 2020 <https://techcrunch.com/2020/03/26/dyson-and-gtech-answer-uk-call-for-ventilator-design-and-production-to-support-covid-19-response/>

⁶¹Ethrington, D (2020) Dyson and Gtech answer UK call for ventilator design and production to support COVID-19 response Tech Crunch March 26th 2020 <https://techcrunch.com/2020/03/26/dyson-and-gtech-answer-uk-call-for-ventilator-design-and-production-to-support-covid-19-response/>

⁶²Davis, R (2020) Ventilator Challenge UK to start production in Covid-19 fight The Guardian 29th March 2020 <https://www.theguardian.com/world/2020/mar/29/ventilator-challenge-uk-to-start-production-in-covid-19-fight>

⁶³Davis, R (2020) March 29th 2020 Ventilator Challenge UK to start production in Covid-19 fight The Guardian 29th March 2020 <https://www.theguardian.com/world/2020/mar/29/ventilator-challenge-uk-to-start-production-in-covid-19-fight>

⁶⁴Gartenberg, C (2020) Dyson developed and is producing ventilators to help treat COVID-19 patients The Verge 26th March 2020 <https://www.theverge.com/2020/3/26/21195433/dyson-ventilators-covent-coronavirus-develop-produce-uk-nhs-donate-vacuum-motor>

⁶⁵BBC News 2020 Coronavirus: What are ventilators and why are they important? 27th March 2020 <https://www.bbc.co.uk/news/amp/health-52036948>

is currently being trialed at several London hospitals⁶⁶. If proven successful, the Mercedes-AMG-HPP group can begin building up to 1,000 of the machines per day from the 6th of April. The CPAP device which is claimed to be an improvement on existing CPAP systems, has already received approval from the MRHA⁶⁷. However, some concerns have been raised about the use of CPAP in patients with contagious respiratory infections as any small leaks around the mask could spray droplets on medical staff⁶⁸. Healthcare workers should consider using the highest level of Personal Protective Equipment when using CPAP machines.⁶⁹

2.6.3 Babcock International and Drägerwerk collaboration

The government confirmed on Monday it had also issued a letter of intent for 10,000 machines to defence contractor Babcock International, who are working with Germany's Drägerwerk, one of the world's largest supplier of ventilators, on a critical care device. This design is also subject to regulatory sign-off but there is limited information available about production timelines or the type of device being developed.⁷⁰

2.7 Importing Ventilators from overseas

In addition to large scale orders placed with UK manufacturers, the government has also sought to procure machines from overseas suppliers through agents and direct contact with suppliers. A medical device supply company, Inspiration Healthcare signed a £4m contract with the government to import devices from Israel and the US. The order is understood to be for fewer than 500 machines with the intention that the order will help fill the void until UK firms can scale up production.⁷¹ The government has faced criticism for not exploring the possibility of sourcing more ventilators using this channel, however officials have stated that several of the machines proposed from overseas suppliers did not meet the necessary standards.⁷²

⁶⁶ Greaves, M (2020) UCL, UCLH and Formula One develop life-saving breathing aids for the NHS University College London News <https://www.ucl.ac.uk/news/2020/mar/ucl-uclh-and-formula-one-develop-life-saving-breathing-aids-nhs>

⁶⁷ Greaves, M (2020) UCL, UCLH and Formula One develop life-saving breathing aids for the NHS University College London News <https://www.ucl.ac.uk/news/2020/mar/ucl-uclh-and-formula-one-develop-life-saving-breathing-aids-nhs>

⁶⁸ Hawryluk, M CPAP Machines Were Seen As Ventilator Alternatives, But Could Spread COVID-19, National Public Radio March 25th 2020 <https://www.npr.org/sections/health-shots/2020/03/27/822211604/cpap-machines-were-seen-as-ventilator-alternatives-but-could-spread-covid-19?t=1585663410016>

⁶⁹ World Federation of Societies of Anaesthesiologists (2020) Coronavirus - guidance for anaesthesia and perioperative care providers March 27, 2020 <https://www.wfsahq.org/resources/coronavirus>

⁷⁰ Big names of UK engineering in push to make 30,000 ventilators, The Financial Times <https://www.ft.com/content/1125e39e-8a76-4769-b6ca-f482efca5bf5>

⁷¹ Davis, R (2020) Ventilator Challenge UK to start production in Covid-19 fight <https://www.theguardian.com/world/2020/mar/29/ventilator-challenge-uk-to-start-production-in-covid-19-fight>

⁷² UK government Business and Industry Response to the Financial Times article on ventilators 28th March 2020 <https://www.gov.uk/government/news/response-to-the-financial-times-article-on-ventilators>

2.8 Potential production issues

There is some skepticism as to whether current production lines can be scaled up to meet the ambitious targets set by manufacturers.⁷³ There are also some concerns that worldwide demands for component parts for ventilators, many of which come from China, could outstrip supply.⁷⁴ Outside of the manufacturers listed above whom have officially announced they have received orders for ventilators, the government has indicated that it is working with several other manufacturers who are building, designing and developing ventilators under the oversight of the MRHA – no additional details on these manufacturers were available at the time of writing.⁷⁵

3. Conclusion

The coronavirus pandemic has put unprecedented pressure on global healthcare systems, with the surge in medical needs exposing gaps in inventory of personal protection equipment and lifesaving devices such as ventilators. The shortage is putting healthcare professionals at increased risk of contracting the virus and patients at increased risk of dying due to lack of available lifesaving equipment. In the face of increasing calls from medical bodies and representative groups, the government has moved to increase supplies of both PPE and Ventilators. To meet the increasing demands for supply the government are assisting manufacturers to scale up production of existing UK devices, working with others to develop new ventilator models and types of PPE as well importing stocks from overseas to meet immediate shortfall. The government are also relaxing administrative protocols that surround bringing this types of products to market in an effort to speed up production.

While the government are confident that their plans to meet demands for both PPE and ventilators are on track and the efforts of UK manufacturers to meet the ambitious targets are encouraging, there is some scepticism as to whether manufacturers will be able to scale up in the short timeframe that has been given.

⁷³ Buck, T (2020) Top German ventilator company warns on global supply crunch Financial Times 30th March 2020 <https://www.ft.com/content/2f2845b3-a1ed-44cb-90af-e04d8d712403>

⁷⁴ Miller, J (2020) European companies face coronavirus hit to supply chains The Financial Times 26th February 2020 <https://www.ft.com/content/67e2d35c-589b-11ea-a528-dd0f971febbc>

⁷⁵ UK government Business and Industry Response to the Financial Times article on ventilators 28th March 2020 <https://www.gov.uk/government/news/response-to-the-financial-times-article-on-ventilators>