ILG0015

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INTRODUCTION

In line with guidance on the Parliament.UK website I should start by introducing myself and explain why I am entering this evidence for the Committee's consideration.

Personal background:

- I am a Chartered Occupational Safety and Health Practitioner with 27 years' experience in the profession of Health and Safety.
- I work as an accredited consultant, being listed on the Occupational Safety and Health Consultants Register . This register was established as an initiative by the Health and Safety Executive (HSE), following the Government's 'Common Sense, Common Safety' report (2010).
- My specialist area is protection of health from hazardous substances (a term which includes chemical and microbiological hazards to health).
- I am a consultee member of the Health and Safety Executive's (HSE) 'COSHH Essentials Working Group' (CEWG). Together with other representatives from industry, academia and trade unions I assist the Executive in preparing 'user-friendly' guidance for employers and employees as to how to keep healthy and safe when working with hazardous substances. That said, the evidence I shall present in this report is submitted on a personal basis and does not reflect the views of the CEWG or the HSE.
- As a result of my professional background I have a reasonably sound knowledge of:
  - health and safety legislation and official guidance;
  - Personal Protective Equipment (PPE) and especially Respiratory Protective Equipment (RPE).
  - The technical standards which relate to the manufacture, testing and supply of PPE and RPE.
  - Microbiology: A component of my B.Sc. degree in biochemistry.
  - Epidemiology: Earlier in my career I was a tutor for the National Examination Board in Occupational Safety and Health, tutoring on their diploma-level courses.

Reasons for submission of this evidence:

- In January 2021 I saw a TV news item which showed workers in a care home tending to COVID-positive patients wearing surgical masks for respiratory protection. I also heard mention of surgical masks as being "PPE", which they are not – at least not as legally defined in the UK.
- I queried this with HSE who in turn directed me to the Infection Prevention and Control (IPC) guidance published by Public Health England (PHE).
- At this point I realised to my considerable alarm that these surgical masks, which are quite inadequate for protecting people against lethal airborne diseases, were mandated for use in the general management of COVID-positive patients (or patients who were suspected to be) in settings such as general wards, ambulances and private homes, care homes etc. The correct RPE (FFP3s and equivalent) which they should have been using in all these workplace environments was restricted just to certain aerosol generating procedures (AGPs).
- I confirm that neither this report nor any of my involvement with issues around respiratory protection of healthcare workers (HCWs) during the COVID-19 pandemic is in any way funded.
- I have involved myself simply through a sense of moral and ethical duty, recognising that so many of these good people (for whom we so enthusiastically clapped last year), have been badly let down by the provision of woefully inadequate respiratory protection that has endangered their lives.

- I also became aware of groups of medical practitioners such as the 'AGP Alliance' and 'FreshAir NHS' who have been struggling to persuade these government departments (a) to recognise that COVID-19 is transmitted via the airborne/aerosol route and (b) to change their policy to enable HCW protection with more effective respiratory protection such as FFP3 masks, reusable or powered respirators.

Aims and Objectives:

- The evidence I am providing is submitted with the sole intention of providing the committee with an independent and unbiased view of all aspects relating to:
  (a) airborne/aerosol transmission; and
  (b) to the respiratory protection of HCWs.
- I apologise to the committee in advance that this is not a short report. As will be seen from my summary below, the subject covers many different facets. Whilst I will be as concise as I can, my purpose is to provide the committee with sufficient detail to be able to arrive at an informed opinion on these matters. The intention is for this document to provide a 'one-stop shop' on each of these different facets.

I should like to emphasize that my purpose in submitting this evidence is not to assign blame or recrimination to any individuals or organisations. In line with the Committee's stated objective in calling for this evidence, I am solely focused upon helping the Government to learn any lessons which need to be learned with a view to changing policy (where it needs to be changed). My motivation for submitting this evidence is to help protect HCWs and their patients, not just in future pandemics but in the remainder of the current pandemic which appears may yet have some way to run given uncertainties about variants emerging which may escape the vaccines.

By way of explaining the protocol in my report:

- Links to documents on the internet which support my evidence will be provided in-text (blue, underlined) rather than as footnotes. I feel this makes it easier for the reader to visit those websites.
- Where I have advice about something which the Select Committee may wish to do, I will put it in **bold type**. For instance, where I have submitted a Freedom of Information Act request for a document and been denied on the grounds of "Not in the Public Interest" the Committee may well wish to request sight of such documents.
  I will summarise these in my closing remarks at section 13.

1. SUMMARY

Since the purpose of this exercise is to 'learn lessons' I shall focus on issues arising from the early days of pandemic (March 2020) where crucial decisions were made upon which the lives and welfare of millions of citizens in the UK would depend.

It will be for the Select Committee and/or the Public Inquiry to determine the rights and wrongs of any individuals or organisations. I would not presume to venture any opinions on this. However, 'prima facie' evidence suggests that tens of thousands of HCWs acquired the disease through having being fed the myth that surgical masks would protect them against the disease when, in fact, airborne viruses (virions) attached to aerosols were circumventing and penetrating these masks and passing unimpeded into their lungs with every breath they took whilst in close contact with infectious patients.

Hundreds of these HCWs died of the disease. Amongst these, tragically, are some who had retired and "answered the Government's call" to come back and help, only to be betrayed by a lack of suitable personal protection. An estimated 122,000 HCWs are now suffering from 'Long Covid'. Many are considering quitting their professions.

Whilst some of these infections may have been acquired at home or in their communities, the statistics suggest that they acquired it in their workplace. I firmly believe that the primary source of infection was the inhalation of aerosols whilst caring for infected patients at close quarter. It will be for the Committee and any subsequent Public Inquiry to decide whether, on the balance of probabilities, this was the case.

As will become apparent from the evidence which follows, the underlying reasons for this situation can be traced back to decisions made by PHE and the Department of Health and Social Care (DHSC) in the first few days of the pandemic (mid March 2020) and the ensuing dogma and policies adopted by these two departments . "Dogma" being the endless debates about "respiratory droplets vs aerosols" and "Policies" being the provision of surgical masks for respiratory protection.

Another organisation which I am sure the Committee will wish to investigate is the HSE, the Regulatory body. As a safety practitioner I have the greatest respect for the work of the HSE but I am astounded that they have stood by, allowing PHE/DHSC to promulgate the myth that surgical masks were "Personal Protective Equipment" which would protect them against a lethal respiratory disease. For whatever reason, the HSE has either been powerless or unwilling to intervene.

The HSE has provided guidance in relation to the statutory reporting legislation known as RIDDOR, which has allowed healthcare employers a 'loophole' by which they do not need to report COVID deaths and disease amongst their workers, provided that the PHE/DHSC guidance of wearing surgical masks was being followed. This could make it very difficult for the Committee to obtain a true picture of the number of casualties arising from this flawed policy. It could also make it particularly difficult for HCWs suffering long-term consequences of the disease to claim entitlement to Industrial Injuries Disablement Benefit if this should prove to be needed.

It is my opinion, shared by a great many front-line medical professionals, that the decisions which related to the mechanisms and routes of disease transmission were wrong, in that the authorities (including the World Health Organisation {WHO}, PHE and DHSC) resolutely rejected the notion that the disease could be spread via the airborne route i.e. via aerosols emanating from an infected person's lungs.

They fiercely defended their view that the main route for transmission was via "respiratory droplets" emitting from an infected person either:

a) being ejected by coughing, sneezing, talking or singing directly into the face of a person close by; or
b) falling onto surfaces within approximately 2 metres. Another person may then touch these surfaces, on which infectious residues (known as fomites) remained infectious for some time and, by then touching their nose, mouth or eyes may start the infection.

What they failed to take into account was that, along with each cough, sneeze etc, thousands of smaller aerosol droplets would also be emitted which, being so small, would not be readily dragged downwards by gravity and could remain airborne for several hours, particularly in rooms with poor ventilation. Clearly the closer a HCW is to the face of an infectious patient, the greater the concentration of airborne virus will be in the invisible 'plume' of aerosol surrounding the patient.

The wearing of face visors and surgical masks by staff would greatly reduce the potential for hand to mouth/nose/eye transfer of fomites – and, indeed, greatly reduce the direct mouth to mouth/nose/eyes transmission route referred to in (a) above.

The IPC guidance also places emphasis on the infectious patient also wearing a surgical mask (where clinically safe to do so) in order to reduce droplet transmission from them to HCWs. Whilst the fluid resistant properties of the surgical masks will achieve this, probably to quite a large extent, virus-laden aerosols from the patient will still escape into the air around them by virtue of the fact that the masks are not tight fitting to the face. As will be seen later in my evidence, the transmission of disease between two persons both wearing surgical masks has been conclusively been proven.

As will be discussed further, later in this report, if fomite transmission was a major reason for disease spread then hospitals, ambulances (etc) would be amongst the safest places to be, with their high standards of infection prevention and control regimes (and auditing thereof), training, cleanliness and widespread availability of hand-sanitisers.

In reality, we know very well, that hospitals have been just the opposite. They have certainly not been amongst the safest work environments to be. That, in itself, is evidence that the policy relating to PPE has been wrong all along. The Chair of your Select Committee is to be commended for recognising (and being willing to publicly state) that between 20-40% of deaths have occurred as a result of infections acquired in hospitals (known as 'nosocomial infection'). He is absolutely right to insist that we need to investigate the reasons for this and learn lessons for the future.

Unfortunately though, I anticipate that the Select Committee will come up against a vehemently held view, expressed by HSE and a sub-group of SAGE namely the Environmental Modelling Group (EMG) who presented a biased and technically unsound paper to the SAGE Meeting 84 on 25th March 2021. I use the term 'technically unsound' from a health and safety perspective. I will elaborate in a critique of that paper at section 10 below.

In the EMG paper, the authors (including Professor Andrew Curran, HSE's Chief Scientific Advisor and Chair of EMG) appear to shift blame away from PHE/DHSC's flawed IPC policy onto Trusts and the healthcare workers themselves for spreading the disease between themselves by not complying with COVID-security rules.

This represents the most unspeakable effrontery to our dedicated NHS staff who, with all the death and suffering they witnessed on a daily basis (including their work colleagues), will have been only too astutely aware of the risks of this terrible disease and the importance of following COVID-security guidance to the best of their ability in order to protect themselves, their colleagues and their patients. Any slip-ups could possibly be explained by physical, mental and emotional exhaustion.

The authors then go on to misuse and abuse the fundamental tenets which underpin good health and safety practices which have served the UK so well for decades (namely the 'hierarchy of risk control' and the 'Precautionary Principle'). So, within my critique of the EMG paper, I shall expand on these points.

It was this preoccupation with the concept of fomite transfer which caused the Government, in the early days, to focus the public's attention on "washing hands and singing happy birthday twice". A cynic might suspect that the real reason for this is that they knew (or suspected) that the disease could be transmitted by the airborne route, but didn't want the public and businesses making a rush for supplies of respirator masks, thereby leaving insufficient for the protection of HCWs.

Whilst that was a fair point, there are other ways of preserving RPE stocks by introducing emergency legislation constraining the sale of such items whilst, at the same time, introducing measures for other forms of face-coverings for the public and businesses.

Similarly it was wrong to mislead HCWs that surgical masks adequately protect them. An analogy might be drawn between sending HCWs to fight a war against a virus on the one hand vs soldiers being sent to fight a battle with rifles loaded with blank ammunition.

It appears that, through lack of planning and preparedness, we didn't have sufficient stocks of FFP3 masks to go round and many in the stockpile had gone past their 'use-by' date.

The Committee may also wish to make a recommendation that, apart from stockpiling RPE, the UK should have sufficient manufacturing capability to ensure a sufficient and continuous supply of respiratory equipment for a long-enduring pandemic to all those who need it. The emphasis should be on reusable respirators (with replaceable filter cartridges) and/or powered respirators rather than disposable FFP3 masks which are relatively expensive and environmentally unfriendly (as regards the waste stream).

The Committee may wish to enquire into the circumstances surrounding the change of policy that occurred on Friday 13th March 2020. Prior to that date, the policy had been to provide HCWs with FFP3 masks. Many had been trained and 'fit-tested' in readiness for this.

There is evidence that, just prior to the 13th March, the Deputy Chief Medical Officer (DCMO) had already issued draft guidance to the NHS that fluid resistant surgical masks (FRSMs) would be used instead of FFP3 masks. The problem was that since COVID-19 was classified as a High Consequence Infectious Disease (HCID), the rules specified that respiratory protection to the standard of FFP3 respirator masks had to be used to protect HCWs and it was evident that there were insufficient to supply these.

There then followed some hurried discussions between the DCMO, NERVTAG and ACDP committees with the result that, within 2 hours and without any scrutiny of evidence-based research papers, COVID-19 was conveniently declassified as an HCID. The minutes of the NERVTAG meeting recorded that SAGE had also approved the declassification, yet SAGE minutes reveal no evidence of the matter having ever been discussed by them.

Within a few days the new guidance mandating surgical masks instead of FFP3 was issued across the UK and within a few weeks the infection and fatality rates amongst HCWs began inexorably to rise.

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 stated that "the mask is worn to protect you, the care worker":

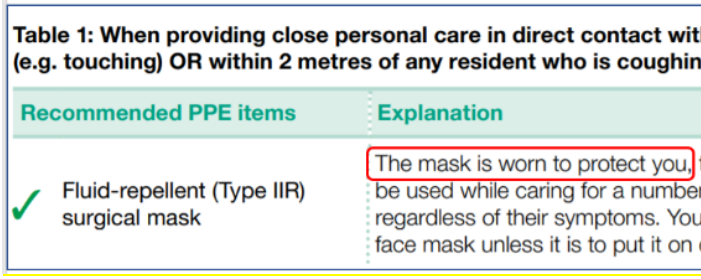


Table 1: When providing close personal care in direct contact wit
(e.g. touching) OR within 2 metres of any resident who is coughin

Recommended PPE items	Explanation
✓ Fluid-repellent (Type IIR) surgical mask	The mask is worn to protect you, be used while caring for a numbe regardless of their symptoms. You face mask unless it is to put it on

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

This unambiguous statement informed the worker that this mask would protect them. The worker would reasonably assume that this means 'protect them against catching COVID-19'. It referred to the mask as 'PPE' which, as will be discussed later, it is not. This is a dangerous and recklessly misleading statement.

The preamble of this document stated:

> *"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' would not have meant 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, constructed nor tested against recognised standards for 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 was repeated in many other documents issued by PHE and other departments. However, the central document which set out official UK policy reiterated the statement in Figure 1 above. In this way, the misconception of surgical masks being 'PPE' was promulgated throughout all associated guidance by other Government Departments, with the notable exception the Health and Safety Executive. 'PPE' is not a term HSE would 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) .

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’.

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. 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.

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, by way of background information for the Committee, 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 that were expounded by the World Health Organisation and PHE/DHSC were 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 hours.

- 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

At the outset of the pandemic, WHO/PHE/DHSC focussed on two main methods of disease transmission. These both stem from the emission of respiratory droplets from infected patients (e.g., coughing, sneezing, speaking or singing).

One method of transmission is where the droplets travel through the air and land directly on the mouth, nose or eyes of another person, from where the disease takes hold.

The other method of transmission is where the 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).

The WHO/PHE/DHSC always considered that droplets emitted from infected patients are 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. Their approach has only been to consider aerosols to be an issue if certain medical procedures are being performed, known as aerosol generating procedures (AGPs).

If PHE/DHSC policy was 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.), then staff wearing surgical masks should not have been contracting the disease.

However, the opposite is true. A report shows that there has been 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).

If PHE/DHSC were correct in their assertion 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 have been contracting COVID-19 through the 'hand-to-mouth' route is highly improbable due to:

- the general standards of cleanliness and hygiene in their various workplaces,
- the diligence with which Infection Prevention and Control measures are implemented and monitored,
- 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 their strategy for respiratory protection into question.

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 Rate. 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%	UK value at October 2020
SARS-CoV (2003)	15%	WHO Consensus value
Pandemic Flu (1918)	2 - 3%	

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 ACDP is involved in compiling and maintaining two lists relate to the hazard severity of pathogens.:

- The Approved List of Biological Agents, and
- The List of High Consequence Infectious Diseases (HCID) (in collaboration with the 4 Nations Public Health HCID Group)

4.1.1. Approved List of Biological Agents

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 2:

Information box: Hazard group definitions When classifying a biological agent it should be assigned to one of the following groups 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 2: 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. 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.

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

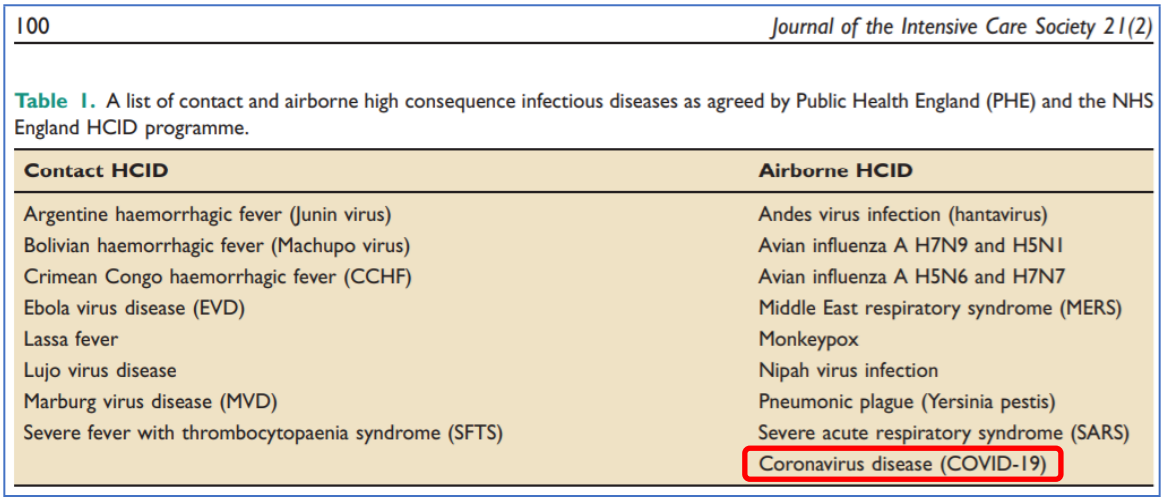
4.1.2.2. Status of SARS in the HCID List

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) 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 1. A list of contact and airborne high consequence infectious diseases as agreed by Public Health England (PHE) and the 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)
	Coronavirus disease (COVID-19)

Figure 3: List of HCIDs per JICS article

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".

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 were so fiercely resistant to the notion that the SARS-CoV-2 virus can be spread by naturally generated aerosols, and that they denied healthcare workers exposed to such aerosol emissions the filtering masks that would protect them from the disease.

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 4: List of HCIDs per Government website

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:

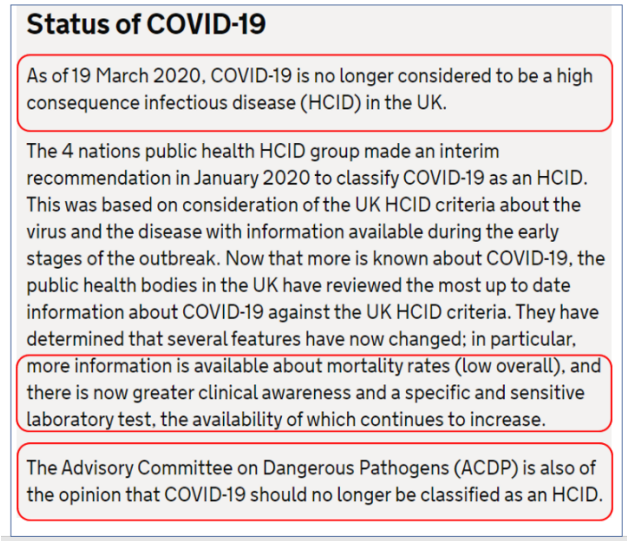
At both times it was known that:

- 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 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 5: Screenshot from PHE's HCID page confirming criteria for removal

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' still remained the case and would have justified retaining 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%. 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%) and yet, in January 2020 the 4 Nations HCID Group and ACDP clearly agreed it was of sufficient concern to be classified as an HCID, despite its relatively low CFR.
    - 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 / 4 Nations HCID Groups' decision to include COVID-19 in the HCID list would presumably have been based on these sorts of figures.

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, 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
Avian influenza A H7N9	From birds. No sustained human-to-human transmission
Avian influenza A H5N1	From birds. No sustained human-to-human transmission
Avian influenza A H5N6	From birds. No sustained human-to-human transmission
Avian influenza A H7N7	From birds. Only one fatal case. Mild or sub-clinical: few hospitalised
Middle East Respiratory Syndrome (MERS)	Limited human-to-human infection. No sustained human-to-human transmission
Monkeypox	From a variety of animals. Limited human-to-human infection
Nipah Virus	From animals. Mostly from pigs. Human-to-human possible
Pneumonic Plague	Human-to-human definite
Severe Acute Respiratory Syndrome (SARS)	Human-to-human definite

Table 2: Transmission of airborne High Consequence Infectious Diseases

It is noted that Avian Flu A (H7N7) had, according to the World Health Organisation, 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'.

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 Select Committee may wish to recommend that the criteria for adding diseases to the HCID list should be reviewed and 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 was that they only allowed 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 has 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.

4.2.2. Aerosols from other sources

This debate has recently been widened with research published in Bristol, 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.

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 RR619 cast serious doubt on the pre-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."
- In her letter to me dated 20th April 2021, Ms Sarah Albon, Chief Executive of the HSE, confirmed that "*surgical masks … should not be used in situations where close exposure to infectious aerosols is likely*". Admittedly this was written ten days prior to the date when WHO and PHE changed their guidance to accept that close exposure to aerosols is now considered a genuine route of disease transmission – but this makes her comments all the more pertinent.

  I have had considerable correspondence with the HSE on this matter between February and April. I will be happy to provide copies to the Select Committee should you so wish.

5.1.2. National Institute for Occupational Safety (NIOSH)

The US National Institute for Occupational Safety and Health commissioned research 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".

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. 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. 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 transmission 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 intended to be a barrier to infection of others though they do offer limited protection to the wearer. (The limited protection is against splashes of blood and other bodily fluids)
- (Note: The tests performed on the mask are from the inside out in order to assess performance in reducing outbound 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.

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.
- Research has shown that these very small aerosols (0.2 to 0.6 microns) arise from the tiny airways (bronchioles) 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.

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

Research carried out in Boston, USA has conclusively confirmed the transmission of SARS-CoV-2 between patients and their healthcare workers despite both parties wearing 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.

  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.

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.

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 [1] 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 sub-paragraph (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).

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 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 flu, 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.

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.

[1] 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.

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. **The Select Committee may wish to request sight of that document since my FoI request has been denied on the basis that it is "not in the public interest"**
    - 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.
- 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 **H**ealth **S**ervice **E**xecutive in Ireland (the Irish equivalent of the NHS) and not the UK **H**ealth and **S**afety **E**xecutive. Such is the level of attention to detail in a document which is relied upon (along with other evidence) by the DHSC's "IPC Cell" to set policy upon which the health, safety and protection of healthcare workers across the UK is founded!

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". **I can provide the Select Committee with copies of this correspondence from PHE if required.**

Whilst that reassurance is welcome news, it is rather contradicted by the rapid evidence review by the Centre for Evidence-Based Medicine in Oxford 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 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.

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 suggests that a member of the ACDP has already admitted that this was exactly the case. **The Select Committee may wish to take evidence from the members of the ACDP Committee to establish the extent to which this is true.**

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'. 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,
    - Have respect for life, the law and the public good,
    - Take steps to prevent corrupt practices and professional misconduct,
    - Minimise adverse effects their work may have on people,
    - Act responsibly, and
        - Do not knowingly mislead others, and
        - Present and review scientific evidence honestly and accurately.
- **The Select Committee may wish to forward a copy of my evidence to Sir David King for an opinion. I am certain that the Committee would benefit from harnessing his expertise, knowledge, background and high standards of personal ethics.**
- 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.
    - This is an area that may warrant closer scrutiny during any future inquiry.

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 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 3 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.
    - 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.
- The ACDP committee was meeting 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).

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 Select Committee may wish to request sight of that document, as it existed on 12th March. My Freedom of Information request to PHE (ref 28/03/LD/3139) has been denied as it is apparently "not in the public interest" for me to see it.**

If this document does recommend FRSMs instead of FFP3s then this will add weight to the argument that the declassification of COVID-19 as an HCID was indeed a 'political manoeuvre' to pave the way to implementing this policy of reduced protection for healthcare workers.

The minutes of the previous NERVTAG meeting 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 suspected 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 confirmed 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.

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. A RESPONSE TO SAGE REPORT S1169 : MASKS FOR HEALTHCARE WORKERS

During my correspondence with Ms Sarah Albon (Chief Executive, Health and Safety Executive) Ms Albon confirmed that the HSE were actively involved in the preparation of a report for SAGE which would be published on 23rd April 2021. Once that paper was published, on 16th May, I replied to Ms Albon with a 'critique' of that paper from the perspective of a health and safety practitioner. I would like to present that 'critique' as a part of my evidence to the Select Committee as follows:

I am not just disappointed, but utterly dismayed, at the way the fundamental principles which underpin good health and safety practice in this country (the 'hierarchy of risk controls', 'precautionary principle' etc) have been so contorted and wilfully misused in an attempt to dismiss the contribution that effective respiratory protection (such as FFP3 respirators, reusable half/full-face respirators or powered respirators) can play in the close-quarter care of infected patients.

Although there are one or two helpful comments in the paper, the overall theme, tone and direction of the paper comes across as having a deliberate and carefully considered intention objective of providing a platform upon which the PHE/DHSC IPC policy-makers may continue on their unswerving path of denying HCWs the respiratory protection which they so richly deserve against this disease.

10.1 Authors

Most scientific papers include, within the document, details of the authors. For documents which serve to advise Government on important matters such as this, it should be made clear exactly who has authored the document since they may, at some stage in the future, be called upon to justify (and be questioned under oath upon) their evidence. This could happen at a public inquiry, judicial review or civil litigation brought by bereaved families or trade unions.

I see that Professor Andrew Curran, HSE's Chief Scientific Advisor, is Chair of EMG. I therefore assume that he is responsible for contributing (or at least overseeing) the content relating to the health and safety content of the document ('hierarchy of risk controls', 'precautionary principle', information about HSE inspections at hospitals etc).

10.2 Suitability of Fluid Resistant Surgical Masks (FRSMs) for protection of HCWs

The authors of this paper cannot possibly have been unaware of the debates and arguments raging as to whether FRSMs provide wearers with sufficient protection against airborne transmission of the disease from person to person.

Given the title of this paper, this was a golden opportunity to have set this matter to rest, once and for all, and confirm that FRSMs do not provide 'inbound' protection against inhaling the virus once airborne due to (a) their construction and (b) the loose fit of the masks. As such, this was an opportunity missed.

One can only speculate that the reason for this arises from an understandable reluctance to admit that all PHE/DHSC guidance hitherto on this topic to date has been wrong and misled HCWs into believing that these masks adequately protect them, thereby engendering a false sense of security. To what extent this may have led to infection, illness and death amongst HCWs is a matter for others to adjudge in a legal setting, but on the face of it there is most certainly a case to answer.

It is good to note on page 8 that the authors confirm, in a discussion about airborne vs droplet transmission, that where pathogens are classed as 'Airborne', "***strict PPE controls are required, including FFP3 masks*** ".

Professor Curran and the other authors should be aware that, as confirmed in a **paper** way back in April 2020, both PHE and NHS England had **classified COVID-19 as an 'airborne' disease**. Furthermore, as already mentioned, since the SAGE document was published last month, **WHO guidance** has now confirmed airborne transmission via aerosols at close range.

10.3 HSE's view on nosocomial transmission arising from hospital inspections

The HSE view, expressed in Ms Albon's letter to me and echoed in the SAGE paper is that there are "multiple factors which affect nosocomial transmission". It seems that HSE place great emphasis on the limited number of

inspections that they have made of hospitals during the second wave. I am no statistician but inspections of just 17 out of the 1200+ hospitals in the UK does not seem sufficient to withstand much scrutiny from a statistical perspective.

On page 15, detailed statistics of HSE's findings are presented (eg that 8 hospitals out of 17 = 47%). Whilst this demonstrates dextrous use of a calculator to perform simple calculations, it would have been more meaningful had they also analysed the actual infection/death rates (i.e. infections/deaths per number HCWs involved in close-contact care of covid patients) between these 17 hospitals. This would have given a better indication as to whether the compliance aspects to which the HSE frequently refers in the paper, had any actual bearing on disease transmission in comparison to infections contracted through close patient care.

No evidence is provided whatsoever that the compliance issues at the 8 hospitals of concern to HSE actually correlate to any increased disease transmission in those hospitals and yet these statistics are then used to steer attention away from providing respiratory protection and focus mostly on management and behavioural issues by staff.

I note that there are multiple references throughout the paper to "non-compliance" with COVID-Secure arrangements not only by Trusts (body corporate) but, in particular, by individual healthcare workers as well (pages 1, 3, 9, 15, 16 and particularly the whole section headed "Behaviour, compliance and comfort" on pages 10-11).

I suspect that most HCWs will see this as a flagrant attempt to divert attention away from the systemic, nationwide failure to provide them with the RPE that they need and instead to blame them, themselves, for their misfortune and the fact that they have contracted the disease in their thousands and died in their hundreds.

The undeniable fact is that we now have WHO confirmation that the disease is transmitted from person to person via exposure to aerosols at close range. We also know that FRSMs do not protect wearers against aerosols at close range. So for SAGE, HSE or and any other authority to cast blame upon the healthcare workers themselves for contracting the disease is frankly outrageous and, to quote a certain Shakespearean character, "the unkindest cut of all".

Those who cast these accusations against them should bear in mind that, through both waves, these dedicated staff have been fully aware of the risks associated with COVID-19, given the sheer magnitude of severe illness, misery, suffering and death that have witnessed on a day-to-day basis. This is particularly poignant when so many of these casualties have been their own friends and work colleagues. Of all the different workforces across the country, these people will have been the most acutely alert to the need for compliance with COVID safety arrangements and will have done their best to keep themselves covid-secure within the constraints and space-limitations of the premises and environments where they work.

10.4 The 'hierarchy of risk control'

Whilst I have been pleased to see that reference to some basic health and safety principles mentioned in the SAGE paper, it is disappointing to see them misused.

Whilst fully accepting that we always endeavour to reduce risk to a reasonably practicable level by elimination, reduction, engineering controls and management controls as a priority, it is wholly inappropriate and a travesty to see them used as a means to dismiss the provision of appropriate respiratory protective equipment.

In this discussion I am only concerned with the care of patients at close-quarters – literally working within a metre or two from the patient's face and therefore, according to WHO, at risk of contracting the disease from exhaled aerosols. This would apply to ambulance crews (in their vehicles and patients' homes), emergency departments, general wards with cohorted COVID patients, COVID-designated areas in care homes etc. I shall work through the hierarchy of controls for this particular scenario:-

- "Elimination" of the hazard :
    - Not possible.
    - As WHO and HM Government now confirm, aerosols will be emitted into the air around them with every exhaled breath, cough, sneeze and whenever the patient speaks.

- The opportunity to 'eliminate' might be viable in future pandemics, given a faster response at Government level to secure the borders, restrict international travel and impose strictly-enforced quarantine measures on returning nationals at secure locations, following the New Zealand model (rather than relying upon individuals' sense of social responsibility to self-isolate).

- "Reduction at Source" :
  - The SAGE paper assigns great significance to the wearing of FRSMs for so-called 'source control'.
  - Without doubt, FRSMs will reduce droplet emission from coughs and sneezes.
  - However, it has been shown that their effectiveness is quite limited when it comes to infectious aerosols, which pass between the parties despite both wearing surgical masks.
- "Substitution" :
  - Bizarrely, this is mentioned in the as an element in the hierarchy in this context.
  - This shows something of a lack of understanding on the part of the authors. This is disappointing, given that HSE's Chief Scientific Officer, as a member of the EMG either co-authored this paper or at least should have had oversight of the H&S content.
  - Whilst 'substitution' is often a very real element in the hierarchy for chemicals (*i.e. either use a less hazardous chemical or a chemical in a less hazardous physical form*) I should be interested to learn how they propose to 'substitute' the trillions of SARS-CoV-2 viruses within an infected person's body for a less hazardous disease!
- "Engineering Controls" : Clearly ventilation is the option which comes to mind, of which there are two main options:
  - General ventilation (aka 'dilution ventilation'):
    - Passive: (opening windows and doors) cannot be relied upon to provide air velocities sufficient to make a great deal of difference to the "close-contact" scenario we are considering here (bedside/ambulance). The opening of windows and external doors is often not reasonably practicable either because there aren't any, or external weather conditions are not conducive or for security reasons.
    - Mechanical : This is most certainly not something to be dismissed. However the installation of new mechanical ventilation systems (or upgrade to existing) to improve general room ventilation is not something that can be done overnight. It is also debatable whether it would produce sufficient air velocity to clear aerosol in the 'close-contact' scenario being considered here.
  - Local Exhaust ventilation (LEV):
    - It would seem impracticable to place a 'captor hood' above a patient's head in the sense that one might use LEV for removal of, say, a plume of welding or soldering fume.
- "Management Controls" e.g.
  - Social distancing : irrelevant when having to provide close-contact care to an infected patient
  - cleaning/disinfection regimes are mentioned. Although clearly relevant to fomite and re-aerosolisation transmission, irrelevant to the circumstance of exhaled aerosol being directly inhaled by another person in close proximity

We have now arrived at the bottom of the hierarchy without having identified any control measures further up the hierarchy which will reduce risk so far as is reasonably practicable.

So we are left with "PPE" (in the true sense of the word "PPE", rather than the 'colloquial' term it has now become, which wrongly includes FRSMs).

The inadequacy of the SAGE paper is best illustrated on page 5, in the section which actually has the audacity to refer to the provision of PPE as a "bolt-on measure".

For the avoidance of doubt, PPE is not a "bolt-on measure". In the context of respiratory protection it is a valuable method for protecting workers' health and safety when in an environment containing an airborne hazard such as, in this case, a pathogenic virus which is known to have lethal consequences. As such, PPE is an intrinsic component of the 'hierarchy of control' and most certainly not a "bolt on".

Given the HSE's involvement in the preparation of the paper, it is disappointing that HSE's own published guidance has not been taken into account. The 'bible' for respiratory protection is **HSG 53 "RPE at work – A practical guide"**. Paragraph 20 makes it clear that it is perfectly acceptable to use RPE where a residual risk remains after other controls have been implemented and/or as an interim measure whilst other control measures (e.g. improvements in ventilation) are put in place.

The authors also seem unaware of HSE guidance at appendix 6 of the same document (or choose to ignore it because it does not suit their agenda).

Paragraph 6 of appendix 6 specifically relates to the selection of RPE for biological hazards as defined in the Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH). It states "*When in an airborne state, micro-organisms can be classed as particles, so they can usually be removed by filter-type RPE. You should always use equipment fitted with the highest efficiency filter possible (protection factor of at least 20) to control exposure down to the lowest levels* ".

SARS-CoV-2 is defined under the COSHH Regulations as a "Hazard Group 3" pathogenic virus which puts it in the same dangerous classification as, for instance, MERS, SARS-1, HIV, Hepatitis B, Hepatitis C, Polio (Type 2), Dengue Virus, Yellow Fever and most encephalitis-causing viruses. According to the HSE's own advice on page 29 of HSG-53, only FFP3 masks will provide a protection factor of 20. Alternatives are reusable respirators with P3 filters (pages 30/32) or powered respirators with TM2/3 filters (page 34).

As stated in HSE's RR619 research paper "no protection factors are assigned to surgical masks", "they do not offer respiratory protection" and "it is a common misperception that they protect against aerosols".

It is therefore absolutely incomprehensible to me as to how the HSE's Chief Scientific Officer can co-author a document which advocates the use of surgical masks for use with COVID-19 patients.

In order to further illustrate the fact that HSE recognises that RPE is not a "bolt on", but is an intrinsic component of the 'hierarchy of control', I would like to consider another working environment where the presence of another airborne hazardous substance presents the risk of serious disease and death, for which no engineering or management controls will adequately reduce the risk to the worker i.e. where PPE must be used, even though PPE is lowest in the hierarchy.

I refer to non-licensed work with asbestos. Both asbestos fibres and SARS-CoV-2 viruses have potentially lethal outcomes, albeit against different timescales.
I refer to HSE guidance "**Asbestos Essentials – EM6**") for the respiratory protection of workers carrying out such work:

- Use suitable RPE with an Assigned Protection Factor of 20 or more.
- Suitable types of RPE:
    - disposable respirator to standards EN149 (type FFP3) or EN1827 (type FMP3);
    - half mask respirator (to standard EN140) with P3 filter; or
    - semi-disposable respirator (to EN405) with P3 filter.

It should be self-evident that there is a direct parallel for workers with airborne viruses circulating within their breathing zone. RPE is a recognised and accepted means of control and not a "bolt-on" measure.

10.5 Risk Decision Frameworks - The 'Precautionary Principle'

This section on page 5 flagrantly seeks to dismiss the importance of adopting the 'precautionary principle'. This is in an overt attempt to escape from the argument that has hitherto been raging between the various experts for over a year as to whether SARS-COV-2 can or cannot be transmitted via the airborne/aerosol route and hence which RPE is appropriate. That is the 'uncertainty' which is under contemplation here. The 'uncertainty' has arisen through:

- on the one hand, those organisations such as PHE, DHSC (IPC Cell) and WHO (which seems to be recognised as the ultimate authority) vehemently maintaining that the primary routes of transmission are indirect through fomites/hand-to-face transmission and droplet transmission, equally vehemently denying the aerosol route of transmission and therefore believing FRSMs are adequate;
- whilst, on the other hand, many groups of healthcare professionals and the organisations which represent their interests, maintain that aerosol transmission has always been possible, over and above the designated AGPs and therefore maintain that FFP3 (or RPE to a similar standard) is required.

The argument for invoking the 'precautionary principle' has been based on this long-standing uncertainty amongst the scientific and medical communities and that "erring on the side of safety" is the obvious way to go, given that HCW lives are on the line.

Happily, the 'uncertainty' has now been dispelled by WHO having switched its position from (a) to (b) by finally confirming that the disease can be passed via the aerosol route between persons in close contact simply via exhaled breath (as previously discussed).

Once the 'uncertainty' ceases to exist, the precautionary principle, through its very definition, no longer has any relevance. The risk control measures required must now suit the scientific certainty.

However, before leaving the subject of the 'precautionary principle' I have to say that the authors have 'cherry-picked' parts of the HSE's "**Reducing Risks – Protecting People**" (R2P2) document, drawing text about "credible scenarios" from paragraph 93. However they mischievously stop just short of the example given in that paragraph which reads "*The credible scenarios can range from a 'most likely' worst case to a 'worst case possible' depending on the degree of uncertainty. For example, by assuming that exposure to a putative carcinogenic chemical will cause cancer, the chemical becomes subject to a very stringent control regime* ".

So, we can be quite justified in substituting "potentially lethal pathogenic virus" for "putative carcinogenic chemical" since both scenarios may result in death (albeit against different timeframes) and therefore conclude that, for either scenario, a "stringent control regime" is warranted.

Consider the circumstance that if one of my clients engaged me to advise on risk controls for a process which involved a "putative carcinogenic chemical" and for which no effective engineering controls were yet in place.

If I were to advise my clients that they should equip their employees with low grade respirator such as a 'nuisance dust mask' or an FFP1 to avoid inhalation of the dust, HSE would most likely prosecute me under section 36 of the Health and Safety at Work etc Act 1974. A direct parallel can be drawn with PHE advising HCWs to wear FRSMs – hardly the 'stringent control regime' one might reasonably expect for a potentially lethal pathogenic virus. I have suggested to Ms Albon of HSE that, since PHE enjoys 'Crown Exemption' from prosecution or enforcement action, that HSE should issue a Crown Censure, though unsurprisingly this idea does not seem to have found favour.

10.6 Miscellaneous

- On page 4 of the SAGE report, considerable importance is attached to the fact that outbreaks have occurred in 'unexpected' speciality areas such as orthopaedics and haematology. It also notes that outbreaks have been known to occur in wards without COVID-19 patients. The authors conclude from this that "direct clinical exposure 'per se' may not be the greatest risk factor in acquiring the disease in a healthcare setting".

  This argument is clearly presented to detract from the potential for direct close-quarter transmission between patient and HCW.

  Of course an equally plausible explanation is the well-known potential that this disease has for 'clustering' (i.e. the 'K factor') and that the outbreaks in these 'unexpected' areas may simply be attributable to a person being present in such places (whether patient or staff) who may be a symptomless 'super-spreader'. This can happen in any workplace, including orthopaedics and haematology departments of a hospital or, indeed, in any other 'unexpected' area for that matter.

- There is one particular section of the SAGE report which, on page 11, refers to a previous paper (given at reference 31: **EMG-NERVTAG. Duration of wearing of face coverings, 15 Sep 2020**).

  The narrative in the SAGE paper sets out just about every type of negative aspect imaginable relating to FFP3 masks, which it attributes to this EMG-NERVTAG paper i.e. facial dermatitis, increased work of breathing, respiratory fatigue, impaired work capacity, increased oxygen debt, early exhaustion at lighter workloads, elevated levels of carbon dioxide and increased nasal resistance. It makes no mention whatsoever of the positive benefits of such masks (i.e. that they actually do work, prevent aerosol inhalation and thereby help to prevent infection and death). This would make for a more balanced and objective view, rather than the skewed opinions offered.

  Nevertheless, taking these points in turn - a quick check in the EMG-NERVTAG paper reveals that:

  - **Facial Dermatitis** : There is no mention whatsoever of 'facial dermatitis' as such. It does, however state that surgical masks can be uncomfortable and increase the likelihood of skin complaints. It says that surgical masks can cause 'retroauricular dermatitis' (behind the ear), due to the earloop type masks. Of course this cannot happen with FFP3 or reusable respirators which are not held to the face in this way.
  - **Increased Work of breathing** : The only mention of difficulty breathing is that it says that 12% to 34% of people report difficulty breathing with surgical masks.
  - **Respiratory fatigue** : There is no mention whatsoever in the EMG-NERGTAG paper of "respiratory fatigue". It does, however, state that both surgical masks and filtering facepiece respirators both had a negative impact on pulmonary capacity, but only whilst wearing the mask during exercise. The study identified "no evidence relating to impacts on breathing (*for either type of mask*) for those who are not exercising".
  - **Impaired Work capacity** : There is no mention of "impaired work capacity" whatsoever.
  - **Increased Oxygen Debt** : There is no mention of "increased oxygen debt" whatsoever. However the EMG-NERVTAG paper does say that there is "no good evidence that face coverings (*of any sort*) significantly impact on normal breathing or oxygen levels (apart from some small effect during exercise)".
  - **Early exhaustion at lighter workloads** : There is no mention of "exhaustion" whatsoever.
  - **Elevated levels of carbon dioxide** : There is no mention of "carbon dioxide" whatsoever.
  - **Increased nasal resistance** : There is no mention of "nasal resistance" nor any adverse effects on the nose whatsoever.

  Given that the above EMG/NERVTAG paper bears no resemblance whatsoever to the items attributed to it in the SAGE paper under consideration here, it may be that the authors have misquoted the reference and in fact are referring to some other, entirely different paper. This speaks volumes about the authors' factual accuracy and attention to detail.

  The SAGE paper then goes on to quote the HSE as "noting that RPE can give a sense of false protection, especially when not worn in accordance with the manufacturer's instructions" and cites the reference **#33**. Once again, there is no such comment on that web page nor, in fact, anywhere I can find on the whole HSE website.

  My response to this comment is that:

  - Wearing **any** PPE wrongly will lead to a false sense of protection. For instance, a surgical mask with ear loops donned with the ear loops crossed over will increase the gap between the mask and the face (see **WHO guidance** for donning surgical masks). So the "false sense of security" is not something peculiar to FFP3s as the authors would seem to believe;
  - It is frankly disgraceful that the authors of this paper should even dare to mention a "false sense of security" in the context of FFP3 masks. This pales into significance when compared with the "false sense of security" that has been engendered on an astronomical scale by the deception perpetrated

by PHE/DHSC upon healthcare workers leading them to believe that surgical masks will protect them from contracting this airborne disease.

The authors of the SAGE paper seem to have had a total fixation upon FFP3 as being the only form of respiratory protection. One might have hoped that they may have had sufficient knowledge about RPE to appreciate that there are other types of equipment that provide as good, if not better, protection than filtering facepieces such as reusable respirators (half masks and full face masks) and powered respirators.

The paper stresses the point that FFP3 respirators are uncomfortable to wear. I would offer the following observations:

- This comment can equally apply to most other forms of PPE.
- Considering the other forms of RPE mentioned above:
  - Reusable masks:
    - Are considered by many to be more comfortable, with the soft rubber seal to the face;
    - Wearers are unlikely to experience any CO2 build up due to there being an exhalation valve (which can be protected with a surgical mask if there is a concern about the HCW possibly being infected and passing it on to the patient).
  - Powered respirators:
    - Offer a pleasant, cooling stream of filtered, purified air over the face;
    - Good for working in hot environments or for those who cannot wear tight-fitting RPE for one reason or another.
- As is always the case, a balance has to be struck between the discomfort and inconvenience which may be experienced by the wearer vs the potential benefit to the wearer.
  - With the greatest of respect, it is presumptuous of the authors to think that they know best.
  - In a survey of almost 500 doctors, undertaken by MedSupplyDrive UK† in October 2020, the question was asked "Would you use a reusable half mask?". The results were a resounding "YES", with 80% saying that they would, 15% saying that they already do and only 5% saying no.
- In a second survey carried out in March-April this year, the question was asked "For respiratory protection, do you feel safe wearing a surgical mask within 1 metre of a COVID-19 positive patient?" Almost two-thirds of the doctors and other healthcare workers surveyed returned a resounding "NO".

† *MedSupplyDriveUK is a charity run by volunteer NHS doctors, medical students and others concerned for the safety of frontline healthcare workers. They assist in the provision of PPE to frontline staff and have helped in the provision of more than a quarter of a million PPE items to more than 500 health and social care establishments across the UK.*

It is pleasing to see that some NHS Trusts, having little faith in the national IPC policy, have already implemented their own initiatives to provide effective RPE for their staff. For instance the South West Ambulance Service Trust have issued their frontline paramedics with Versaflo powered respirators with hoods. I know that some hospitals have also given short shrift to the IPC policy and equipped their staff, including porters, Estates workers etc with FFP3 respirator masks or powered respirators.

Although the vaccination has provided many healthcare workers with some valuable protection, the potential remains for resistant variants to emerge. As recorded in a subsequent set of **SAGE minutes**:

- "Step 3 of the roadmap is … likely to lead to 'R' being greater than 1";
- "It remains highly likely that there will be a further resurgence in hospitalisations and deaths…";
- "The full impact will not be seen until mid-June at the earliest".

This pandemic is clearly not over yet. No one should rest on their laurels, based on vaccination alone.

HSE, PHE and DHSC should be taking full advantage of the present 'lull' before the third wave to resolve this RPE issue once and for all. Failure to do so would represent the ultimate betrayal of our healthcare workers.

Finally I should like to close by drawing attention to the **EU policy** for respiratory protection of health care workers which, for almost a year now, has been that filtering facepiece masks to a minimum of FFP2/N95 standard, should be worn whenever coming in contact with people who have symptoms of COVID-19 and only wear a surgical mask if FFP masks are not available.

It speaks volumes that, in some parts of Europe, the public, just travelling on a bus, are required to protect themselves against inhalation of the virus through a requirement that they wear, not just 'face-coverings', but proper FFP2 or N95 respirator masks. Yet in the UK we cannot even provide our healthcare workers in covid-facing clinical settings with a similar level of protection.

In my long career as a safety practitioner I remember a time, not so long ago, when the UK used to lead Europe (if not the world) as an exemplar of best practice for protecting the health and safety of workers.

This was particularly true in connection with protection of workers from hazardous substances (chemical and microbiological). I have to say that I am dismayed to see how far we now lag behind.

11. STATUTORY REPORTING OF DISEASE UNDER THE 'RIDDOR' REGULATIONS

Employers have a legal obligation to report certain deaths and diseases which befall their employees to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013, as amended (RIDDOR).

Clearly guidance was needed by duty-holders as to how this should be applied during the pandemic. The HSE has displayed online guidance.

That guidance contains what some commentators might regard as a 'loophole' or 'cop-out' for healthcare employers. If the employer provided the precautions set out in PHE guidance (such as the rules about wearing surgical masks) and there was no evidence of these rules having been broken by the employee concerned, then no report needs to be made of the case of disease, nor of the death.

Given that the rules about surgical masks have now been proven to be flawed (*the disease being transmitted by aerosols and surgical masks not protecting against aerosols*) the statistics relating to HCW illness and deaths arising COVID-19 will be woefully deficient and cannot be relied upon.

Furthermore, it could make it particularly difficult for HCWs suffering long-term consequences of the disease to claim entitlement to Industrial Injuries Disablement Benefit if this should prove to be needed.

The Select Committee may wish to discuss proposals with the Industrial Injuries Advisory Council (IIAC) as to whether the UK will follow other countries' lead (e.g. Belgium and Norway) and declare COVID-19 to be a compensatable occupational disease for Health and Care Workers. They deserve it.

12. THE CURRENT POSITION

As explained in my introduction, having been prepared with the Committee's of "learning lessons", my evidence has focussed on the events of last year, earlier in the pandemic. However it does not seem right to conclude this evidence without some mention of the current position.

Although it took a long time to happen, WHO has at last accepted the principle of disease transmission. It discreetly updated its website on April 30th 2021. Despite this probably being the most significant news about the pandemic, the moment passed quietly without any news conference or public announcement as has usually been the case.

Within a few days, equally quietly and without great publicity, PHE similarly updated its websites.

One assumes that there may be some embarrassment amongst the parties involved, given that the overwhelming strength of scientific evidence has eventually forced them into accepting that they have been wrong about this all along. There may also be some fear amongst these same parties about possible blame, recrimination and even possibly litigation against them on account of the lives lost and ruined by long term health issues.

The Select Committee (and any other form of inquiry) should not allow itself to be swayed by any claims that, for example, it was the increased transmissibility of the 'Kent' or 'Delta' variants which has justified this U-turn about aerosol transmission. The ability for an aerosol particle to escape capture by a surgical mask and infect the wearer (*or to escape from an infectious wearer and infect another person*) is not influenced in any shape or form by what tiny viruses may be contained within that aerosol particle. It is a matter of simple physics, not microbiology or epidemiology.

The revised IPC guidance issued by PHE on 1st June 2021 remains unclear, ambiguous and confusing to clinicians with whom I have spoken. **The Select Committee should request that this central document be revised and reissued without delay.**

I am certain that the medical practitioners in the "AGP Alliance" (which comprises 16 professional bodies and unions) who, together with the partners with whom they are collaborating over this issue, are meeting with DHSC and PHE representatives today (3rd June) will be happy to work with the PHE authors to help them rephrase some of the more confusing and contradictory elements that the new guidance contains.

This is an area where clarity in terms of avoiding misinterpretation by 'frontline' clinicians and managers is crucial to preventing further avoidable disease transmission and loss of life amongst healthcare workers and their patients.

13. RECOMMENDATIONS FOR THE SELECT COMMITTEE

As a part of my evidence to the Select Committee I have identified (in bold type) a number of suggestions for the Committee's consideration. It may be helpful if I summarise these here:

- As mentioned in section 1 the Select Committee may wish to make a recommendation that, with future pandemics in mind, apart from stockpiling RPE, the UK should have sufficient manufacturing capability to ensure a sufficient and continuous supply of respiratory equipment for a long-enduring pandemic to all those who need it.
- As mentioned in section 4.1.2.3 the Select Committee may wish to recommend that the criteria by which diseases are added to the 'List of High Consequence Infectious Diseases' are reviewed and revised to take account of the additional criteria that I have suggested (which reflect a 'common sense' approach to defining what is meant by 'High Consequence'). With literally millions of deaths around the world having arisen from this disease it is ludicrous that it is not considered to be a disease of high consequence.
  Once a pandemic has taken hold, and if there are issues relating to the turn-round time of ambulances between patients (as was troubling Professor Van Tam at the NERVTAG meeting on 13th March 2020), then introduce separate guidance which allows for 'on-site' decontamination at hospitals or other locations. This would be better than pretending that the disease is no longer of 'high consequence'.
- As mentioned in section 5.1.1 the Select Committee may wish me to forward the correspondence that I have had with the HSE's Chief Executive (Ms Albon) between February and April. I will be happy to provide this if required.
- As mentioned in section 6.2 the Select Committee may wish to request sight of document mentioned by the ARHAI in their report i.e. the alleged letter from the HSE to the IPC Cell stipulating that FFP3s shall only be used for AGPs and nothing else.
- As mentioned in section 7 I will be happy to provide correspondence from PHE in which they denied that their change in PPE guidance was linked to any shortage of PPE. In that same correspondence they also agreed that surgical masks are not (and never have been) designated as 'Personal Protective Equipment'.
- As mentioned in section 8 the Select Committee may wish to take evidence from the members of the ACDP Committee and/or a BBC Reporter (David Shukman) in order to investigate a statement made by an anonymous member of the ACDP Committee that the decision to declassify COVID-19 was influenced by shortage of PPE. The extent of Professor Van Tam's influence over that committee may also be established.
- As also mentioned in section 8 the Select Committee may wish to forward a copy of this evidence to Sir David King for an opinion. I am certain that the Committee would benefit from harnessing his expertise, knowledge, background and high standards of personal ethics.
- As mentioned in section 9 the Select Committee may wish to request sight of the draft IPC guidance sent by Professor Van Tam to NHS England on 12th March 2020.
  It would be important to see the version of the document as it existed on that day, since it has been updated many times since then. My 'Freedom of Information' request to see it has been denied by PHE (Ref 28/03/LD/3139) on the basis that it is "not in the public interest".

  Should it transpire that this document does recommend FRSMs instead of FFP3s then this will serve as evidence that the declassification of COVID-19 as an HCID (which occurred the following day) was indeed a 'political manoeuvre' to pave the way to implementing this policy of reduced protection for healthcare workers.
  The Select Committee may also wish to determine whether it was appropriate to deny my 'Freedom of Information' request on the grounds of not being in the public interest.

- As mentioned in section 11 the Select Committee may wish to recommend (or instruct) the 4 Nations IPC Cell to revise their latest version of IPC guidance (issued 1st June 2021) in order to improve clarity of understanding, remove inconsistencies and avoid ambiguity.

  The Committee may also wish to recommend (or instruct) that the IPC Cell collaborate closely with the 'AGP Alliance' so that the stakeholders concerns and comments can be addressed.

- As also mentioned in section 11 the Select Committee may wish to discuss proposals with the Industrial Injuries Advisory Council (IIAC) as to whether the UK will follow other countries' lead (e.g. Belgium and Norway) and declare COVID-19 to be a compensatable occupational disease for Health and Care Workers.

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June 2021