Respiratory Protection of UK Health and Care Workers against SARS-CoV-2 Virus Infection

An Independent Review

5 March 2021

(Updated 15 April 2021)

David Osborn BSc, CMIOSH, SpDipEM Chartered Safety and Health Practitioner Trident HS&E Ltd





Change Log

5 March 2021: Original report published

15 April 2021: Added section 5.6 Updated section 9 to include further details obtained since initial issue of report

TABLE OF CONTENTS

FOREWORD	3
1. EXECUTIVE SUMMARY	4
2. GOVERNMENT POLICY ON PERSONAL PROTECTION AGAINST SARS-CoV-2	6
2.1. Care Homes	6
2.2. Official UK Guidance on Respiratory Protection (PHE/DHSC)	6
2.3. HSE Guidance on Respiratory Protection	7
3. HOW THE VIRUS INFECTS HUMANS	9
3.1. 'Routes of Entry'	9
3.2. The 'hand-to-mouth' route of entry in respect of healthcare workers	9
4. SARS-CoV-2: The Risk to Human Health	
4.1. SARS-CoV-2: The Severity of the Hazard	
4.1.1. Approved List of Biological Agents	
4.1.2. List of High Consequence Infectious Diseases (HCID)	
4.2. SARS-CoV-2: Transmission and Spread	
4.2.1. Aerosol Generating Procedures	
4.2.2. Aerosols from other sources	
5. CONSIDERATIONS OF SURGICAL MASKS vs FFP3 RESPIRATORS	
5.1. Authoritative Research Reports	
5.1.1. Health and Safety Laboratory research for the Health and Safety Executiv	e21
5.1.2. National Institute for Occupational Safety (NIOSH)	
5.2. Official Guidance and International Standards	
5.3. Approvals by Regulatory Bodies	
5.4. A Comparison of the Efficacy of FFP3 Respirators and Surgical Masks	
5.4.1. Filtration Efficiency	
5.4.2. Face-Fit	
5.5. Review by the Centre for Evidence-Based Medicine (CEBM)	
5.6. Direct SARS-CoV-2 Transmission between Persons Wearing Surgical Masks	
6. UK LEGISLATION RELATING TO PERSONAL PROTECTIVE EQUIPMENT (PPE)	
6.1. Provisions of United Kingdom Statutory Legislation	
6.2. Application of the Term 'PPE' by Public Health England	
7. PPE SUPPLY SHORTAGES	
8. THE 'UNIVERSAL ETHICAL CODE FOR SCIENTISTS'	
9. DECISION-MAKING TIMELINE: 13 - 21 MARCH 2020	
10. CONCLUSIONS	
APPENDIX: GLOSSARY OF ACRONYMS	

FOREWORD

I became involved with this issue in January 2021 after watching a news clip¹ in which care home workers were shown tending to COVID-positive patients using only surgical masks as respiratory protection, which I considered to be insufficient.

I contacted the Health and Safety Executive (HSE) and outlined my concerns. HSE responded that the guidance for Personal Protective Equipment in care-home settings was issued by Public Health England (PHE) and that "there was no evidence in the film clip that these standards were not being met".

I checked the relevant PHE guidance documents and confirmed that they did indeed advise that "fluid-resistant surgical masks must be worn when providing direct care within two metres of a suspected or confirmed COVID-19 case". I considered this guidance to be severely flawed in several respects for reasons that are explained in this report.

I became aware of campaigns being run by groups of healthcare professionals such as the AGP Alliance, Fresh-Air NHS and organisations representing their interests, including the College of Paramedics, RCN, Unite and GMB Unions.

I was finally convinced of the need to write this paper after reading a number of particularly well-informed reports²³ by the BBC Science Editor, Mr David Shukman, which included moving interviews with a paramedic who had contracted COVID-19 and with the Chief Executive Officer of the College of Paramedics.

David Osborn 5 March 2021

The Author:

David Osborn is a Chartered Occupational Safety and Health Practitioner with 25 years' experience in the profession. His specialist area is protection of health from hazardous substances (chemical and microbiological).

The author has no competing interests.

The Report:

This work is not funded.

This report has not been peer-reviewed.

¹ <u>'Covid comes to St Cecilia's' Paul Brand ITV News (Jan 2021)</u>

² 'Double masks – should we use them' - David Shukman, BBC Science Editor (Feb 2021)

³ 'How healthcare workers came to feel expendable' - David Shukman, BBC Science Editor (Feb 2021)

1. EXECUTIVE SUMMARY

This report:

- Provides critical commentary on current guidance by Government departments concerning the protection of healthcare workers from contracting the disease COVID-19 through inhalation of airborne SARS-CoV-2 virions (virus particles).
- Critically reviews the decision taken by the Government in March 2020 to remove SARS-CoV-2 from the official list of 'High Consequence Infectious Diseases' (HCIDs). This decision served as the Government's justification for downgrading respiratory protection for healthcare workers working with COVID patients from filtering facepiece (FFP) respirator masks to surgical masks. Evidence will be presented that:
 - the decision to remove the virus from the HCIDs list was based upon criteria which do not reflect the 'real world' scenario of this pandemic,
 - the decision to downgrade protection to surgical masks contradicts pre-existing (and still current) guidance by the acknowledged UK experts and regulatory body, the Health and Safety Executive (HSE), which unambiguously states that FFP3 filtering masks should be used in rooms containing Severe Acute Respiratory Syndrome (SARS) patients. For the avoidance of doubt, COVID-19 is a SARS, caused by the virus SARS-CoV-2.
- Considers the main 'routes of entry' of the SARS-CoV-2 virus into the human body and the relevance of this to the healthcare environment specifically.
- Presents credible evidence that:
 - o SARS-CoV-2 is transmitted via airborne aerosols, and
 - surgical masks are ineffective at protecting workers against inhalation of aerosols containing SARS-CoV-2 virions.
- Confirms, by reference to UK legislation and relevant standards, that surgical masks are not, and never have been, Personal Protective Equipment (PPE). Evidence will be presented that:
 - the relevant Government departments (PHE/DHSC) are seriously misleading healthcare workers by referring to surgical masks as 'PPE',
 - $\,\circ\,\,$ this misinformation leads workers to a false belief that they are being adequately protected, and
 - $\circ~$ this seriously compromises the health and safety of these workers and endangers their lives.
- It is hoped that the information provided in this review may assist the groups of healthcare workers and their trade unions in their various campaigns to persuade the Government to properly protect them by providing appropriate respirators such as FFP3 masks, powered respirators or similar.
- The standard Government response that "safety is always a priority" must surely be seen by those campaigners as becoming increasingly trite and exasperating as the death toll of healthcare workers in the UK heads inexorably towards the one thousand mark. To date, 25 ambulance staff have died, and this has understandably led to considerable anxiety amongst paramedics who, through necessity, spend significant amounts of time in close proximity to infected patients.

- It is probable that, at some stage in the future, there will be a formal review of the current pandemic with a view to identifying the lessons learned and how we can do better next time (for sadly but surely will be a next time). There is already a justifiable groundswell of opinion that such a review should be held as a formal public inquiry.
- However, it must be stressed that the main objective of this review is not to dwell on the rights
 and wrongs of the past year. Instead, it seeks to provide a persuasive and reasoned argument as
 to why the Government and its key departments, such as PHE and DHSC, should change their
 policy to adopt the 'Precautionary Principle'⁴ and provide healthcare workers with the protective
 equipment that they so richly deserve.
- As the vaccine programme is rolled out, healthcare workers will inevitably gain protection. Nevertheless, this cannot be an excuse for failing to provide effective respiratory protection for them. This pandemic is by no means over, and there is always potential for variant strains of the virus to evolve which may diminish the effectiveness of our current vaccines.
- The Government has already shown what it is capable of by establishing mass-testing laboratories at commendable speed. It should apply the same vigour and determination to the mass-production of suitable respiratory protective equipment to ensure an adequate supply.

⁴ <u>Reducing Risks, Protecting People, HSE's decision making process C100</u>. The HSE's approach to decision-making when reducing risks to protect people. Defined as the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty and rules out lack of scientific certainty as a reason for not taking preventive action.

2. GOVERNMENT POLICY ON PERSONAL PROTECTION AGAINST SARS-CoV-2

2.1. Care Homes

The Public Health England guidance for keeping safe from COVID-19 whilst working in care homes ⁵ states that "the mask is worn to protect you, the care worker":

Table 1: When providing close personal care in direct contact with the resident(s) (e.g. touching) OR within 2 metres of any resident who is coughing				
Re	commended PPE items	Explanation		
1	Fluid-repellent (Type IIR) surgical mask	The mask is worn to protect you, the care worker, and can be used while caring for a number of different residents regardless of their symptoms. You should not touch your face mask unless it is to put it on or remove it.		

Figure 1: PHE guidance on COVID-19 safety in care homes

This unambiguous statement informs the worker that this mask will protect them. The worker will reasonably assume that this means 'protect them against catching COVID-19'. It refers to the mask as 'PPE' which, as will be discussed in section 6, it is not. This is a dangerous and misleading statement.

The preamble of this document states:

"For the purpose of this document, the term 'personal protective equipment' is used to describe products that are PPE or medical devices that are approved by the Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA) as protective solutions in managing the COVID-19 pandemic."

The subtle distinction between 'Personal Protective Equipment' and 'Medical Devices' will not mean much to most workers. If they are told that a certain type of mask is 'Personal Protective Equipment' then they have an absolute right to expect that it has been designed, constructed and tested against recognised standards to protect them against the hazard (COVID-19 in this instance). Surgical masks are neither designed nor constructed nor tested against recognised standards for respiratory protection of the wearer.

As will be discussed later, 'PPE' has a very clear definition in UK law which does not include surgical masks. Surgical masks, which are instead classed as medical devices, protect the patient from the wearer but provide extremely limited protection the other way round – certainly not sufficient protection against inhaling airborne viruses.

It takes more than a convenient 're-interpretation' by PHE to overturn a definition that has been the law of the land for thirty years and make something that is not PPE into PPE.

2.2. Official UK Guidance on Respiratory Protection (PHE/DHSC)

The misleading use of the term 'PPE' to describe surgical masks is repeated in many other documents issued by PHE and other departments. However, the central document which sets out official UK policy ⁶ reiterates the statement in Figure 1 above. In this way, the misconception of surgical masks being 'PPE' is promulgated

⁵ <u>'COVID-19: How to work safely in care homes': PHE (Nov 2020)</u>

⁶ <u>COVID-19: Infection Prevention Control (IPC) Guidance: PHE (Jan 2021)</u>

throughout all associated guidance by other Government Departments, with the notable exception the Health and Safety Executive. 'PPE' is not a term HSE will ever use to describe a surgical mask as it directly contradicts both the legal definition and its own guidance, as explained below.

2.3. HSE Guidance on Respiratory Protection

The HSE publishes a series of guidance notes relating to biohazards, with reference to a limited number of serious diseases. This includes guidance specifically on Severe Acute Respiratory Syndrome (SARS)⁷.

Under section 6 of the guidance, the HSE provides advice specifically for healthcare workers: "Until the cause and route of transmission are known, in addition to standard precautions, infection control measures for inpatients should include [...] airborne precautions, e.g., use of FFP3 filtering masks for persons entering the room".

Although this is a brief statement, it speaks volumes and is worthy of closer scrutiny for several reasons:

- There is no qualification stating that FFP3 masks are only required for aerosol generating procedures (AGPs).
- It clearly indicates that, at the time it was published following the first SARS outbreak, the HSE either:
 - knew or suspected that the SARS-CoV virus was transmissible from person to person via the airborne route (it would be surprising if they did not, given the amount of research being done into person-to-person aerosol transmission at the time), or
 - did not have sufficient information on this but applied the 'Precautionary Principle' in line with the long-established framework for decision-taking which is at the core of the HSE's operating philosophy (as set out in the document 'Reducing Risks: Protecting People'⁴.

Whilst accepting that this guidance was written before the current pandemic and with the 2003 SARS outbreak in mind, it should equally apply to the current SARS pandemic for the following reasons:

- The 2003 outbreak was caused by the coronavirus SARS-CoV; the 2020 pandemic was caused by SARS-CoV-2. They are both 'Severe Acute Respiratory Syndromes'.
- The coronaviruses SARS-CoV and SARS-CoV-2 have both been assigned the same hazard group (HG3) under the scheme for classification of pathogenic organisms (see section 4.1.1). There is no reason to believe that any lesser standard of precautions would be applied to this coronavirus than to its predecessor.
- The guidance is still 'live' on the HSE website and has not been altered in any way during the year since the start of pandemic. It is therefore clear that the HSE consider that guidance remains appropriate for the current SARS coronavirus.

On those occasions when HSE has been required to publish documents relating to respiratory protection during the pandemic, it has never entered into this discussion nor implied its approval of Government policy purporting that surgical masks are 'PPE'.

⁷ Biosafety: Severe Acute Respiratory Syndrome (SARS)

Of course, the HSE confirms that FFP3 masks should be used for AGPs (or FFP2 if FFP3s are unavailable). However, as regards other, non-AGP scenarios, it has never publicly indicated that FFP3s are inappropriate or unnecessary for attending patients in the infectious stage of COVID-19 (or suspected of being so).

In its 'Rapid Evidence Review'⁸, undertaken for the Government's Chief Scientific Advisor, the HSE confined its report to a comparison of the performance of different types of filtering facepiece masks (the FFP2/3 standards used in the UK compared with the American N95 standard).

Some commentators may point to the mention of FRSMs in this document as signalling HSE's approval. This is not the case. It simply reports the policy and guidance that other Government Departments are giving. The only reference made to surgical masks is in Annex 1 (page 7), where the guidance on wearing Fluid Resisting Surgical Masks (FRSM) for non-AGP activities is specified.

As shown in Figure 2 below, the HSE makes it quite clear in (a) the column headers of this table, and (b) the associated 'References' section that the requirements for wearing FRSMs in non-AGP areas is 'Official UK guidance' issued by PHE and DHSC (not HSE). In so doing, the HSE wisely distances itself from that decision.

Guidance (see references below	1 (Official UK Guidance for Infection prevention and control in healthcare settings 2020)			2 (PHE poster when to use a surgical face mask or FFP3 respirator on gov.uk)			3 (PHE posters including videos on gov.uk)	4 (PHE posters including videos on gov.uk)	5 (WHO Infection prevention and control during health care when COVID-19 is suspected)		
	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 e.g.: ICU/ITU/HDU	Aerosol generating procedures (any setting)	In cohorted area (but no patient contact) For example: Cleaning the room, equipment cleaning, discharge patient room cleaning, etc	Close patient contact (within one metre) For example: Providing patient care, direct home care visit, diagnostic imaging, phlebotomy services, physiotherapy, etc	When carrying out aerosol generating procedures (AGP) on a patient with possible or confirmed COVID- 19 In high risk areas where AGPs are being conducted (e.g.: ICU)	Personal protective equipment (PPE) for aerosol generating procedures (AGPs)	Personal protective equipment (PPE) for non- aerosol generating procedures (non-AGPs)	Direct Care of Patients with COVID- 19	Workers undertaking AGP
Mask/Respirator	FRSM	FRSM	FFP3	FFP3	FRSM	FRSM	FFP3	Respirator (type not specified)	FRSM	Surgical mask	FFP2, N95 o equivalent

Figure 2: Extract from HSE Rapid Evidence Review for the Government Chief Scientific Adviser (December 2020)

Agency (PHA) Northern Ireland, Health Protection Scotland (HPS) and Public Health England as official guidance.

⁸ Rapid Evidence Review: Equivalence of N95 and FFP2 masks: HSE 2020

3. HOW THE VIRUS INFECTS HUMANS

This section is not intended to be a detailed exploration of the virus's mechanism of infection. The intention is simply to outline the basic principles and consider why healthcare workers should be subject to a lower, rather than higher, level of infection and mortality rate than people in other occupations. This should be the case if the principles of disease transmission and protective measures expounded by the World Health Organisation and PHE/DHSC are correct.

3.1. 'Routes of Entry'

It may seem patently obvious but, for the virus to cause disease, it must enter the body one way or another. As explained below, there are a limited number of routes by which viruses and other pathogenic (harmful) organisms can enter the body:

• Inhalation

Breathing air contaminated by droplets or aerosols containing the virus. The inhaled droplets or aerosols are drawn directly into the respiratory system/lungs.

• Percutaneous (through the skin)

The skin provides a good barrier against infection. Although it is possible that virus could enter the body via damaged skin (cuts, sores, etc.), any such issues are beyond the scope of this report.

However, it should be noted that research suggests SARS-CoV-2 can remain viable on human skin for about nine hours⁹.

• Eyes

Any virus reaching the eyes can drain down through the lachrymal (tear) duct into the nasal cavity from where they can initiate the disease.

• Mouth

Virus entering the mouth can pass into the respiratory system and the digestive system (the gut) and initiate the disease.

Other routes of entry (exchange of bodily fluids, etc.) are not considered here.

3.2. The 'hand-to-mouth' route of entry in respect of healthcare workers

The World Health Organisation and PHE/DHSC focus on two main methods of disease transmission. These both stem from the emission of droplets from infected patients (e.g., coughing, sneezing, speaking or singing). These droplets fall onto surfaces. Others then touch these surfaces, and the viruses transfer onto the hands. That itself is not a problem since the virus will not absorb through the skin. However, if the person then touches their eyes, nose or mouth, the virus can get into the body as described above and the infection can take hold.

'Hand-to-mouth' transfer can easily happen when eating, drinking, smoking, etc. That is why there is a major focus on hand hygiene (regular handwashing and use of hand-sanitisers).

⁹ Survival of SARS-CoV-2 and influenza virus on human skin: Clinical Infectious Diseases (3 October 2020)

The WHO/PHE/DHSC appear to consider that droplets emitted from infected patients will be of such a size and weight that they will quickly fall to the ground (e.g., within a metre or two) and not therefore remain airborne for long. They only consider aerosols (very small droplets) to be an issue if certain medical procedures are being performed, known as aerosol generating procedures (AGPs).

They do not, despite the mountainous weight of evidence now assembled, seem willing to accept that aerosols produced by natural means (coughing, sneezing, talking, etc.) are relevant in disease transmission. That is the nub of the matter which groups such as the AGP Alliance are so very concerned about, with good reason.

If PHE/DHSC are correct that surgical masks are appropriate for dealing with COVID-positive patients in non-AGP circumstances (such as general wards, emergency departments, ambulances, 'COVID designated areas' in care homes, etc.), staff wearing surgical masks should not be contracting the disease.

However, the opposite is true. There is an elevated death rate in nursing staff, doctors and other healthcare workers of 44.9 deaths per 100,000, which is above that of the general working population. Nurses (both male and female) saw elevated death rates at 79.1 per 100,000 (males) and 24.5 per 100,000 (females)¹⁰.

If we assume that PHE/DHSC are correct that healthcare staff are safe (via the inhalation route) with the policy of FFP3 for AGPs and FRSM for everything else, then the only other plausible explanation for these excess deaths is the 'hand-to-mouth' route.

The notion that healthcare workers are contracting COVID-19 through the 'hand-to-mouth' route is highly improbable due to:

- $\circ\;$ the general standards of cleanliness and hygiene in their various workplaces,
- $\circ\;$ the diligence with which Infection Prevention and Control measures are implemented and monitored,
- $\circ~$ the ubiquitous provision of hand-washing facilities, hand-sanitisers, etc., and
- the high standards of training they receive.

If 'hand-to-mouth' really is the route of entry into their bodies, it would be reasonable to expect very much lower infection and mortality rates than the general working population, even though they may be working with COVID-positive patients.

Since the statistics show otherwise, the airborne/inhalation route appears to be the only realistic explanation. This in turn calls into question the current strategy for respiratory protection.

¹⁰ Report reveals COVID deaths by Occupation: ONS/IOSH (February 2021)

4. SARS-CoV-2: The Risk to Human Health

As a general rule, health and safety 'risk' can be considered to comprise two main components: (a) the severity of the hazard, and (b) the likelihood of the hazard actually causing harm. When considering risks from a disease, the 'likelihood' factor correlates to the transmissibility of the disease (how quickly and easily it can spread). We will now consider these two factors.

4.1. SARS-CoV-2: The Severity of the Hazard

Several quantifiers are used to determine the severity of a virus to human health (pathogenicity). The most commonly used is the Case Fatality Ratio (CFR), often wrongly referred to as the Case Fatality Rate¹¹. The CFR estimates the proportion of deaths among identified confirmed cases. Another is the Infection Fatality Ratio (IFR), which estimates the proportion of deaths amongst all infected individuals.

The values obtained for these parameters have varied widely throughout the pandemic, and it is beyond the scope of this report to provide exact figures. There are many reports on the internet for this.

However, the following figures for CFR provide an estimate which enable a comparison between this and previous serious disease outbreaks.

Virus	CFR	Comments
SARS-CoV-2	2.95% ¹²	UK value at October 2020
SARS-CoV (2003)	15% ¹³	WHO Consensus value
Pandemic Flu (1918)	2 - 3% 14	

Table 1: Estimated CFRs comparing pandemics

These criteria, along with other considerations, lead the UK's panel of experts on microbiological risks to classify the severity of hazards into two lists. These have significant implications for the management and control of microorganisms (bacteria, viruses, etc.) which can cause serious diseases and are hazardous to health (known as 'pathogens').

These lists inform regulatory decisions by the HSE under health and safety legislation and key decisions relating to the management of serious outbreaks and pandemics by the UK Government and departments such as PHE and DHSC.

The panel of experts is the Advisory Committee on Dangerous Pathogens (ACDP), which provides scientific advice to ministers via DHSC and to the HSE. It is headed by the Chair, Professor Thomas Evans of the University of Glasgow. The full membership of the Committee is available online.¹⁵

The two lists which the ACDP compile and maintain are:

- The Approved List of Biological Agents, and
- The List of High Consequence Infectious Diseases (HCID)

¹¹ Estimating mortality from COVID-19. Scientific Brief: WHO (4 August 2020)

¹² Global COVID-19 Case Fatality Rates – Centre for Evidence-Based Medicine (7 October 2020)

¹³ Consensus document on the epidemiology of severe acute respiratory syndrome (SARS) – WHO (November 2003)

¹⁴ Mortality from pandemic A/H1N1 2009 influenza in England - BMJ 2009;339:b5213

¹⁵ <u>Membership of the Advisory Committee on Dangerous Pathogens</u>

4.1.1. Approved List of Biological Agents¹⁶

This list is used by the HSE to define the minimum level of safety precautions for people working with biological agents, for instance in laboratories. They are classified into hazard groups 1 to 4 according to carefully defined criteria, as shown in Figure 3:

When c	tion box: Hazard group definitions lassifying a biological agent it should be assigned to one of the following according to its level of risk of infection to humans.
Group 1	Unlikely to cause human disease.
Group 2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
Group 3	Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available.
Group 4	Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Figure 3: Classification of biological agents

Note: The term 'prophylaxis' means treatment which will prevent infection and/or may reduce the effect of an exposure or an infection. This will include vaccines.

SARS-CoV (the virus which caused the SARS outbreak in 2003) was classified as Hazard Group 3.

SARS-CoV-2 (the virus causing the current pandemic) was also classified by ACDP as Hazard Group 3. This decision was made in January 2020.¹⁷ It could be argued that SARS-CoV-2 should have been assigned to Hazard Group 4 since there was no vaccine available in January 2020. However, it was reasonable to assign Hazard Group 3 since this was a novel virus and, given that the genetic structure of the virus had been mapped, the ability to develop a vaccine was considered likely.

The 'Approved List' has never been updated with an entry for SARS-CoV-2. However, it is assumed that the pre-existing entry 'SARS-related coronavirus' includes SARS-CoV-2 by definition.

4.1.2. List of High Consequence Infectious Diseases (HCID)

The list of HCIDs is the most persuasive list in terms of informing the Government's response to the current pandemic. It has a particular and direct relevance to the Government's decision in March 2020 to downgrade the requirements for respiratory protection of healthcare workers from FFP3 respirators to surgical masks. As such, this is worthy of detailed consideration and scrutiny.

¹⁶ Approved List of Biological Agents: Advisory Committee on Dangerous Pathogens (April 2016)

¹⁷ COVID-19: ACDP assign SARS-CoV-2 as Hazard Group 3: Gov.UK (July 2020)

First, we need to understand the criteria by which a disease is added to this list. We then need to understand how COVID-19 might fit into this list of diseases, i.e., whether its hazardous properties match the criteria to the extent that it should be included in this list.

4.1.2.1. Criteria for inclusion in the HCID List

In the UK, a high consequence infectious disease (HCID) is defined according to the following criteria:

- acute infectious disease
- typically has a high case-fatality rate (CFR)
- may not have effective prophylaxis or treatment
- often difficult to recognise and detect rapidly
- ability to spread in the community and within healthcare settings
- requires an enhanced individual, population and system response to ensure it is managed effectively, efficiently and safely

4.1.2.2. Status of SARS in the HCID List

Diseases in the HCID list are divided into two distinct groups:

- Contact HCID: Spread by direct contact with blood or other bodily fluids from an infected person, and
- Airborne HCID: Spread by respiratory droplets or aerosol transmission from an infected person.

In January 2020, the ACDP was monitoring information being produced from sources in Wuhan and was sufficiently persuaded of the need to add COVID-19 to the list of airborne HCIDs.

As can be seen by an article published in the Journal of the Intensive Care Society (JICS)¹⁸ by four managers of Intensive Care Units in English hospitals, COVID-19 was present on the HCID list:

100	Journal of the Intensive Care Society 21(2)
Table I. A list of contact and airborne high consequence infectious di England HCID programme.	seases as agreed by Public Health England (PHE) and the NHS
Contact HCID	Airborne HCID
Argentine haemorrhagic fever (Junin virus)	Andes virus infection (hantavirus)
Bolivian haemorrhagic fever (Machupo virus)	Avian influenza A H7N9 and H5N1
Crimean Congo haemorrhagic fever (CCHF)	Avian influenza A H5N6 and H7N7
Ebola virus disease (EVD)	Middle East respiratory syndrome (MERS)
Lassa fever	Monkeypox
Lujo virus disease	Nipah virus infection
Marburg virus disease (MVD)	Pneumonic plague (Yersinia pestis)
Severe fever with thrombocytopaenia syndrome (SFTS)	Severe acute respiratory syndrome (SARS) Coronavirus disease (COVID-19)

Figure 4: List of HCIDs per JICS article

¹⁸ <u>COVID-19: An update from England's HCID Intensive Care Unit Leads: JICS (5 April 2020)</u>

It should be noted that SARS, i.e., the disease caused by the 2003 SARS-CoV virus, is also listed under the 'Airborne HCID' category.

The World Health Organisation defines 'airborne transmission' as "the spread of an infectious agent caused by the dissemination of droplet nuclei (aerosols) that remain infectious when suspended in air over long distances and time".¹⁹

It should be noted that, within this definition:

- WHO draws no distinction at all between aerosols generated by natural processes such as coughing and those produced by 'aerosol generating procedures' (AGPs), and
- It is only aerosols (droplet nuclei) which are mentioned in the definition, not 'respiratory droplets'.

This proves that, prior to the current pandemic, the authorities knew and had accepted the scientific evidence arising from the 2003 outbreak that these SARS coronaviruses are transmitted from person to person via aerosols, and that these remain suspended in air over long distances and time. It also demonstrates that in January 2020, when COVID-19 was added to the HCID list, it was accepted that the disease could be transmitted by aerosols that were naturally emitted in human breath (i.e., not just limited to those generated by AGPs).

It is therefore strange that PHE/DHSC are now so fiercely resistant to the notion that the SARS-CoV-2 virus can be spread by naturally generated aerosols, and that they seek to deny healthcare workers exposed to such aerosol emissions the filtering masks that will protect them.

It should also be noted that the date of online publication by these four ICU managers was 5 April. It must have come as a surprise to them to learn that 23 days earlier on 13 March, the ACDP had decided that COVID-19 should be removed from the HCID list and this was ratified a few days later on 19 March by the UK's '4 Nations Public Health HCID Group'.

To this day, the HCID list is shown on the Government website as follows, with COVID-19 being conspicuous by its absence:

List of high consequence infectious diseases A list of HCIDs has been agreed by a joint Public Health England (PHE) and NHS England HCID Programme:			
Contact HCID	Airborne HCID		
Argentine haemorrhagic fever (Junin virus)	Andes virus infection (hantavirus)		
Bolivian haemorrhagic fever (Machupo virus)	Avian influenza A H7N9 and H5N1		
Crimean Congo haemorrhagic fever (CCHF)	Avian influenza A H5N6 and H7N7		
Ebola virus disease (EVD)	Middle East respiratory syndrome (MERS)		
Lassa fever	Monkeypox		
Lujo virus disease	Nipah virus infection		
Marburg virus disease (MVD)	Pneumonic plague (Yersinia pestis)		
Severe fever with thrombocytopaenia syndrome (SFTS)	Severe acute respiratory syndrome (SARS)*		

Figure 5: List of HCIDs per Government website

¹⁹ Transmission of SARS-CoV-2: implications for infection prevention precautions - WHO (July 2020)

4.1.2.3. Changing the status of COVID-19 (removal from the HCID list)

Just as soon as the ACDP and the 4 Nations HCID Group had confirmed the removal from the HCID list, it only took PHE 2 days to re-issue their Infection Prevention and Control guidance for pandemic coronavirus, removing the requirement for FFP3 respirators to be worn in all but the specified AGP scenarios. This revised guidance was issued on 21 March.

The decision to remove COVID-19 from the HCID list was clearly pivotal in this matter and therefore warrants a careful examination of the facts. This could, of course, happen in the future as a part of some civil litigation or public inquiry.

We will return to the criteria given in section 4.1.2.1 above and consider how these may have applied (a) in January 2020 when the decision was made to include the disease in the list; and (b) in March 2020 when the decision was made to remove the disease from the list:

At both times it was known that:

- This was an acute infectious disease,
- There was not yet any effective prophylaxis (e.g., vaccine) or treatment,
- The disease had the ability to spread in the community and within healthcare settings, and
- It was clear that an enhanced individual, population and system response would need to be mounted in order to ensure that the disease would be managed effectively, efficiently and safely.

This leaves us with two remaining criteria to consider:

- Often difficult to recognise and detect rapidly
- Typically has a high case-fatality rate (CFR)

It can be seen from the following statement, taken from the PHE's HCID web pages ²⁰ that it was indeed these two criteria which were used to justify removal of COVID-19 from the list:

Status of COVID-19

As of 19 March 2020, COVID-19 is no longer considered to be a high consequence infectious disease (HCID) in the UK.

The 4 nations public health HCID group made an interim recommendation in January 2020 to classify COVID-19 as an HCID. This was based on consideration of the UK HCID criteria about the virus and the disease with information available during the early stages of the outbreak. Now that more is known about COVID-19, the public health bodies in the UK have reviewed the most up to date information about COVID-19 against the UK HCID criteria. They have determined that several features have now changed; in particular, more information is available about mortality rates (low overall), and there is now greater clinical awareness and a specific and sensitive laboratory test, the availability of which continues to increase.

The Advisory Committee on Dangerous Pathogens (ACDP) is also of the opinion that COVID-19 should no longer be classified as an HCID.

Figure 6: Screenshot from PHE's HCID page confirming criteria for removal

²⁰ High Consequence Infectious Diseases (HCID) Status of COVID-19: PHE (19 March 2020)

Taking these in turn:

- 'Often difficult to recognise and detect rapidly'
 - As PHE correctly states, by March it was now possible to rapidly detect the causative virus and that testing capacity was steadily increasing.
 - However, the other part of this criterion, 'difficult to recognise', had not changed at all and in fact had worsened with the knowledge that symptomless transmission was taking place. In other words, infected persons could be 'super-spreading' without even knowing that they had the disease.
 - So, although testing capacity was increasing, many carriers of the disease would 'slip under the radar' of any testing programme that was put in place. Since the testing programme was reserved for people who had shown symptoms (or been exposed to people who showed symptoms) the issue of symptomless transmission made it very difficult to recognise the precise pathways of transmission through the community. This remains the case today, and 'surge-testing' has to be employed to do so.
 - Overall, therefore, the criterion 'often difficult to recognise and detect rapidly' had not been satisfied and could have equally justified keeping COVID-19 on the HCID list.
- 'Typically has a high Case Fatality Ratio' (i.e., high mortality rate)
 - Estimates for CFR can vary widely and be skewed one way or another by many factors. It can be a challenge to accurately determine the denominator of the ratio, i.e., the number of people infected with the virus. Patients who only have mild symptoms (or are asymptomatic) and people who are misdiagnosed may not be included in this figure when they should be. This will reduce the denominator and thereby overestimate the CFR.
 - However, early (but credible) estimates of CFR were reported in the January Lancet journal as averaging around 2.9%.²¹ Although there was some uncertainty about the exact value, the CFR was clearly considerably less than MERS (37%), SARS-2003 (15%), and Ebola (average 50%).
 - By March, more statistics were available and further CFR values were available. On the face of it, the CFR had not changed significantly and seemed to range between 2% and 5%.
 - The ACDP decision to include COVID-19 in the HCID list would presumably have been based on these sorts of figures. Unfortunately, since the committee has not put the minutes or any documentation about this into the public domain, it is not possible to know what information they used to support their decisions in January or March 2020.

At this point, it would be appropriate to take ourselves back to 13 March 2020 and look at all the evidence available to the ACDP as they considered the question of whether it was appropriate to remove COVID-19 from the HCID List.

They had the set of six criteria set out in section 4.1.2.1 above. Perhaps the availability of testing was a relevant factor, and maybe it could be argued that the CFR had reduced a little. However, we should consider other, quite different evidence that was available to the committee which has a bearing on the actual question of whether COVID-19 is an infectious disease of 'high consequence' or not.

Setting aside the six criteria and considerations of CFR, testing capacity, etc., for a moment, we should consider the meaning of the term 'disease with high consequences' in plain English. Back on 13 March 2020,

²¹ <u>A novel coronavirus outbreak of global health concern: The Lancet (24 January 2020)</u>

most of the rest of the world realised that COVID-19 was a disease which already had high consequences, not just in terms of illness, deaths and strain on health services, but also economies. Yet the PHE/ACDP considered that this was not a disease of 'high consequence'.

Figures that would have been available to them from the World Health Organisation, published the previous day on 12 March, stated that 4,613 people had already died of the disease. There were also 125,260 confirmed cases of the disease and so, assuming a CFR of, say, 2.5%, a further 3,132 deaths were foreseeable. Yet PHE/ACDP considered that this was not a disease of 'high consequence'.

Graphs would have been available to them on that day which showed that the above figures were increasing steadily and inexorably, day by day, as the situation was deteriorating across the world and showing no signs of nearing its peak. Yet PHE/ACDP considered that this was not a disease of 'high consequence'.

The day before that, on 11 March, the World Health Organisation had formally declared COVID-19 to be a global pandemic. Yet PHE/ACDP considered that this was not a disease of 'high consequence'.

It may be informative to examine the other eight diseases listed in the 'airborne HCID' column of the HCID table given at section 4.1.2.2 since these are diseases which had long since been agreed to have 'high consequences':

Airborne 'High Consequence Infectious Disease'	Disease Transmission
Andes virus infection (hantavirus)	From rodents: No human-to-human ²²
Avian influenza A H7N9	From birds. No sustained human-to-human transmission ²³
Avian influenza A H5N1	From birds. No sustained human-to-human transmission ²³
Avian influenza A H5N6	From birds. No sustained human-to-human transmission ²³
Avian influenza A H7N7	From birds. Only one fatal case. Mild or sub-clinical: few hospitalised ²³
Middle East Respiratory Syndrome (MERS)	Limited human-to-human infection ²⁴ . No sustained human-to- human transmission
Monkeypox	From a variety of animals. Limited human-to-human infection ²⁵
Nipah Virus	From animals. Mostly from pigs ²⁶ . Human-to-human possible
Pneumonic Plague	Human-to-human definite ²⁷
Severe Acute Respiratory Syndrome (SARS)	Human-to-human definite ²⁸

Table 2: Transmission of airborne High Consequence Infectious Diseases

²² Facts about Hantavirus: Centers for Disease Control and Prevention

²³ Influenza (Avian and other zoonotic): WHO (November 2018)

²⁴ Middle East Respiratory Syndrome Coronavirus Transmission: Centers for Disease Control and Prevention (February 2020).

²⁵ Monkeypox: WHO

²⁶ Nipah virus infection: WHO

²⁷ <u>Plague fact sheet: WHO</u>

²⁸ Severe Acute Respiratory Syndrome (SARS): WHO

It is noted that Avian Flu A (H7N7) had, according to the World Health Organisation²³, only caused one fatality and is typically 'mild or subclinical' in its consequence. Yet PHE/ACDP appear to rate COVID-19 as being of less consequence than H7N7.

There is a strong case to argue that the existing set of six criteria by which a disease can be added to the HCID list should be revised to take account of some other factors which the current pandemic has taught us will be important for managing future pandemics.

Another crucial factor known about in March 2020 is the lag time between the onset of symptoms and maximum infectivity. For SARS this was 5 to 7 days, whereas for COVID-19 the value is zero. In other words, a person can be at maximum infectivity as soon as symptoms start to show and they realise that they are becoming ill. In fact, it is even possible that the value may be negative, with maximum infectivity before symptoms show.

With SARS, a greater opportunity existed during those five days to isolate and test the patient before they became most infectious. This is a factor which has made the current pandemic very much more difficult to manage and should therefore be a consideration when determining whether a disease is of 'high consequence'²⁹.

The criteria should include a weighting for 'human-to-human' transmission. It is logical to assume that diseases which can be passed readily from human to human will be of far higher consequence in terms of transmissibility and rate of spread around the world than those which pass only from animals or birds to humans (whilst fully accepting the point that such viruses could one day mutate to form a human-to-human strain).

The criteria for adding diseases to the HCID list should be revised to include provision such that diseases can be added once they have caused sufficiently widespread disease, at which point they have self-evidently become 'high consequence'. If specific criteria are required, then these could be (a) the disease has spread at a certain rate, (b) caused a certain number of fatalities within a specified timescale, and (c) WHO have declared a 'public health emergency of international concern' and/or 'global pandemic'.

4.2. SARS-CoV-2: Transmission and Spread

4.2.1. Aerosol Generating Procedures

A key feature of PHE guidance is that they only allow for FFP3 masks to be worn:

- when certain, carefully defined, aerosol generating procedures (AGPs) are being carried out, and
- in critical care wards where COVID-19 patients are present.

There is considerable debate about whether other medical processes and procedures should be included in the official list of defined AGPs and hence greater use be made of FFP3 masks to protect those involved. These issues are being championed by the AGP Alliance and are not further discussed here.

²⁹ Comparing SARS-CoV-2 with SARS-CoV and influenza pandemics: The Lancet (July 2020).

4.2.2. Aerosols from other sources

This debate has recently been widened with research published in Bristol ³⁰, which reports that the coughing of COVID patients emits aerosols consistent with airborne transmission of SARS-CoV-2. They report that SARS-CoV-2 aerosolisation is likely to be high in all areas where patients are coughing, and that PPE policy needs to be updated to reflect these risks.

The research team identified that because viral loads (hence the degree of contamination of aerosols) are higher earlier in infection, the risk of infection to staff in acute medical units, general medical wards or the emergency department is equal to, or even greater than, the risk in the critical care wards where FFP3 masks are mandatory.

The implication of this is that FFP3 masks (or other equivalent respirators) should be provided in a host of other settings beyond intensive care and high dependency wards and AGP-generating processes. This would include settings such as paramedics in patients' homes, the insides of ambulances, 'COVID designated areas' within care homes, etc.

It is interesting to note that the World Health Organisation ³¹ classifies airborne droplets according to their size, i.e.:

- Respiratory droplets are between 5-10 microns in diameter.
- Aerosols (otherwise known as 'droplet nuclei') are less than 5 microns in diameter.

The Bristol researchers provide strong evidence that very fine aerosol particles (less than 0.6 microns) are unlikely to be involved in causing infections, so the focus appears to have been on aerosols between 0.6 and 5 microns. This overturns the central plank of DHSC/PHE's argument that only the mode of transmission concerned with respiratory droplets (5-10 microns) needs to be addressed in its infection protection strategy.

In fact, other research suggests that even a slightly smaller range should be considered (down to 0.2 microns). An article published in the Journal of Aerosol Medicine and Pulmonary Drug Delivery ³² reviewed a number of research papers. The conclusions can be summarised as follows:

- Normal breathing (let alone coughing, sneezing or talking) can result in infective viruses being exhaled.
- These exhaled aerosol particles are generated deep in the lung, acquiring virus contamination through the continual collapsing and reopening of small airways during inspiration.
- The particles do not arise in the upper but in the lower, very small airways. At the beginning of an exhalation in the first ~200 mL, there are no or very few particles, and at the end of the exhalation the concentration increases.
- These mucus aerosols (size range between 0.2 and 0.6 microns) can transport viruses out of the lungs of patients and (due to their small size) remain present in the room air for many hours.
- These aerosol particles are difficult to filter out of the air.

³⁰ <u>Aerosol emission from the respiratory tract: an analysis of relative risks from oxygen delivery systems.</u>

³¹ Transmission of SARS-CoV-2: implications for infection prevention precautions - WHO (July 2020)

³² Breathing Is Enough: For the Spread of Influenza Virus and SARS-CoV-2 by Breathing Only - JAMP (July 2020)

- Surgical masks can efficaciously reduce the emission of influenza virus particles into the environment in respiratory droplets, but not in aerosols. The particles that carry the viruses are so small that they cannot be retained sufficiently by the (surgical) mask material.
- Because of their physical properties, new strategies must be developed to protect people from these aerosol-borne viruses.

The paper goes on to explain that, although some of these statements relate to influenza viruses, "it is highly probable that these results can also be applied to the SARS-CoV-2".

5. CONSIDERATIONS OF SURGICAL MASKS vs FFP3 RESPIRATORS

5.1. Authoritative Research Reports

5.1.1. Health and Safety Laboratory research for the Health and Safety Executive

HSE Report RR619³³ cast serious doubt on the existing Health Protection Authority/NHS 'UK Pandemic Influenza Infection Control Guidance' which was in place at the time, since that guidance recommended that "workers who are in close contact with patients should wear surgical masks". The authors clearly disagreed with this guidance, as can be seen in the following summary of their observations and findings:

- "Surgical masks are not intended to provide protection against infectious aerosols."
- "There is a common misperception amongst workers and employers that surgical masks will protect against aerosols."
- Laboratory tests showed the following:
 - Surgical masks would only provide around a sixfold reduction in exposure to aerosols (though many of the masks they tested offered considerably less protection than that).
 - By contrast, properly fitted respirators could provide a 100-fold reduction in exposure to aerosols.
 - Live viruses were detected in the air behind all the surgical masks they tested and so would have been inhaled by the wearers.
 - It should be noted that these tests were not done under circumstances of AGPs (as currently defined intubation, bronchoscopy, etc.). They were done under circumstances simulating (a) simulated sneezing and (b) "naturally occurring ambient airborne particles" (i.e., relatively static air as would be the case with an infected person simply talking, let alone coughing and sneezing). Claims that FFP Respirator masks are only required for AGPs are therefore incorrect.
- The most compelling statement concerned the previous SARS outbreak in 2003 (given that the current pandemic is also caused by a SARS coronavirus):
 - "Retrospective studies on the clinical attack rates of SARS during the management of outbreaks in the hospital setting suggested that surgical masks afforded some protection, but this was not enough to significantly reduce the risk of infection."

5.1.2. National Institute for Occupational Safety (NIOSH)

The US National Institute for Occupational Safety and Health commissioned research ³⁴ into the protection afforded by surgical masks compared with N95 filtering facepieces (equivalent to the UK FFP2 respirators). Tests were performed on five different types of surgical masks, "none of which exhibited adequate filter performance and facial fit characteristics to be considered Respiratory Protection Devices".

³³ Research Report RR619 Evaluating the protection afforded by surgical masks against influenza viruses: HSE (2008).

³⁴ Surgical Masks Filter and Fit Performance: Minnesota University for NIOSH (May 2008)

5.2. Official Guidance and International Standards

There are various types of respirators designed to protect people from inhaling airborne contaminants. A comprehensive guide to respiratory protection is produced by the Health and Safety Executive.³⁵ The experts in PHE/DHSC should take note of this document since it provides authoritative guidance on the subject from which they will certainly benefit. In particular, they should note that surgical masks are not mentioned at all in the context of respiratory protection. The reasons for this will become apparent in section 5.3 below.

If a quick yet authoritative resumé of the difference in function between surgical masks and protective masks is required, the British Standards Institute offer a concise explanation.³⁶ This explains the applicable standards which are legally binding on manufacturers. Certain key phrases have been underlined, and remarks added in brackets by the author of this report.

- Surgical masks to EN 14683:2019+AC:2019
 - Surgical face masks are intended to limit the <u>transmission</u> of infective agents (i.e., from the wearer outwards to others, such as patients).
 - Surgical face masks can also incorporate a microbial barrier that is designed to be effective in reducing the emission of infective agents from the nose and mouth of a carrier or a patient with clinical symptoms.
 - Surgical masks are <u>intended to be a barrier to infection of others</u> though they do offer <u>limited</u> protection to the wearer. (The limited protection is against splashes of blood and other bodily fluids)
- (Note: The tests performed on the mask are <u>from the inside out</u> in order to assess performance in reducing <u>outbound</u> emissions/exhalation from the wearer. No tests whatsoever are performed in the "inbound" direction since wearer-protection is not primarily the purpose of this type of mask.)
- Protective masks to EN 149:2001+A1:2009
 - Protective masks are designed to protect against particulates such as dust particles and various viruses in the air.
 - These masks, unlike surgical masks, protect the wearer from inhaling infectious agents or pollutants in the form of aerosols, droplets, or small solid particles.
 - The wearer must be free of facial hair for this type of mask to be effective and should be 'fit tested' to ensure that the wearer has the appropriate, specific mask.

5.3. Approvals by Regulatory Bodies

Surgical masks are classified as medical devices and are approved for use in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA).

Personal Protective Equipment, including filtering facepiece masks (e.g., FFP2, FFP3) are approved for use in the UK by the Health and Safety Executive.

³⁵ <u>Respiratory Protective Equipment (RPE) at work. A practical guide - HSE</u>

³⁶ Guide to masks and face coverings for use in the UK during the COVID-19 pandemic: BSI (May 2020)

It has been the HSE's long-standing position that surgical masks are not PPE. They commented in their Research Report RR619 (referenced above): "The European PPE Directive 89/686/EEC covers Respiratory Protective Equipment (RPE). This directive excludes surgical masks, and they are not certified for use as RPE in the UK."

5.4. A Comparison of the Efficacy of FFP3 Respirators and Surgical Masks

There are two main factors which influence the protection given by masks/respirators:

- Filtration efficiency of the materials from which the mask is made, and
- 'Face-Fit', i.e., an effective, tight fit to the face to prevent inward leakage of unfiltered contaminants as the wearer inhales.

Considering these in turn:

5.4.1. Filtration Efficiency

- The Centre for Health-Related Aerosol Studies (part of the University of Cincinnati) conducted research which demonstrated the inability of surgical masks to filter out aerosols less than .6 microns.³⁷
- As discussed in section 4.2.2, these are the very small aerosols (0.2 to 0.6 microns) which arise from the tiny airways deep in the lung which are highly contaminated with viruses through the continual collapsing and reopening of small airways as the infected patient breathes in and out.
- The researchers concluded that: "The results suggest that the tested surgical mask may not be able to provide substantial protection against aerosol particles at least up to ~500 nm". It should be noted that this test was performed in an 'inbound' (inhalation) direction, thereby assessing the level of protection for the wearer which, in the case of surgical masks, was ineffective.
- One test showed that a surgical mask leaked aerosols with a filter penetration of 9% compared with a value of only 0.1% for an N95 mask sealed to the face. In other words, the actual fabric material of the surgical mask allowed 90 times more aerosol-sized particles through than the material of the N95 mask. It should be remembered that FFP3 respirator masks are considerably more efficient at filtration than N95 masks.

5.4.2. Face-Fit

Face-fit is the most important factor since, in the absence of a tight fit, the contaminant simply bypasses the filter altogether, so arguably it does not matter how efficient the filtration material is.

Surgical masks do not provide a tight fit to the face. Virus-laden aerosols can enter around the edges, particularly either side of the nose.

Whilst plenty of data exists relating to the face-fit efficiency of tight-fitting masks such as FFP3 respirators, comparative face-fit data for surgical masks is hard to come by. This is because face-fit tests are not normally carried out on them since they are not tight-fitting.

³⁷ Effect of Particle Size on the Performance of N95 Respirator vs Surgical Mask: Centre for Health-Related Aerosol Studies (2013).

However, some comparative measurements were obtained by Dr Richard Saint Cyr using a conventional TSI Portacount Respirator Fit Tester with the following results (units being expressed as the percentage of particles within the size range 0.01 to 1 microns being blocked):

- FFP3 Respirators: 99.4% to 99.7%
- Surgical Mask: 63%

In other words, approximately one third of the air outside the mask was able to circumvent the mask and gain access to the breathing zone inside, completely unfiltered. This renders considerations about the filtration efficiency of the mask fabric rather irrelevant.

5.5. Review by the Centre for Evidence-Based Medicine (CEBM)

In order to present both sides of the argument, attention is drawn to a report issued by CEBM ³⁸ which supports the DHSC/PHE policy relating to surgical masks. Although the report was mainly concerned with staff working in primary and community care, it may foreseeably be used to support the policy as applied in secondary care.

The report headline claims that "Standard surgical masks are as effective as respirator masks (e.g., N95, FFP2, FFP3) for preventing infection of healthcare workers in outbreaks of viral respiratory illnesses such as influenza". This will no doubt have been of great comfort to those in Government departments who wished to promulgate the belief that surgical masks provide effective personal protection of staff against viral respiratory illnesses.

However, it is relevant to consider the context and timing within which this report was produced.

As discussed in section 4.1.2, the decision to 'downgrade' respiratory protection from FFP3 respirators to surgical masks was implemented by DHSC/PHE on Saturday 21 March 2020 following the removal of COVID-19 from the HCID list on March 13.

The CEBM report was published on Monday 23 March and it included mention of the PHE advice issued on Saturday 21 March. Coincidentally, it is noted from the 'references' section that four of the five internet searches were undertaken on Saturday 21 March. The timing of this activity might possibly be interpreted as a rather hurried exercise to collate whatever information might be available to support the DHSC/PHE move towards surgical masks.

The report gives no indication as to who commissioned and funded the work, as is usually the case with research papers. However, given the timing and context of the work, it could be assumed that the report may have been compiled at the request of DHSC or someone connected with Government. PHE state that they did not commission this report.

Although the authors of the report included the caveat that "there is no direct evidence from COVID-19 outbreaks", the context and timing of this report would appear to infer a relevance to the newly-declared pandemic.

Most health and safety practitioners will raise an eyebrow at the headline's claim that "standard surgical masks are as effective as respirator masks such as FFP3". It would be interesting to see what the experts at the Health and Safety Executive have to say about this statement.

³⁸ Efficacy of standard face masks vs respirator masks in preventing COVID-type respiratory illnesses... CEBM (23 March 2020)

It is noted that authors cite PHE guidance (in the form of a poster) which states that surgical face masks are to be worn in cohorted areas and close contact with a patient.

- To the reader this appears, on the face of it, to be authoritative pre-existing official guidance which helps CEBM reach their verdict that FFP3 masks add no value over surgical masks for non-AGP activity.
- CEBM state that PHE published this "more recently" (21 March 2020).
 Reference 5 indicates that CEBM accessed this information on 21 March 2020.
 As previously discussed, PHE were not in a position to issue this guidance downgrading respiratory protection until the ACDP and the '4 Nations Public Health HCID Group' had adjusted the HCID list. It is difficult, therefore, to see how this could be considered pre-existing official guidance.
- One might question the wisdom of providing 'evidence-based' advice calling upon evidence which, on the face of it, seems only to have been formally issued on the same day as their research was done or, at best, just a few days beforehand.

CEBM make frequent references to a report by the Chinese Cochrane Centre ³⁹, and this appears to provide a central plank to their assertions that surgical masks are effective. However, a subsequent report published in PLoS One ⁴⁰ concluded that this report offered a "debatable interpretation" of the estimates of N95 respirators in protecting healthcare workers. This is because the authors had not considered the clustered design of randomised control trials (RCTs). In fact, some contrary evidence was offered to the effect that wearing N95 respirators can prevent 73 more clinical respiratory infections per 1,000 healthcare workers compared to surgical masks. This evidence was based on two randomised control trials (RCTs) involving 2,594 participants.

CEBM noted that:

- Primary and community care settings are 'low-risk' so respirator masks would not be needed, and
- Guidance produced by the US Centres for Disease Control recommends respirator masks for both high and low-risk settings. However, CEBM commented that this guidance was most likely based on the 'precautionary principle' and probably did not anticipate the supply shortages currently faced by frontline staff.

This gives us our first insight into the fact that the UK Government was both:

- Abandoning the 'precautionary principle' (the central principle of health and safety in the UK), and
- Linking the change in policy on respiratory protection to shortages of PPE. (This will be further discussed in section 7 below.)

It is a shame that the CEBM researchers spent so much time searching for Chinese and other sources of information but did not think to seek already-published research carried out here in the UK by the HSE in the form of RR619. Given HSE's findings (summarised in section 5.1.1 above) it would have been difficult to make the claim that "Standard surgical masks are as effective as respirator masks".

³⁹ Effectiveness of N95 respirators versus surgical masks against influenza - Chinese Cochrane Centre (13 March 2020).

⁴⁰ Protect Healthcare Workers from COVID-19. A GRADE rapid review of N95 respirator effectiveness - PLoS One (3 June 2020)

CEBM is, however, to be commended for dismissing the claims in pre-existing PHE/DHSC guidance that both surgical masks and N95/FFP2 respirators offer a similar level of protection, both associated with up to an 80% reduction in risk of infection.

Even though CEBM had discredited this '80%' claim, in the next version of the official guidance (version 1.1) ⁴¹, PHE/DHSC ignored the CEBM concerns about the credibility of this information and reiterated their claim that surgical masks and N95/FFP2 both offered up to 80% risk reduction. The inclusion of such a statement in official guidance which sets the scene for national Infection Prevention and Control policy and the safety of healthcare workers may be viewed by some as unconscionable.

5.6. Direct SARS-CoV-2 Transmission between Persons Wearing Surgical Masks

A study carried out in Boston, USA ⁴² has confirmed the transmission of SARS-CoV-2 between patients and their healthcare workers despite the wearing of surgical masks and eye protection. Ordinarily it would be very difficult to prove that the person who became infected had not acquired the disease from a different source, perhaps elsewhere in the workplace, out in the community or from within their family.

This study used 'whole genome sequencing' (a detailed examination of the entire genetic structure of the virus DNA). The results showed that there were "zero single nucleotide polymorphism differences" between the virus in the person who originally had the infection and the person who acquired the infection from them during the encounter. In layman's terms, we can take this as proving, beyond reasonable doubt, that:

- the COVID-19 disease passed between those two persons despite the wearing of surgical masks; and
- the person who acquired the disease did not acquire it from another source.

It must be said that this was quite a small study, examining just 3 encounters, but the results are nevertheless quite convincing. It should be noted that one of the cases involved the healthcare worker passing the disease to the patient, rather than the other way round.

The researchers report that:

- Respirators (such as N95 or FFP3 masks) "add the most value when caring for patients with known or suspected COVID-19 or for sustained encounters at close quarters with untested individuals and/or unmasked individuals in communities with high incidence of disease".
- The risk is highest with prolonged encounters at short range with patients early in the course of their infection when their viral loads are highest, particularly if one of the parties is unmasked.

(It is understood that this is likely to be the case in settings such as ambulance crews in people's homes, ambulance crews in their vehicles, emergency departments, X-ray facilities and general wards where staff are only issued with surgical masks for protection.

⁴¹ COVID-19: Guidance for infection prevention and control in healthcare settings. Version 1.1 - PHE/DHSC (27 Mar 2020)

⁴² Transmission of SARS-CoV-2 between patient and healthcare workers despite medical masks – Clinical Infectious Diseases (March 2021)

6. UK LEGISLATION RELATING TO PERSONAL PROTECTIVE EQUIPMENT (PPE)

6.1. Provisions of United Kingdom Statutory Legislation

There are many types of PPE. Since this review is focused on the risk of inhalation of the COVID-19 virus, this section will only consider PPE that is specifically intended to be used as Respiratory Protective Equipment (RPE).

The relevant items of legislation in the UK are:

- The Health and Safety at Work etc Act 1974, section 2, general duties of employers to their employees;
- The Personal Protective Equipment at Work Regulations 1992: Regulation 4 imposes an absolute ⁴³ duty upon employers to provide PPE that is suitable for the risks to which they are exposed at work.
- The Control of Hazardous Substances Hazardous to Health Regulations 2002 (COSHH) (as amended).
- Regulation 7, paragraph 9 states that:

"Personal protective equipment provided by an employer in accordance with this regulation shall be suitable for the purpose and shall—

- (a) comply with any provision in the Personal Protective Equipment Regulations 2002 which is applicable to that item of personal protective equipment; or
- (b) in the case of respiratory protective equipment, where no provision referred to in subparagraph (a) applies, be of a type approved or shall conform to a standard approved, in either case, by the Health and Safety Executive."

Surgical masks are not covered by (a) above. Neither are they of a type approved nor to a standard approved by the Health and Safety Executive. Surgical masks are therefore not PPE within the meaning of UK law and no amount of convenient 'redefinition' by PHE or DHSC will make them so.

6.2. Application of the Term 'PPE' by Public Health England

The author has written to PHE concerning their misuse of the term PPE for surgical masks.

In their reply, PHE claim that it is widely accepted within the healthcare profession and that this is based on 'peer-reviewed published evidence'. They cite the document upon which they rely for this evidence which is 'Standard Infection Control Precautions and Transmission Based Precautions Literature Review: Surgical Face Masks Version 1' (Oct 2020), published by ARHAI Scotland (Antimicrobial Resistance and Healthcare Associated Infection). ⁴⁴

The authors of that review actually call into question the applicability of the Health and Safety at Work etc Act, COSHH Regulations and PPE regulations referred to in section 6.1 above. For the avoidance of doubt, this legislation applies across the UK without exception, including in healthcare settings. The key point here

⁴³ Under UK legislation, an 'absolute' duty is a duty which must be done. It is not permissible to argue that it is impracticable, costly or difficult to do. A Court would not accept any defence for noncompliance with the duty.

⁴⁴ Standard ICPs and Transmission Based Precautions Literature Review: Surgical Face Masks - ARHAI Scotland (Oct 2020)

is that surgical masks are not PPE in any setting, healthcare or otherwise. The authors should realise this as they correctly reference the HSE web page for pandemic flu⁴⁵, which clearly states that they are not considered as 'PPE' under the PPE Regulation 2002. It explains in simple and straightforward terms that, although they do provide a physical barrier to large droplets, they do not provide respiratory protection against smaller droplets and aerosols.

In the previous paragraph the HSE "recommend FFP3 masks where exposure to aerosols is considered significant". Now that there is abundant evidence that aerosols are 'significant' in the transmission of COVID-19 this recommendation becomes all the more pertinent. To be clear, whilst the HSE highlight aerosol generating processes, they do not exclude other scenarios where aerosols are found to be significant from their recommendation about FFP3 masks.

The authors also refer to a statement on a different HSE web page entitled 'Face coverings and face masks at work during the coronavirus pandemic'. The statement given on that page is that "surgical face masks are designed to be worn in medical settings to limit the spread of infection. They are not considered to be PPE when worn outside of healthcare activities".

The ARHAI authors seem to be misinterpreting this to infer that surgical masks are considered PPE when worn inside healthcare activities. Although this is an excusable assumption (and HSE might consider clarifying their wording), that is not the case. The authors need to appreciate that certain protocols exist within and between Government departments. In this case, it means that matters relating to the wearing of masks, respirators and other PPE within the healthcare sector fall entirely within the remit of DHSC and PHE since medical matters are involved. The HSE do not interfere in medical matters.

However, due to DHSC, PHE, Government ministers and the media constantly referring to surgical masks as 'PPE', the HSE is, by this comment, simply reminding workers outside of healthcare that surgical masks are not PPE, which is of course the case.

DHSC/PHE also rely heavily on another document produced by ARHAI. This is entitled 'Rapid Review of literature: Assessing the IPC and control measures for the prevention and management of COVID-19 in health and care settings v 11.0 5/2/2021' (*no URL known*). This is therefore worthy of some examination:

- They state that "the HSE position regarding RPE has remained unchanged; currently the use of
 respirators, such as FFP2 or FFP3, are only for the highest risk aerosol generating procedures
 which are undertaken in medical settings and during dental procedures (correspondence
 provided by the UK IPC Cell)".
 - The above statement would infer that HSE position is that FFP2/3 must not be used for other scenarios. It is beyond belief that the HSE would take that stance. The author has submitted a Freedom of Information request to have sight of the correspondence with the UK IPC Cell which makes this claim.
 - Although not privy to the documentation which may be held by the UK IPC Cell, there is no evidence whatsoever in the public domain that HSE have ever said that FFP2/3 respirators are only for use in AGPs. As discussed above, the HSE "recommend FFP3 masks in all circumstances where exposure to aerosols is considered significant". They do not limit this recommendation only to AGPs.

⁴⁵ Pandemic Flu - Workplace Guidance - HSE

- Page 29 of the document states that "the Health and Safety Executive advises that in the event of severe shortages of medical masks, face shields may be considered as an alternative".
- It is inconceivable that the Health and Safety Executive would ever make such a statement. Face shields and visors provide no respiratory protection whatsoever. The ARHAI authors refer to a document entitled "What is the current evidence for the effectiveness of using a visor rather than a surgical face mask in preventing the transmission of COVID-19 in a healthcare setting?".
- Upon further investigation it is discovered that this publication was written by the Health Service
 Executive in Ireland ⁴⁶ (the Irish equivalent of the NHS) and not the UK Health and Safety
 Executive.
- Such is the level of attention to detail in a document which serves as the basis of policy upon which the health, safety and protection of healthcare workers across the UK is founded.

⁴⁶ Effectiveness of using a visor rather than a surgical face mask to prevent transmission of COVID-19 – Health Service Executive, Ireland

7. PPE SUPPLY SHORTAGES

There have been suggestions that the decision to change policy from FFP3 respirators down to surgical masks for frontline healthcare workers may have been, in some part, attributable to shortages of FFP3 respirators due to the high level of demand arising from the pandemic.

The author queried with PHE whether the policy to switch from FFP3 respirators to surgical masks was driven by a shortage of FFP3 respirators. The PHE have categorically denied this, responding that their guidance on this was based on the mode of transmission and "was not related to shortages or rationing of PPE".

Whilst that reassurance is welcome news, we should once again turn to a rapid evidence review by the Centre for Evidence-Based Medicine in Oxford⁴⁷ who reported on 23 March 2020 that "Shortages of surgical masks and filtering facepiece respirators has led to the extended use or re-use of single-use respirators and surgical masks by frontline healthcare workers, however the evidence base underpinning these practices is unclear".

Whilst accepting that there most probably were (and maybe still are) shortages of FFP3 masks, this is not a valid reason for telling workers that a lower standard of protection (i.e., surgical masks) will adequately protect them from the disease. Organisations are not generally inclined to spend time and money on additional precautions if they have been led to believe that the existing precautions (masks in this case) are perfectly satisfactory. Such additional precautions might have included improved ventilation, additional Perspex screens and instructions to staff to reduce the amount of time spent in the close vicinity of COVID-positive patients to the absolute minimum required for the performance of duties.

When considering stockpiles of respiratory protective equipment for possible future pandemics, the use of reusable 'semi-disposable' P3 masks manufactured to the BS EN 405:2001+A1:2009 standard might be considered. These can generally be used repeatedly for up to 28 days. The requirements of the PPE Regulations 1992 would need to be considered in terms of providing clean, hygienic storage containers together with disinfectant cleaning wipes. HSE guidance is available.⁴⁸

⁴⁷ Extended use or re-use of single-use surgical masks and filtering facepiece respirators – CEBM (5 June 2020)

⁴⁸ Use of tight-fitting respirators and reusable half masks during the coronavirus pandemic – HSE (31 December 2020)

8. THE 'UNIVERSAL ETHICAL CODE FOR SCIENTISTS'

As discussed in section 4.1.2.3, the policy change enabling the wider use of surgical masks occurred immediately following the decision by the ACDP to remove SARS-CoV-2 from the HCID list. This could be taken to suggest that the decision-making process within that committee may have been influenced by knowledge of a shortage of FFP3 respirators. In fact, a BBC report ⁴⁹ suggests that a member of the ACDP has already admitted that this was exactly the case.

The following observations are offered:

- Neither political, economic nor PPE availability issues materially change the hazardous properties of a virus.
- All the committees involved in these decisions (including ACDP, NERVTAG, the '4 Nations Public Health HCID Group') are predominantly composed of scientists, mostly with a medical, microbiological or public health background.
- Scientists are expected to work to a high standard of ethics. A number of different codes of ethics for scientists have been published, but one of the most widely accepted codes is the 'Universal Ethical Code for Scientists' ⁵⁰. This was introduced in 2007 and supported by the Government's Chief Scientific Advisor of the day, Sir David King. Some key principles of the code are to:
 - Promote the values of Rigour, Respect and Responsibility,
 - $\circ~$ Have respect for life, the law and the public good,
 - $\circ\;$ Take steps to prevent corrupt practices and professional misconduct,
 - Minimise adverse effects their work may have on people,
 - o Act responsibly, and
 - Do not knowingly mislead others, and
 - Present and review scientific evidence honestly and accurately.
- In the above-mentioned BBC article, a member of the ACDP is reported as having stated that:
 - The decision to remove COVID-19 from the list of 'High Consequence Infectious Diseases' was "pragmatic" because they knew that the stockpile of PPE was limited.
 - They "couldn't have given everybody an FFP3 there was no question of getting that quantity".
 - Public Health England and the Department of Health may "possibly" have used the decision as a cover for a change in clinical guidance.
 - $\,\circ\,\,$ This is an area that may warrant closer scrutiny during any future inquiry.

⁴⁹ COVID PPE: How healthcare workers came to feel 'expendable' – BBC (6 February 2021)

⁵⁰ <u>Universal Ethical Code for Scientists – Government Office for Science (Sept 2007)</u>

9. DECISION-MAKING TIMELINE: 13 - 21 MARCH 2020

The following is an analysis, based on such information as is available in the public domain, of the timeline of the days in March 2020 which led to the downgrading of respiratory protection for healthcare workers:

Friday 13 March, 11.00am: Two important committee meetings were concurrently in progress via Zoom:

- 'NERVTAG' (New & Emerging Respiratory Virus Threats Advisory Group) met with the Deputy Chief Medical Officer (DCMO) Professor Jonathan Van Tam and his colleagues from the Department of Health (DHSC). The minutes of that meeting ⁵¹ record that:
 - New IPC guidance was proposed and the DCMO had already sent a draft to the NHS the previous day.
 - The DCMO explained that:
 - the new guidance allowed for faster decontamination of ambulances,
 - that under the HCID specification it takes three hours to decontaminate an ambulance, and
 - guidance is required for a simpler and faster method,
 - The new guidance recommends the use of fluid resistant surgical masks (FRSM) outside of AGP hotspots, as opposed to the HCID recommendations of FFP3 respirators.
 - Representatives of DHSC who accompanied the DCMO at the meeting noted that they are "moving away from FFP3 towards FRSM".
 - NERVTAG members then discussed the argument for the reclassification of COVID-19 from a high consequence infectious disease (HCID). This would have to be done by the ACDP.
 - The DCMO agreed to discuss this issue with Professor Tom Evans (ACDP Chair) and communicate the recommendation from NERVTAG to ACDP that they urgently reconsider the classification of COVID-19 as a HCID (in other words urging them to declassify it).
 - The DCMO then left the NERVTAG meeting and phoned Professor Evans who was in the middle of his ACDP meeting (see below).
 - A short while later Professor Evans confirmed that ACDP members unanimously agreed that COVID-19 should be removed from the HCID list.
 - This was communicated back to the ongoing NERVTAG meeting by Dr Jim McMenamin.
 - Professor Evans subsequently confirmed the decision by letter to Professor Van Tam ⁵².
 - The NERVTAG minutes are finalised with a note that "ACDP & SAGE have declassified COVID-19 and it is no longer a HCID".
 - It is difficult to understand the reference to "SAGE having declassified COVID-19".
 - An examination of all SAGE minutes between 10 March and 29 March (including the meeting on 13 March) show that HCIDs were not discussed at any of their meetings.
 - This would have been known to the DCMO who had attended all the recent SAGE meetings.

⁵¹ NERVTAG COVID-19 Meeting – New and Emerging Respiratory Virus Threats Advisory Group (13 March 2020)

⁵² Letter Prof T Evans (Chair ACDP) to Prof J Van Tam (DCMO) (13 March 2020)

- The ACDP committee was meeting ⁵³ at the same time as NERVTAG:
 - The agenda of was solely to discuss safe transport of clinical samples (packaging and labelling). Discussion of COVID-19 as a HCID was not on the agenda.
 - Under 'Any Other Business', Professor Evans informed the group that he had been contacted by DHSC (presumably the DCMO) regarding the classification of COVID-19 as a HCID. The minutes record that the Committee unanimously agreed that COVID-19 should not be classified as a HCID. It is incredible that such an important decision was taken under 'AOB', seemingly with minimal discussion and with no time to refer to any documents or evidence supporting such a move.

Thursday 19 March: '4 Nations Public Health HCID Group' also confirm COVID-19 is no longer a HCID.

Saturday 21 March: PHE formally issue revised IPC guidance (when to use a face mask or FFP3).

Saturday 21 March: CEBM searching internet sources for evidence which may support use of FRSMs.

Monday 23 March: CEBM finalise and publish report claiming "FRSMs as effective as respirator masks for preventing infection of healthcare workers".

The minutes of the NERVTAG meeting suggest that the draft of the document containing the new Infection Prevention and Control policy had already been written and sent to the NHS on the 12 March (including the change in PPE requirements). This was the day before the NERVTAG meeting and the decision of the ACDP meeting. This suggests some remarkable prescience of the decisions that would be made by the NERVTAG and ACDP committees the following morning.

The minutes of the previous NERVTAG meeting⁵⁴ on 6 March reveal that a draft of the revised IPC guidance had been introduced by PHE representatives, stating that healthcare workers would wear a surgical facemask rather than a FFP3 respirator when dealing with <u>suspected</u> COVID-19 cases.

The NERVTAG Chair (Professor Peter Horby) immediately asked PHE to clarify why this had changed. Dr Jake Dunning of PHE responded that because not all suspected cases would actually be COVID-positive, it was reasonable to preserve stocks of FFP3 respirators for the <u>confirmed</u> cases and AGPs.

This indicates that PHE were content to accept the risk of infection to healthcare staff dealing with suspected, as yet unconfirmed cases such as ambulance crews, GPs and staff in emergency departments.

It also clearly demonstrates that, at that time, PHE considered that the full PPE protection of FFP3 respirators should be afforded to healthcare workers who were dealing with confirmed cases.

Yet just six days later, on 12 March, the guidance sent by the DCMO to NHS England had been changed to the effect that even staff who were dealing with confirmed cases would only be provided with surgical masks and not be given FFP3 respirators for protection. This was a major 'U-turn' in policy and a fateful decision to which thousands of subsequent infections of healthcare workers may arguably be attributed.

Further scrutiny of the NERVTAG minutes on 6 March reveals that the driver for this U-turn was a looming shortage of FFP3 respirators. Two NERVTAG members reported that their hospitals were experiencing issues with the supply of FFP3 respirators, and this seemed to be a wider issue.

⁵³ ACDP COVID-19 Meeting – Advisory Committee on Dangerous Pathogens (13 March 2020)

⁵⁴ NERVTAG COVID-19 Meeting – New and Emerging Respiratory Virus Threats Advisory Group (6 March 2020).

The main difficulty clearly faced by the DCMO and his colleagues was that the protocols for personal protection of healthcare staff whilst dealing with a suspected or actual case of HCID require the use of FFP3 respirators (or powered respirators) and downgrading respiratory protection to surgical masks would not be consistent with HCID rules. It is not therefore surprising when, on 13 March, the DCMO had words with the NERVTAG and ACDP committees, who readily agreed to declassify COVID-19 as an HCID.

Yet PHE have categorically denied that the switch from FFP3 respirators to surgical masks was driven by a shortage of FFP3 respirators. They cling to the reasoning that their guidance is based on the 'mode of transmission' and "was not related to shortages or rationing of PPE". A year later, when it is understood that the PPE supply situation is very much improved, PHE/DHSC continue to deny healthcare workers the protection they so deserve. Whilst their Minister, Jo Churchill MP, states that "frontline staff should determine PPE requirements based on risk assessments at an organisational level", in practice Health Trusts and Clinical Commissioners point back to PHE guidance as evidence that surgical masks are satisfactory.

10. CONCLUSIONS

There is a groundswell of evidence from credible sources of scientific information that aerosols play a significant role in the transmission of the SARS-CoV-2 virus.

There is abundant evidence that fluid resistant surgical masks provide a woefully inadequate standard of protection against inhalation of aerosols and indeed they are neither designed, constructed, nor certified to do so. A major source of such evidence is the UK's acknowledged experts on all matters pertaining to respiratory protection, the Health and Safety Executive, in particular the research work it undertook for the Government in 2008 in order to prepare for just such a pandemic as now grips the country. Their tests revealed the presence of live viruses on the inside of every single surgical mask tested.

Serious questions need to be asked about the decision-making processes that took place in March 2020.

The decisions made and advice given by scientists of all disciplines need to be scrutinised against the code of conduct referred to in section 8. It is recommended that an independent scientist of the calibre of Sir David King (who championed that code of ethics) should be invited to lead such an inquiry.

In the event that these matters do eventually come before a Court or a public inquiry then there is a distinct possibility that, on the balance of probabilities:

- The disease caused to healthcare workers may be attributed to the inhalation of SARS-CoV-2 virus through the inadequate protection afforded to them by the wearing of surgical masks,
- The information upon which they and their employers relied was misleading, in that it assured them that these masks adequately protected them,
- This, in turn, resulted in a false sense of security for the workers and their employers, and
- This, in turn, meant that other safety precautions were not implemented which might have had a beneficial effect in reducing their risk of contracting the disease.

Organisations are not generally inclined to spend time and money on additional precautions if they have been led to believe that the existing precautions (masks in this case) are perfectly satisfactory. Such additional precautions might have included provision of readily available and reasonably practicable risk control measures in healthcare settings, for example:

- improved ventilation
- additional Perspex screens
- reducing the amount of time spent in the close vicinity of COVID-positive patients to the minimum required for the performance of duties.

Policymakers in Government fail to heed the concerns and entreaties of medical professionals from across a wide range of health-related disciplines. They appear fixated upon the principle that it is only 'respiratory droplets' (sized between 5 and 10 microns) that need to be considered in terms of disease prevention and steadfastly resist the notion workers need to be properly protected against naturally occurring aerosols (smaller than 5 microns). Day by day this dogma becomes more and more untenable as fresh evidence emerges, healthcare workers become infected with this, and sadly a number go on to die.

Their central principle of policy is that the primary mode of transmission is hand-to-mouth. This means that infected respiratory droplets (e.g., from coughs and sneezes) are of a size that they fall to the ground or onto

a surface within a metre or so. From there someone touches that surface with their hand and then touch their mouth, nose or eyes, and the virus gains entry into the body and starts the disease.

The key point here is hand-hygiene (thorough washing of hands, use of hand-sanitisers, etc). NHS and healthcare workers are probably the most unlikely people in the world to experience hand-to-mouth contamination. They work to world-class standards of infection prevention and control and are highly trained and disciplined. Additionally, the entire IPC regime is subject to regular management monitoring and independent auditing by the Care Quality Commission.

If the hand-to-mouth route is the primary cause of disease as the Government steadfastly maintains, these workers would be experiencing a lower rate of infection than the rest of the population. Yet the statistics presented in section 3.2 clearly demonstrate an above-average rate of infection and death in other occupations. The only other credible explanation is that these workers are contracting the disease via the air they breathe when caring for and treating COVID patients. This calls into question the policy-makers assertion that surgical masks are providing an effective level of protection.

As discussed in section 7, the use of 'semi-disposable' P3 masks might be considered as a stockpiling strategy for possible future pandemics.

Further, the criteria pertaining to the inclusion of diseases on the HCID list should be reviewed in line with the observations made in section 4.1.2.3 above.

The Health and Safety Executive's approach to decision-making when reducing risks to people involves the 'Precautionary Principle'⁵⁵. The HSE explains that this is:

"The precautionary principle describes the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty and rules out lack of scientific certainty as a reason for not taking preventive action."

This report has shown that the Government and its key departments such as Public Health England and the Department for Health and Social Care need to pay closer attention to this approach in order to improve their response to the current pandemic, as well as to those that might arise in the future.

⁵⁵ <u>Reducing Risks, Protecting People, HSE's decision making process C100</u>

APPENDIX: GLOSSARY OF ACRONYMS

Acronym	Meaning
ACDP	Advisory Committee on Dangerous Pathogens (Expert Committee DHSC)
AGP	Aerosol Generating Procedure
ARHAI	Antimicrobial Resistance and Healthcare Associated Infection
BMA	British Medical Association
CEBM	Centre for Evidence-Based Medicine, University of Oxford
CFR	Case Fatality Ratio (sometimes called 'Case Fatality Rate')
DCMO	Deputy Chief Medical Officer
DHSC	Department of Health and Social Care
FFP	Filtering facepiece (tight-fitting respirator mask - FFP3 more efficient than FFP2)
FRSM	Fluid Resistant Surgical Mask (otherwise known as 'medical masks'
НСР	Healthcare Professionals
HDU	High Dependency Unit
HPA	Health Protection Authority (predecessor organisation of Public Health England)
HPS	Health Protection Scotland
HSE	Health and Safety Executive (Regulatory Body)
IOSH	Institution of Occupational Safety and Health
IPC	Infection Prevention Control
JICS	Journal of the Intensive Care Society
MERS	Middle East Respiratory Syndrome
MHRA	Medicines and Healthcare products Regulatory Agency (a department within DHSC)
N95	A filtering facepiece to an American standard. Equivalent to our FFP2
NERVTAG	New and Emerging Respiratory Virus Threats Advisory Group (Expert Committee DHSC)
ONS	Office for National Statistics
OSHCR	Occupational Safety and Health Consultants Register
PHE	Public Health England
PPE	Personal Protective Equipment (as defined under Health and Safety Legislation)
RCN	Royal College of Nursing
RCT	Randomised Control Trial
RPE	Respiratory Protective Equipment (e.g., FFP Respirator masks, powered respirators etc)
SAGE	Scientific Advisory Group for Emergencies
SARS	Severe Acute Respiratory Syndrome
URL	Uniform Resource Locator (address used to access a website on the internet)
WHO	World Health Organisation