OPEN LETTER

To : Ms Sarah Albon, Chief Executive, Health and Safety Executive

Date: 7 February 2022

Dear Ms Albon

- **Allegation: Offences committed by the members of the NHS Four Nations IPC Cell etc under section 36, Health and Safety at Work etc Act 1974 (HSWA)**
- **Concern: Unethical/illegal research project commissioned**
- **Concern: Failure to protect healthcare staff with Respiratory Protective Equipment**

Introduction

In this letter I shall cover the above three topics, providing a summary overview of each within the body of this letter and then providing further supporting details in annexes 1-3.

Staff in the NHS and the wider health and social care sector have performed wonders during this pandemic and they continue to do so as large numbers of patients remain hospitalised. However, I am afraid that I cannot assign any such praise to the individuals who issue guidance on infection prevention and control (IPC). I have previously alerted you to the fact that their guidance is seriously flawed. It has imperilled the health and safety of healthcare workers by failing to provide for suitable respiratory protection. It continues to do so.

I am bitterly disappointed that, after my correspondence with you over 6 months ago and despite my appeal to you for HSE to stamp its statutory authority upon the matter, you have failed to do so.

Although the latest version of IPC guidance (17/1/2022) has shown some improvement, it is still woefully lacking in clarity about the respiratory precautions specifically required for protection of healthcare workers (HCWs) against COVID-19. Associated guidance for GPs stands out as being particularly poor as NHS-England are sending out mixed and confusing messages (see annex 3). Guidance to the ambulance services is similarly confused (also see annex 3).

In this letter:

- I make the case that the actions of those involved with the issue of the IPC guidance represent a criminal offence under HSWA (section 36), ultimately punishable by fine and/or imprisonment;
- I respectfully remind you that the HSE, as the appointed regulatory authority in this area, are yourselves under a legal duty (HSWA, section 18) to take enforcement action to ensure compliance with the statutory provisions, such as those contained within section 36, together with the provisions set out in sections 2 and 3 of the Act and the Control of Substances Hazardous to Health (COSHH) Regulations 2002.
- I call on you to exercise that duty, whether simply by 'formal letter' to duty-holders, the issue of Improvement Notices against them and/or prosecution of offenders in the Courts or, as appropriate, issue a Crown Censure for Government Departments against whom you cannot enforce;
- You should make it crystal clear that:
  - the presence of PPE in the COSHH 'hierarchy of controls' is crucially important (despite being dismissively described at SAGE as a "bolt-on").
  - the fact that it is (rightly) positioned low in the hierarchy does not mean that this should be used as an excuse for not deploying it. As you say in HSG53 (para 10) Respiratory Protective Equipment (RPE) will "protect the wearer from breathing in harmful substances when other controls are either not possible or insufficient on their own".
  - when someone is providing close-quarter care to an infectious patient, all of the control measures higher in the hierarchy will either be irrelevant or ineffective, leaving PPE (RPE in particular) as the only mitigation capable of protecting the worker against acquiring infection from the 'cloud' of infectious air they are breathing which has been exhaled by the patient.
- You should instruct all healthcare employers that staff must be equipped with proper RPE in line with the COSHH Regulations whenever working with patients or individuals[†] known or suspected to be infected with COVID-19. You should also make it crystal clear that surgical masks (including Fluid Resistant Surgical Masks {FRSM}) are **not** Respiratory Protective Equipment and must **never** be used to protect employees against inhalable hazards such as pathogenic microorganisms.

[†] *For the purposes of this letter, any reference to 'patients' also includes any individuals receiving diagnosis or care in any setting – including acute, primary care, the ambulance service, the independent sector, mental health and learning disabilities, care homes, domiciliary care, maternity and paediatrics.*

I accept that it is not the role of the HSE to issue guidance or instructions on Infection Prevention and Control, but it most certainly **is** the role (and legal duty) of HSE to issue guidance and to enforce compliance on matters pertaining to Health and Safety. You will know this, but for the benefit of other readers of this open letter, these are two distinct, quite separate entities:

- **IPC** relates to the protection of patients from infection arising from the care they receive, including infection from healthcare workers which may be transmitted to them via droplets emanating from the nose and mouth of those workers, for which purposes surgical masks are the accepted control measure (albeit not wholly effective in respect of aerosol emission).
- **Health and Safety** relates to the protection of workers from health risks they face whilst at work. In this context it includes inhalation of airborne SARS-CoV-2 virions emitted from patients in their care, arising from simple, natural processes of the patient exhaling, talking, coughing, sneezing, shouting, sobbing, crying and just ordinary breathing.

The authors of the IPC guidance have strayed way outside their remit for 'protection of patients' for which they undoubtedly are the competent authority, into 'protection of workers' for which they are undoubtedly not the competent authority. The HSE is the competent authority in this area, particularly in the field of respiratory protection. We need to see more evidence of this in practice.

Background

First, I should recap on our previous correspondence. In his letter to me (*17/6/2021: ref CETO-198-21*) Mr [redacted], your Lead for Health and Social Care Services Sector, confirmed that:

- responsibility for policy relating to PPE in healthcare settings rests solely with the Department of Health and Social Care {DHSC} and Public Health England {PHE}, (*now the UK Health Security Agency {UK-HSA}*), together with the devolved administrations;

- this policy is set out in the document known as the "Four Nations COVID-19 IPC Guidance";

- the HSE denies any responsibility for "directing, influencing, approving or supporting" their PPE policy in any way. The HSE therefore denies claims made by the ARHAI (NHS-Scotland) that
  (a) the HSE have approved the PPE section within UK IPC COVID-19 guidance; and
  (b) that it is HSE who have adopted a position that respirators, such as FFP2 or FFP3, are only for use with "Aerosol Generating Procedures" (AGPs), as has been repeatedly stated by ARHAI in their 'Rapid Reviews' up until October 2021.

- The HSE has provided "technical input" to those responsible for the IPC guidance, but you have denied my Freedom of Information request to have sight of that "technical input". Please progress the appeal that is still unresolved (your ref: 202108316, submitted 26 August 2021)

The main contributors to the Four Nations IPC Guidance are a group of individuals collectively known as the "UK COVID-19 Infection Prevention and Control Cell" (aka "the IPC Cell"). Unlike most committees and groups which contribute advice and guidance in respect of the current pandemic, the IPC Cell does not publish notes or minutes in the public domain.

In this letter I am submitting a formal complaint to you that the members of the IPC Cell, together with any other persons‡ involved in dictating, directing, approving and publishing this guidance have breached section 36(i) of HSWA.

> ‡*This may include senior Medical Officers within DHSC, executives within PHE/UK-HSA, Directors within NHS England/NHS Improvement and the other 3 nations equivalent organisations.*

There is sufficient prima-facie evidence to suggest that the offence has led to the potentially avoidable deaths of hundreds of healthcare workers and the debilitating disease known as Long COVID in thousands of other healthcare workers. I therefore respectfully request that you give this complaint the serious consideration that it deserves.

I, together with a number of suitably qualified medical doctors, consultants and professors are happy to assist the inspectors you assign to this investigation if so required.

I will now briefly set out details of the offence and summarise the issues involved. Then, at annex 1, I will work through the issues one at a time providing the necessary detail to explain each point.

SUMMARY OF KEY POINTS

1) ALLEGED BREACH OF SECTION 36, (HSWA)

1.1) What Section 36 offence is alleged has been committed?

The persons involved in issuing IPC Guidance have caused duty-holders (NHS Trusts and other healthcare employers) to breach health and safety regulations (COSHH). This is an offence under section 36(i) of HSWA.

1.2) What offence have the healthcare employers been induced to commit?

The offence committed by the healthcare employers whilst following the IPC guidance is that they have contravened Regulation 7(9) of the COSHH Regulations. This regulation (together with its Approved Code of Practice and HSE guidance) specifies that, where workers need to be protected against inhalation of airborne microbiological hazards, certain types of respirator masks must be used which provide a minimum level of protection which is not provided by any type of surgical mask.

1.3) Are SARS-CoV-2 viruses which cause COVID-19 disease airborne? When was this known?

The statement in (1.2) above only holds true if COVID-19 is transmitted by the airborne route. In annex 1 below, I shall demonstrate that the relevant authorities (including HSE) have known for well over a year that COVID-19 is an airborne disease, but the IPC authors have failed to update their guidance in respect of PPE, thereby imperilling thousands of healthcare workers across the UK. This failure, which some commentators might argue amounts to gross negligence, is a serious aggravating factor in the section 36 breach.

1.4) Are the IPC authors excused from the section 36 offence by the 'HSWA caveat'?

Most iterations of the IPC guidance have included a 'caveat' that the "guidance is of a general nature" and an employer "should comply with all applicable legislation, including the HSWA".

The key question here is whether IPC guidance is:

a) Mandatory, and therefore binding upon duty-holders (NHS Trusts, Boards etc); or
b) optional, which duty-holders may take account of, but may deviate from if they wish.

The phrase "guidance is of a general nature" is clearly intended to lead duty-holders towards (b). However, in annex 1, I shall demonstrate that the IPC guidance is far from 'optional' and represents a quasi-legal imperative with which they are compelled to comply and for which they may otherwise face court proceedings or enforcement action from the Regulator.

As for the requirement to "comply with all H&S legislation", this is an absolute impossibility when the IPC guidance has mandated a requirement to do something which is diametrically opposite to the requirements of health and safety legislation.

2) NIHR-FUNDED RESEARCH PROJECT

In annex 2 I shall discuss an issue which relates to a research project known as a 'Randomised Controlled Trial', for which funding of over £1.1million of tax-payers' money was sought by UK-HSA from the National Institute for Health Research (NIHR). This project, award ID 135521 is entitled "*WIPPET: The impact of different grades of respiratory protective equipment on sickness absence due to respiratory infections including SARS-CoV-2 in healthcare workers*".

I suspect that many people will be outraged at the extraordinary waste of public money for a project to be which is completely unnecessary, given that:

- A wealth of evidence already exists on this topic;
- The fact that at least 30 hospitals have already switched from providing FRSMs to FFP3s and data has already been published demonstrating the reduction in HCW and nosocomial infection rates.

However my main concern is that the project organisers are deliberately and wantonly intending to put healthcare workers in harm's way by cladding them in surgical masks which, as discussed in 1.2 above, are illegal, contrary to the current 4-nations IPC guidance (17 Jan) and do not protect them against airborne disease. The researchers then propose to see how many of them get sick (and possibly some may even die) as a result of this, compared with healthcare staff who wear proper respiratory protection such as FFP3 masks.
I believe that since this appeared on the NIHR website the storm of outrage may have prompted them to withdraw from the scheme, so it is assumed that UK-HSA may plan to progress and fund it themselves and I will comment accordingly. As with so many things in this pandemic, the situation is confused.

3) FAILURE TO PROTECT HEALTHCARE STAFF WITH RPE – HSE INACTION

In annex 3 I shall discuss the current version of IPC guidance, issued 17 January 2022. That same day the IPC Cell issued a consensus statement in which they confirmed their belief that the IPC guidance remains "fit for purpose". This 'consensus' is certainly not shared by myself or, more importantly, a large number of practitioners from a wide variety of medical professions who see it as being entirely unfit for purpose. It is unclear as regards the transmission route of COVID-19 which is crucial to enabling the duty-holders to understand whether 'airborne precautions' requiring the use of RPE are applicable or not.

It completely fails to address the crucial issue which those medical professionals have, time and time again, raised with the 'IPC Experts' that, when providing close-quarter care to infectious patients, none of the control measures higher up the COSHH 'hierarchy of control' mitigate against exposure through the inhalation of infectious bioaerosols. Effective RPE is needed, not FRSMs.

Throughout all of Europe, USA, Canada, China (and I believe most other Asian countries) healthcare workers caring for covid patients are routinely issued proper RPE. By way of comparison, in the early days of the pandemic 42,600 healthcare workers were dispatched to Hubei province to assist with the outbreak. They were properly equipped with good RPE (FFP3 masks or equivalent) and not one single one of these workers acquired the disease (source Zhu, Zong). This contrasts sharply with the UK where over 122,000 HCWs have acquired the disease and over 1,500 have died. This speaks volumes about the inadequacy of PPE used by our HCWs in the UK.

Although the most recent update of guidance indicates a slight shift towards FFP3 protection, the authors still refuse to explicitly state that COVID-19 is airborne and RPE must therefore be used.

It is unfortunate that these events have occurred during your tenure as HSE Chief Executive since I believe that this will eventually come to be viewed as the largest single health and safety disaster to befall the United Kingdom workforce since the introduction of asbestos products. The main difference being that when asbestos was introduced, its lethal properties were unknown. However, when COVID-19 was introduced into the UK, the potentially lethal properties of SARS-CoV-2 were already known to politicians, health officials, scientists and HSE. At that time the World Health Organisation had just declared a "public health emergency of international concern" and the Chinese government had locked-down Wuhan's 13 million inhabitants (a step not taken lightly).

In my view, which I believe to be widely shared, HSE has not exercised its statutory role in that:

- HSE has known since April 2020 (if not before) that COVID is transmitted via the airborne route;
- HSE knows very well that surgical masks do not protect workers against airborne/inhalable risks;
- HSE therefore knew that PHE/DHSC IPC PPE guidance was flawed and endangered HCWs;
- HSE has failed in its duty to assert its authority and get this malpractice stopped.

May I respectfully point out that the HSE exists solely by virtue of statutory legislation (the HSWA); hence by the will of Her Majesty's Government and therefore by the collective will of the people of the United Kingdom to prevent injury, ill health and death amongst its workers in all sectors of industry. In time of a global pandemic this especially includes the 1.3 million employees in the NHS (the largest employer in the UK), together with the other half-million workers in the wider health and social care sector.

In terms of 'collective will', most citizens would have expected that our brave healthcare workers would be afforded the highest standard of personal protection to keep them as safe as possible from this dreadful disease, particularly the thousands of us who stood on our doorsteps and, with an outpouring of emotion, 'clapped for carers' in the early days of the pandemic. They will be dismayed to learn that this has not been the case and these wonderful people, who have cared for us through the darkest of days have been so badly let down by those responsible for their 'duty of care'.

It is particularly upsetting to learn that the fatalities included a number of retired staff who 'answered the Government's call' to come back and help out in hospitals, ambulances etc (despite the obvious vulnerability presented by virtue of age), only to be provided with surgical masks for 'protection' and die.

Happily, some NHS Trusts seem to have begun to doubt the wisdom of the IPC guidance and are providing proper RPE for all their staff working with COVID patients, not just those undertaking AGPs. At time of writing there are only about 14% of these more enlightened Trusts. I entreat you to ensure that this figure increases to 100% without delay, whether this by via your powers of persuasion or via your powers of statutory regulation and enforcement.

Throughout the pandemic, terms have been used such as “the battle against the virus” and the “a war against COVID”. These are no understatements and remind me of my earliest correspondence with PHE, CQC and members of parliament in January 2021 “***By way of analogy, in a war against a deadly virus, equipping healthcare workers with only surgical masks to protect them, may be considered (in a real war) akin to providing the infantry with blank ammunition in their rifles or bullet-proof vests made of cardboard*** ”. Just the same as with FRSMs being provided for protection against COVID-19, they are led into a false sense of security and only find out the peril when it is too late. Sadly this message fell upon deaf ears and no notice was taken.

Taking the analogy of war one step further, it is sobering to reflect upon the fact that 110,000 more citizens have died from COVID-19 than died during the whole of the blitz in World War 2 (over 3 times more). This death toll may have been significantly reduced if strong health and safety leadership had snuffed out the flawed and dangerous guidance emanating from the IPC cell as it started to emerge and insisted on proper RPE for HCWs, thereby preventing infections, not only to them but via onward transmission from them to others (both within and beyond hospital walls).

Evidence given to Select Committees by Directors of PHE/NHS in March 2020 was that the decision to recommend FRSMs for use with COVID-19 patients instead of FFP3s was nothing to do with PPE shortages, though it has been widely reported that this may not be entirely true. Even if it was true, then employers should have been more open in communicating the lesser protection provided by FRSMs. Had they known this, knowing the dedication of our NHS staff, I am sure that they would have still done their job professionally and to the best of their ability as that is their vocation.

Had they been given accurate information about the hazards, PPE and other control measures as required by COSHH Regulation 12 (including the limitations of the respiratory protection they were being given) then they may have elected not to remain in close contact with infectious patients when not actually involved in their clinical care. HSE’s guidance on COSHH reflects this: “*If the health risk is serious … a good appreciation of the risk is especially important*”. The people potentially exposed need to be told, clearly and honestly about the control measures. However, this duty has not been well met by the health authorities’ systematic and deliberate issue of communications, posters, notices and audio-visual messaging which purport that surgical masks will keep them safe from the disease.

I appreciate that this is rather a lengthy letter and it may be unclear exactly as to what I am looking for in the way of a response so, to clarify. As regards the allegation of the section 36 offence: I fully understand that, as when any breach of H&S legislation is reported to you, you bound by certain confidentiality constraints in respect of the alleged perpetrator(s). I know that you cannot discuss the details of your investigation with the complainant and I do not expect you to do so. I would, however, appreciate your confirmation that you are treating this seriously, will investigate it thoroughly and in the fullness of time report on the outcome of your investigation to the forthcoming Public Inquiry into the Government’s handling of the COVID-19 pandemic.

If you decide to dismiss the allegation, then please confirm that you have done this together with your reasons, so that I may pursue alternative legal strategies to ensure that COSHH Regulation 7(9) is more diligently enforced by yourselves and ensure that workers are properly protected as the law requires.

Other than that, I am not seeking any other reply. That said, you may wish to comment on concerns I express where I believe HSE may have acted, and are continuing to act improperly. Since this is an ‘open letter’ which will be publicly accessible, as a courtesy to you I propose to display any response that you might care to make alongside this letter on my website. Any personal information will be redacted.

I have, for the past year of my life been trying to achieve one simple thing – i.e. “Keep our healthcare workers safe by providing them with the correct protective equipment for the tasks they have to undertake”. This should not really be too much to ask. All I have seen is continual buck-passing, obfuscation, questionable evidence and doubtful competency amongst some of the parties involved in the healthcare sector. This is a question of accepting good science and recognising the moral and ethical duties involved towards the health and safety of our healthcare workers.

I have set out my views in this letter and the accompanying annexes. For the avoidance of doubt, I do not intend to enter into further debate or discussion concerning this matter with the HSE, nor with other parties involved. That said, if any party does write to me in response to this letter I shall post that correspondence on my website adjacent to this letter together with any comments of my own.

Finally, as mentioned in our previous correspondence, I have served as a member of the HSE's 'COSHH Essentials Working Group' assisting your COSHH Policy Team with the valuable work they do providing Direct Advice Sheets and the online COSHH Essentials facility. Notwithstanding the points raised above, I have the greatest respect for the HSE and the work that you do.

It pains me greatly to have to write this letter to you. At no time in my 27-year career in health and safety would I have dreamed that I would ever need to write such a letter to you, and I do not do this lightly. However, please accept that this stems from a deep-seated sense of personal and professional ethics and a recognition of what is right and what is wrong. I hope to continue working with the CEWG long into the future, but if you feel that the spirit of this letter is unconducive to my continuing my work with the group then I shall reluctantly tender my resignation.

Yours Sincerely

DFJ Osborn BSc CMIOSH SpDipEM

iosh Chartered Safety and Health Practitioner

QSHCR Registered Consultant

(Contact details provided on accompanying e-mail)

cc: Ms Sarah Newton, Chair, Health and Safety Executive

The Rt Hon Chris Skidmore MP, Member for Kingswood;

The Rt Hon Sajid Javid MP, Secretary of State for Health and Social Care
Baroness Eluned Morgan AM, Minister for Health and Social Care (Wales)
Humza Yousaf MSP, Cabinet Secretary for Health and Social Care (Scotland)
Mr Robin Swann MLA, Health Minister (Northern Ireland)

The Rt Hon Stephen Timms MP, Chair, Work and Pensions Select Committee
The Rt Hon Greg Clark MP, Chair, Science and Technology Select Committee
The Rt Hon Jeremy Hunt MP, Chair, Health and Social Care Select Committee

Professor [redacted], National Medical Director, NHS England & NHS Improvement
Professor [redacted], National Clinical Director IPC, NHS England & NHS Improvement
Dr [redacted], Chief Executive, UK Health Security Agency
Dr [redacted], Chair, Four Nations IPC Cell
Dr [redacted], Head of IPC, NHS England & NHS Improvement

Dr Barry Jones, Chair, Covid Airborne Protection Alliance
Professor Emeritus Raymond Agius, Co-Chair, BMA Occupational Medicine Committee,
Dr David Bailey, Chair, BMA Welsh Council

Annex 1: Alleged Breach of Section 36, Health and Safety at Work etc Act 1974 by IPC Cell etc

In this annex I shall provide further details as outlined in section 1.1 to 1.4 above i.e.:
1) What Section 36 offence has been committed?
2) What offence have the healthcare employers been induced to commit?
3) Are SARS-CoV-2 viruses which cause COVID-19 disease airborne? When was this known?
4) Are the IPC authors excused from the section 36 offence by the 'HSWA caveat'?

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1) What Section 36 offence has been committed?

Section 36(i) of HSWA makes it an offence for a person (e.g. *members of the IPC Cell and directors in this instance*) to cause another person (*in this instance, NHS Trusts, Boards and other organisations whose undertaking involves provision of healthcare services*) to commit an offence under the Act.

The legislator's intention behind this section is directed towards people who provide advice, guidance, instruction or direction which influences duty-holders to do (or not do) something which results in danger to their employees' health or safety and which constitutes an offence under the Act or Regulations made under the Act (such as COSHH, Control of Asbestos etc).

So, for example, if I as a health and safety consultant had provided guidance to a client that some work they needed to do removing asbestos insulating materials could be undertaken with employees using a simple 'nuisance dust mask' (or a surgical mask) for their respiratory protection, you would have me in Court on a Section 36 charge before my feet could touch the ground – quite deservedly so. This, in principle, is no different from the issue of IPC guidance having instructed that "Fluid Resistant Surgical Masks must be worn when providing direct care within 2 metres of a suspected/confirmed COVID-case".

Section 36(i) also provides for enforcement action to be taken against the person giving the flawed advice regardless of whether any enforcement action is taken against the person receiving the flawed advice. I am not advocating enforcement action against healthcare employers who have followed IPC guidance. However they do need clear direction from HSE and they need it without delay.

Similarly, it not necessary for the harm to the duty-holder's employees to have been proven to have actually occurred for the offence to be considered legally valid. In other words, in this context, it is not necessary to prove beyond doubt that a person has acquired COVID-19 by virtue of providing close-range care of infectious patients whilst equipped with a FRSM (although there are multiple examples of this supported by whole genome sequencing e.g. report by a Sheffield research team).

It is sufficient only that a risk exists (i.e. a possibility of danger) as per 'R vs Board of Trustees of the Science Museum 1993', as neatly summarised on page 23 of your excellent publication 'Reducing Risks - Protecting People'. This document also describes the 'Precautionary Principle' that sets out the expectation for good health and safety management practice. It is central to HSE's approach to regulation and enforcement i.e.: "*the philosophy that should be adopted for addressing hazards subject to high scientific uncertainty and rules out lack of scientific certainty as being a reason for not taking preventive action".* I hope you will keep this closely in mind when reacting to this letter.

Given the uncertainty (in some peoples' minds) about airborne vs droplet transmission the precautionary principle should have been adhered to – as indeed it was until the disease started to bite into the UK. On 10th March 2020, Health Protection Scotland, when issuing IPC version 9, it appears that the precautionary principle to was no longer relevant, reference to it was removed from the guidance (seemingly abandoning the principle) and protection reduced to FRSMs.

The question then remains as to whether the IPC guidance did, in its own right, cause the duty-holders to commit a health and safety offence. This is something which lawyers may consider at some time in the future and I will revert to this point in section (4) below.

Suffice it to say for now that, right from a very early stage in the pandemic, the Directors and Executives in NHS Trusts will have been in receipt of direction from some of the most senior healthcare officials in the country that they must comply with the IPC guidance. There will have been an understandable concern that, if they did not follow this guidance, then they or their Trusts may have been vulnerable to litigation in the event that patients acquired the disease and the staff caring for them had been wearing other types of PPE such as FFP3 masks against IPC advice.

2) What offence have the healthcare employers been induced to commit?

The Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH) 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. You confirmed this to me in the email from the HSE Concerns and Advice Team (CAT) (your ref: 103197; 23 March 2021 09:45).

Your Chief Scientific Advisor (CSA), Professor [redacted], also confirmed this in his recent witness evidence to the Science and Technology Select Committee (26 October 2021). In his response to question the MP's question #2512:

- Fluid Resistant Surgical Masks (FRSMs) are "*good for source control*" in other words they *"protect other people from the wearer"* and "*probably give the wearer a little bit of protection from other people* "; whereas
- "*What we, in HSE, would describe as Respiratory Protective Equipment (RPE), which has proper standards … the different standards will determine the level of protection that you get. Typically, in a high-risk area in a hospital, you might be using an FFP3 respiratory mask*."

The CSA's own laboratory at Buxton had previously, through an earlier research project RR619 demonstrated that surgical masks do not protect against inhalation of virus-laden aerosols in close proximity with sources of aerosol emission, having found live viruses behind every mask tested (not the case with FFP3 masks). I reject the assertion in your letter of 20th April 2021 that "RR619 does not contradict the 4-nations COVID-19 IPC guidance" An aerosol is an aerosol whether it is generated by one of the AGPs mentioned in the official list or someone coughing, sneezing, talking or just breathing. Even the WHO now accept that. Breathe on a mirror and you will see this is the case. I refer you a statement in RR619 "*No protection factors are assigned to surgical masks, as they are not designed to offer respiratory protection. However, there is a common misperception that they will provide protection against aerosols"*. I don't think we can be any clearer than that.

Your CSA and Dr [redacted] (HSE's Head of Science Quality and Impact) both represent the HSE at PEROSH (The Partnership for European Research in Occupational Safety and Health). The PEROSH website states that "*Unlike surgical masks, which primarily protect other people, tested class FFP2 or FFP3 respiratory protective devices protect the wearers themselves against the inhalation of pathogens.*" ("pathogens" being microbes such as the SARS-Cov-2 virus which causes the COVID-19 disease). Further information about this may be found in sections 5 to 7 of my written evidence to the Commons Health and Social Care Select Committee 'lessons learned inquiry'. Evidence which the Committee completely ignored.

Surgical masks (including FRSMs) are not "PPE" within the definition of UK law. Despite this, since the outset of the pandemic, politicians, the media, PHE and DHSC have wrongly used the term "PPE" to describe surgical masks. This has misled healthcare workers the length and breadth of the UK into a false sense of security believing that these masks protect them against the disease when they do not.

Fluid resistant masks do provide some degree of protection against liquids directly impacting upon the mucosa in the nose and mouth of the wearer. As such it may be argued that they provide some degree of personal protection in this respect, but they are still not "PPE" (as defined in law). Furthermore, they are neither designed, constructed, testified nor certified to protect the wearer against very small airborne droplets (aerosols) which may be inhaled. To prevent infection taking hold in the respiratory system (airways and lungs) properly certified RPE (FFP3 etc) must be used. Surgical masks are not RPE, they never have been and I doubt they ever will be.

As you will of course know (*but for the benefit of other readers of this open letter*) the legal status pertaining to respirator masks is confirmed in the Approved Code of Practice (ACoP) to the COSHH Regulations "LEGAL-5" (paragraph 160). Compliance with an ACoP requirement is, to all intents and purposes, a mandatory requirement since the Code has a special legal status. A Court will find the duty-holder at fault if they have not complied with the Code, unless they can prove that they have implemented other measures which provide a level of safety which is the same, or better, than that which is set out in the Code.

The ACoP requirement states that "*To be suitable, RPE must be capable of adequately controlling the inhalation exposure using as a guide the equipment's assigned protection factor as listed in HSG53 (Respiratory Protective Equipment at Work)*".

By association, this effectively transfers the same quasi-legal status of the ACoP over to HSG53, where appendix 6, paragraph 6 specifies a minimum protection factor of 20 for pathogenic micro-organisms (i.e. FFP3, Reusable masks with P3 filter or powered respirators).

FRSMs do not provide this level of protection. Indeed they are not even assigned a protection factor at all due to the potential for inward leakage of air, particulates and aerosols due to the fact that they are not tight-fitting. Neither are the materials from which they are constructed as effective as Filtering Face Piece (FFP) respirators in terms of blocking tiny particles such as aerosols and droplet nuclei.

It cannot, therefore, be the case that FRSMs represent a "*measure which provides a level of safety which is the same, or better, than that which is set out in the ACoP*". Thus, any provision of an FRSM for the purposes of respiratory protection against an airborne, microbiological hazard represents an offence under the COSHH Regulation 7(9).

In earlier versions of IPC guidance, PHE used to include a qualifier that "the term 'personal protective equipment' is used to describe products that are either PPE or medical devices that are approved by the HSE and the MHRA as protective solutions in managing the COVID-19 pandemic". In my view it takes more than a convenient 'redefinition' like this to turn something that is not legally-speaking "PPE" into "PPE". An example of this may be found at section 5.1 in the June issue, whereas I note that in the corresponding paragraph (6.5.1) of the latest version the text has been omitted. I wonder whether this may be due to HSE having requested the IPC authors to desist from using the term "PPE" when talking about surgical masks? If so, I would very much like to know, as this would indicate to whether any notice has been taken of HSE's influence and guidance.

3) Are the SARS-CoV-2 viruses which cause COVID-19 transmissible by the airborne route?

The statement in section 2 above only holds true if COVID-19 is airborne.

In January 2020 PHE provisionally declared COVID-19 to be an **airborne** HCID (High Consequence Infectious Disease), assigning it the same status as SARS (2003-2004) and MERS (2012-present).

In March 2020 COVID-19 was declassified as a HCID. Whilst that remains a contentious issue, seen by many as a convenient political 'means to an end' in order to justify the downgrading of respiratory protection from FFP3 to FRSM (see section 9 of my written evidence), it is not the issue here. The key point here is that these previous diseases were all classified as 'airborne'. It is clear from the PHE explanation that the basis for declassification was concerned with the availability of laboratory tests and lower mortality rates associated with SARS-CoV-2. There was no suggestion that its status as 'airborne' had altered and so, de facto, that remains unchanged to this day – Covid is airborne.

Members of DHSC/PHE/NHS who were involved in declassification as an HCID and subsequent production of 4-nations guidance had published a paper in 2013 identifying SARS coronavirus as transmissible both by aerosol and droplet, for which they recommended FFP3 masks should be worn whilst patient infectious. This does not fit comfortably with their insistence during most of this pandemic that this SARS coronavirus is only transmissible by droplet and not aerosol.

For many years IPC practitioners have clung to a paradigm/concept that particles of liquid with a size greater than 5µ (microns) should be called "droplets" and those less than 5µ should be called "aerosols". Whilst on the face of it, this seems to be a fairly minor issue about terminology, the importance in the real world of a pandemic is huge. That is because it has been (unwisely) used by the World Health Organisation and PHE/IPC Cell to determine whether a HCW should wear a FRSM or FFP3, the difference between these being literally a matter of life, death or prolonged disability. It has also been a fundamental principle behind the IPC guidelines and thence to the National Infection Prevention and Control Manual (NIPCM) which sets out 'Transmission Based Precautions" which the former Minister for Prevention Public Health and Primary Care confirmed pertains to all patient-facing roles across the UK. I note that these are still set at the 5µ threshold.

The principle being that they believe that a "droplet" will fall to ground under gravity within 2 metres and would therefore not be an inhalable risk. It is a fanciful and bizarre notion that an infectious droplet of 6µ warranted a different status (droplet transmission) from an infectious droplet of 4µ (airborne transmission) in size. I shall not develop that line of argument here since the credibility of that argument is being thoroughly dismantled by so many other competent medical/scientific practitioners. A very good explanation being given on a YouTube video, which is well worth watching.

The IPC guidance ubiquitously refers to the wearing of RPE "if an unacceptable risk of transmission remains". It is a mystery as to how a frontline HCW providing close-contact care to a patient is expected to determine the size of the droplets as ±5µ or the concentration of virus particles therein and don the appropriate RPE or FRSM accordingly, bearing in mind that droplets around this size are totally invisible to the human eye.

A full review of all the evidence proving that COVID-19 is airborne would be beyond the scope of this letter. However I shall collate some of the basic facts, together with a consideration of how the switch from 'airborne precautions' (FFP3) to 'droplet precautions' (FRSMs) came about. I shall also highlight how the seeds of misinformation, ambiguity and confusion began to be sowed in March 2020 and how these persist to this day:

(a) Long before the current pandemic, HSE knew that SARS-CoV virus (aka SARS-CoV-1 from the 2003 outbreak) was transmissible via the airborne route. To this day HSE guidance still advises 'Airborne precautions', including FFP3 masks for SARS, should that virus re-emerge.

(b) Once the novel coronavirus disease emerging from Wuhan was recognised as a potential global threat to health, scientists were soon able to examine it and identify the key features and establish that there were a great many similarities between the morphology and morphometry (shape/size) of the virus with its predecessor SARS-CoV-1. Although the virus had 30% less spikes than its predecessor, the overall particle size and the length of the spikes were virtually the same. Almost 80% of the genetic structure is the same between the two - not that this will have anything to do with its ability to become entrained in bioaerosols, which will be the same for both types of virus. To this day, SARS-CoV-1 is identified in the HCID list as 'airborne' and, because the two are virtually identical, the same attribute ('airborne') must apply to SARS-CoV-2.

(c) IPC guidance in Health Protection Scotland (HPS), a fore-runner to the amalgamated 4-Nations IPC guidance, specified the same precautions (FFP3) in version 8.1 (5 Mar 2020) before it was changed, just a few days later to version 9 (10 Mar 2020), in breach of the HCID rules in force at the time, which specified that FFP3 masks must be worn.

Bearing in mind that England, Wales and Northern Ireland were still complying with HCID rules, which were not changed until 3 days later when COVID-19 was formally declassified as an HCID, it is an interesting supposition that the authors, upon realising that they had committed a gaffe by issuing formal guidance which broke the rules, may have hurriedly sought to regularise matters – not by revoking or amending the errant guidance but by seeking to revoke the status of COVID-19 as an HCID instead.

(d) Another key difference between version 8.1 and version 9 of the HPS guidance is that the "Precautionary Principle" (present in 8.1) was abandoned in version 9. Some commentators might interpret this as 'throwing caution to the winds'.

(e) On 5th March the Chief Medical Officer (CMO) confirmed at a Parliamentary Select Committee meeting that the virus emanating from China had a "very strong force of transmission" and, being airborne, had the capacity to travel worldwide once it had got started. I am sure that most competent scientists and epidemiologists would whole-heartedly agree with the CMO's statement. History proved him right.

(f) However, at the next meeting of the Select Committee on 17th March (after declassification as HCID and downgrading of PPE), the Director for Acute Care (DAC), NHS England (Q.170) tells the Committee that:

- A virus cannot go anywhere.
- It does not float around in the air;
- It comes out in droplets when you cough;
- Those droplets will go only a certain distance (2 metres); and
- Beyond 2 metres you are not going to get the virus.

There appears to have been a somewhat magical transformation of this same virus which, just two weeks previously had been more appropriately described as having a 'strong force of transmission, capable of travelling worldwide'.

(g) It was certainly clear to doctors at the front line that all was not well with the new IPC policy. At the same meeting (Q.132) the DAC was told of a report by an A&E doctor in London that

- "*It's absolute carnage in A&E, utter chaos*".
- "*We don't have any proper PPE, not the FFP3 masks we need*";
- "*I feel like we are being thrown to the wolves here. Some of us are going to die*", (prophetic words indeed!).

The A&E doctor would most probably have been outraged by the DAC's reply, given his senior position in the NHS, appearing to say that the doctor might need some education about what PPE was now appropriate given the recent changes in PPE guidance.

(h) At the next Select Committee meeting on 26th March, the Medical Director of Public Health England (Q.256) was asked a direct question "What is significant exposure", to which she replied that "droplets and aerosols are significant exposure for certain". This was an interesting response from a director of PHE which had, itself, so recently issued new IPC guidance with downgraded PPE on the basis of the disease being transmitted by droplets and claiming that aerosols were not significant in transmission. Perhaps no one had updated the lady on the latest "spin" to be applied.

(i) The following month things became very much clearer, thanks to HSE's Chief Scientific Advisor (HSE-CSA) and colleagues in the Environmental Modelling Group (EMG), a sub-group of SAGE. They brought some clarity to the issue with a number of papers, including an evidence summary on 14 April 2020. He confirmed that aerosols below 10μ (microns) reach the deepest parts of the lung; below 20μ reach the thorax and those up to 100μ are still inhalable, impacting in the nose and throat. These sizes are not considered absolute, but generally considered appropriate ±5μ.

A similar view, defining aerosols as being 100μ or less, may be found in a paper published

by Donald Milton at around the same time.

It is helpful to know that, whether they are considered as 'droplets' by medical people or 'aerosols' or 'droplet nuclei' by scientists, airborne liquid droplets less than 100μ are "aerosols" and they are inhalable. This effectively demolishes the 5 micron aerosol threshold expounded by WHO and PHE/UK-HSA/IPC Cell. Anything "inhalable" which is also hazardous/toxic/pathogenic requires RPE to keep the worker safe (as per the COSHH Regulations).

As a person breathes in, all aerosols below 100μ enter the nose or mouth. The larger fraction can embed in, for example, the epithelial cells in the nose (Wu et al) from where the virus can take hold and the infection start to spread. The smaller fraction can embed in the alveolar type 2 cells (Zhao et al), deep in the lungs from where the virus can take hold. Both types of cells (epithelial and AT2) are considered primary targets for the virus due to the expression of the protein Angiotensin-Converting Enzyme (ACE2) (Zhou et al). The spikes of the virion bind onto the ACE2 at the surface of the cells in order to penetrate into the cells where virus reproduction takes place.

(j) Sadly, although maybe predictably, not all members of the medical/IPC fraternity shared HSE's view that COVID-19 was airborne and transmissible via aerosols. After all, having already reduced the level of protection to FRSMs this would require an admission that they had been wrong back in March with potential blame and legal culpability for the widespread disease and deaths of HCWs, together with the subsequent deaths of the public through Healthcare Associated Infections.

(k) When, following the publication of the above-mentioned EMG paper in April 2020, it became clear that the HSE CSA's advice was not being accepted and the nonsense of the 5μ aerosol/droplet threshold was going to continue (together with FRSMs), the HSE was remiss (arguably derelict in its duty) by failing to assert its authority and not stepping in to protect the workers which it knew (or should have known) were endangered by the withdrawal of RPE.

If there were legal reasons (e.g. emergency powers) or pressures were applied on you from elsewhere in Government then this would be a reasonable excuse. However in your letter to me (20 Apr 2021 : CE-156-21) you did confirm that no such pressure had been applied.

(l) The following month, further relevant advice was provided by the CSA/EMG in an important paper warning that "the virus is likely to be stable for long periods of time in air" and that, as regards the survival of the virus in indoor settings, "*SARS-CoV-2 is stable in the aerosol state in indoor environments*".
Note: the authors' underlining of this statement in their paper suggests the importance they attached to this particular attribute of the virus.

Sadly, although the paper was available for consideration at the SAGE meeting on 12 May 2020 it was "not considered or discussed at the meeting". The decision not to schedule discussion on this crucial evidence at that or, so far as I can see, any subsequent SAGE meeting raises serious concerns about the governance arrangements at SAGE.

Even more concerning is the fact that this paper was not published on the Government website until 20 August 2021. Whatever the reason for the delay, the information would have been available to inform IPC policy, should have been acted upon and IPC guidance updated to reflect the risk of airborne transmission.

(m) Although the PHE/IPC Cell rejected your CSA's information about aerosols, other parts of Government seemed willing to accept the notion of aerosol transmission. In autumn 2020:

- Government public-information videos were broadcast clearly demonstrating that COVID-19 is airborne, with exhaled virus particles/aerosols being shown drifting in the air;
- the PHE "Green Book" publication (Immunisation against infectious disease - issued November 2020) confirmed person-to-person spread through respiratory aerosols.

(n) Moving forward to autumn 2021:

- Government public-information videos were again broadcast, clearly demonstrating that COVID-19 is airborne, with exhaled virus particles/ aerosols hanging in the air.
- The Respiratory Evidence Panel produced a report confirming that:
  - "*a crucial consideration for public health and mitigation measures is that virus-laden respiratory particles can be inhaled directly from the air, and that this is more likely to happen at short range*"; and
  - "*close contact transmission (< 2 metres) is expected to be the main transmission mode, whether it is through direct contact with ballistic particles or through inhalation of particles suspended in the air*."
  - "*Definitions used by SAGE and PHE/UK-HSA are based on the work by Milton, recognising the 100µ threshold between droplets and aerosols*" i.e. recognising the sub-fractions of 'thoracic aerosols' and 'respirable aerosols' previously expounded by the HSE-CSA and the EMG group some 18 months earlier.

(o) The question of aerosol transmission (and HSE's view on it) was confirmed by HSE's Chief Scientific Advisor who informed a Commons Select Committee meeting on 26 October 2021:

- Q2525: "*We have provided evidence to show that the airborne route was very important right back in April 2020* ".
- Q2499: "*Airborne transmission of small particles is absolutely critically important* "
- Q2500: "*We think that the airborne route has become more important and is clearly, if pushed, the most critical* "
- A Professor, Director of Infectious Diseases from University of Pavia, confirmed "*I essentially agree with the Chief Scientific Advisor. Airborne transmission is the most important way of transmission of COVID-19/SARS-CoV-2* ".

Further evidence of airborne transmission can be found from various sources such as:

- a compelling (albeit small-scale) experiment with hamsters described at the recent PROTECT-COVID-19 conference led by the HSE
- A more detailed and comprehensive study of transmission between hamsters;
- A similar study of transmission between ferrets;
- Transmission between persons in New Zealand quarantine facility;
- Modelling of COVID-19 on the Diamond Princess cruise ship.

I have presented multiple items of evidence in support of airborne transmission. More can be provided if required. However the opinion of HSE's CSA is already quite clear on this and so I really do not believe that any further evidence should be necessary. HSE should act and enforce on matters concerning RPE in line with 'good science'. To my mind the HSE's CSA is the ultimate authority when it comes to the science behind workplace health and safety. His opinion should hold sway over those who cling to 'droplet' theory.

It is both astonishing and shameful that, despite the sheer weight of evidence available to them confirming that COVID-19 is transmitted via the airborne route, IPC guidance still does not specifically state that COVID-19 is an airborne disease and recommend RPE whilst working in close proximity to infectious patients. I shall revert to this in annex 3.

4) Are the IPC authors excused from the section 36 offence by the 'HSWA caveat'?

Most iterations of the IPC guidance have included a "caveat" that the "*guidance is of a general nature*" and an employer "*should comply with all applicable legislation, including the HSWA"*. The key question to be considered is whether, and to what extent, is national IPC guidance is mandatory and binding upon duty-holders (Directors and Executives of NHS Trusts/Boards etc). Alternatively, is it optional, which duty-holders may take account of, but are free to deviate from if they so wish?

There are two compelling factors which, on the face of it, make compliance with IPC guidance and the associated National IPC Manual, mandatory and binding on duty-holders:
1) Direction from Public Health England and NHS England/Improvement; and
2) Legal considerations.

4.1) Direction from PHE and NHS-England / NHS-Improvement (NHS-E/I)

As discussed in section 1 above, senior management of NHS Trusts will most likely have been concerned that, if they deviated from central IPC Guidance, this would leave their Trusts (and possibly themselves as individuals) vulnerable to litigation if they did not strictly adhere to it.

A patient (or bereaved relative) would have had a strong case for a civil claim if they caught the disease whilst in the care of the hospital and the staff had not been wearing the prescribed equipment (surgical masks) that is designed to protect the patient from diseases which may be passed to them from the HCW. Besides which, the Trusts' Directors and Executives would have had a reasonable expectation that PHE and NHS-E/I were providing the best advice to keep their staff and patients safe.

In the early days of the pandemic letters were sent out to Chief Executives of NHS Trusts e.g.:
- Letter 28 March 2020 from the National Medical Director, NHS E/I jointly with the Medical Director, PHE setting out the expectation that HCWs in close contact with infectious patients will wear FRSMs, not respirators except in a few certain prescribed circumstances.
- Letter 10 April 2020 from the Strategic Incident Director COVID-19, NHS-E/I and the Medical Director, PHE stressing that "It is most important that all PPE is used in line with the UK guidance to maintain staff safety and supplies."

It would be a very brave Chief Executive indeed who disregarded such instructions from some of the most senior healthcare officials in the country. This, in itself would 'cause' them to comply with the guidance ('cause' within the meaning of the Section 36 offence, which is under consideration here.)

4.2) Legal status of 4-Nations IPC Guidance

As a general rule, "guidance" means just that - "guidance", which is not compulsory. Certainly in health and safety terms the duty-holder is free to take other action than that which is recommended, but they can be confident that if they do follow the official guidance they will normally be doing enough to comply with the law.

However, under certain circumstances the guidance may be assigned a more compulsory status by virtue of reference to it from a requirement established higher in the hierarchy of regulatory instruments (such as a Code of Practice, statutory instrument {Regulations} or Act of Parliament).

When considering compliance with the COSHH regulations in section 2 above, we established the link or 'pass-through' from a statutory obligation, via a Code of Practice to 'guidance'. The summary below is provided to assist comparison with healthcare legislation as follows:

1) **ACT**: Health and Safety at Work etc Act 1974 (HSWA):
   - Section 10(1) : Established the Health and Safety Commission and Health and Safety Executive (functions since combined) as the Regulator
   - Section 15(1) : the Secretary of State may issue Regulations (Statutory Instruments);
   - Section 16(1) : the Regulator may approve and issue Codes of Practice

2) **REGULATIONS**: Control of Substances Hazardous to Health Regulations 2002;
   - i.e. the 'statutory instrument' created by the Act
   - Regulation 7(9)(b) : Respiratory Protective Equipment to be 'approved' type or standard

3) **CODE OF PRACTICE**: COSHH approved Code of Practice L.5, para 160:
   - ACoP paragraph 160 : RPE must provide protection factor listed in Guidance HSG53

4) **GUIDANCE: HSG53** : Official Guidance issued by the Regulator the Health and Safety Executive
   - Appendix 6: RPE to have minimum protection factor of 20 for microbiological risks

i.e. this latter requirement therefore has an underlying quasi-legal imperative

A similar 'legal pathway' exists in healthcare legislation. A link or 'pass-through' from a statutory obligation, via a Code of Practice to 'guidance' exists which assigns a quasi-legal status from the Health and Social Care Act 2008 to the 4-nations IPC guidance:

1) **ACT**: Health and Social Care Act 2008 (HSCA):
   - Section 1: Established the Care Quality Commission as the Regulator
   - Sections 20 & 161: the Secretary of State may issue Regulations (Statutory Instruments);
   - Section 21: The Secretary of State may issue Codes of Practice
   - Section 23: The CQC must issue guidance about compliance with the Regulations

2) **REGULATIONS**: Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
   - i.e. the 'statutory instrument' created by the Act
   - Regulation 21: In order to comply with these Regulations, in relation to health care associated infections, the duty-holder must have regard to the CQC's guidance and the Secretary of State's Code of Practice
   - Regulation 15(2): As regards premises and equipment, appropriate standards of hygiene must be maintained

3) **GUIDANCE**: CQC Official Guidance: (Authority assigned direct from Regulation 21)
   - Guidance : Reg 15(2): Providers must comply with guidance from the Department of Health about the prevention and control of infections i.e.
     - The Code of Practice Code of Practice made by the Secretary of State under section 21 of the Act (HSCA); and
     - **Related guidance issued by the Department of Health and Social Care**
     - Each and every edition of the 4-Nations IPC Guidance since version 1.0 (March 2020) through to the latest version (17 January 2022) starts with the text "Issued jointly by the Department of Health and Social Care…"

This establishes a quasi-legal link between the Regulations and national IPC guidance.

It is noted that the level of duty in Regulation 21 is for the duty-holder to "have regard to" the CQC guidance not, for example, "shall comply with". However, the issue under consideration here is not to prove that an absolute legal duty is imposed by the guidance. The issue is more concerned with the extent to which the obligation may be perceived as a requirement by the duty-holder, and thereby influences their management decisions.

I therefore believe that the commanding language and imperative tone of the guidance regarding FRSMs put pressure upon Trust directors and executives and caused them to pay strict adherence to the national guidance. Text such as "FRSMs must be worn" for close-contact patient care is an unambiguous instruction which is highly persuasive. It does not come across as an optional course of action from which they are free to deviate.

As I am sure that the Directors/Executives would confirm, the pressure must have been quite considerable, in that departure from the official national guidance would not only leave them liable to civil litigation (as discussed) but also open to censure or enforcement from the CQC if they are unable to demonstrate that they have met the duty to protect patients from cross-infection in some other way. For instance, such censure or enforcement could be foreseeable if their hospital was to suffer greater-than-average rates of infections or deaths than other similar establishments, and some other types of masks were being worn in their hospital rather than FRSMs that were mandated in the IPC guidance.

It is therefore quite understandable that most duty-holders have elected to simply stay with the IPC guidance as being the easiest, cheapest and safest thing to do (i.e. "safest" meaning the most defensible option in terms of litigation).

So the IPC guidance placed the duty-holders in an unenviable and untenable position, insofar as close-quarter care of patients within 2 metres was concerned. IPC said "must wear FRSMs", and the COSHH ACoP said "must wear RPE with APF 20". It is impossible to comply with these two diametrically opposite requirements at the same time and so the majority of Trusts chose to stay with the NHS requirement.

After all, in terms of compliance with the health and safety legislation they would have had a reasonable expectation that if the use of surgical masks was unsafe and not an acceptable form of "PPE" for the hazard in question, then the HSE would have made their views known or even intervened using their enforcement powers. This will have been reinforced by the fact that HSE inspectors visited hospitals, saw HCWs wearing surgical masks whilst working at close-quarter with confirmed or suspected COVID-19 and did not raise any issues with hospital management about the practice. In doing so, HSE gave its tacit approval to the practice.

Directors and executives of ambulance Trusts may have interpreted your inaction as a tacit signal of approval for paramedics being 'protected' by FRSMs. Your inspectors will have known (either from site visits or news reports) that paramedics were wearing surgical masks whilst attending sick patients in their homes and then conveying them to hospital in ambulances. I cannot believe that any self-respecting HSE Inspector, knowing that surgical masks are not RPE and seeing these dedicated staff being 'protected' by flimsy masks will not have shared my deep concern through their training and professional ethics. Yet the HSE has corporately sat back and not intervened. This leads one to wonder whether HSE Inspectors were under instruction not to pursue the issue of FRSMs during inspections.

In conclusion, I believe it is self-evident that the IPC guidance has been sufficiently persuasive that it has caused duty holders to be in breach of COSHH for a period of 20 months. That is the HSWA Section 36 offence to which this letter refers.

The inclusion of the "caveat" text inserted by the IPC authors that an "employer must also comply with the HSW Act" is meaningless on the basis that the employer cannot comply with both opposite requirements. It no way exonerates the authors from the section 36 offence.

One 'defence' which the IPC authors may attempt to use is that they followed World Health Organisation guidance. However, the role of WHO is to provide guidance to all nations of the world, rich and poor, so through necessity it has to provide guidance which takes into account countries with healthcare systems very much more rudimentary and less-well equipped in others. So they have to strike a balance.

In the UK we are proud to have tremendous scientific and medical capabilities together with state of the art research facilities. We are in no way obligated to follow WHO guidance when we are perfectly capable of carving out our own path in the way we manage the pandemic and protect our healthcare workers. The UK does not have to, and should not 'hide behind the apron strings' of WHO. Besides, the very reliability of WHO guidance throughout the pandemic is very open to debate, but that is beyond the scope of this report.

Given the sheer number of healthcare-acquired infections, deaths and long-term incapacity which may be attributable to the failure to provide HCWs with respiratory protection, this may be the most serious criminal offence involving mass casualties ever seen in the United Kingdom. I therefore respectfully request that the HSE investigate the matter thoroughly and impartially.

I suggest that if this matter is considered in a Court or Inquiry, it is likely to be deemed that:

- the authors and publishers of the IPC guidance owed a 'duty of care' to healthcare workers and others who may be affected by their guidance;
- the 'duty of care' was breached by the delivery of guidance which has endangered health and arguably cost lives.
- The health of workers has been harmed and lives have been lost as a result of that breach.

You will of course recognise that the above 3 elements are the criteria which constitute 'negligence'.

Normally, when work-related deaths occur and there is a suspicion of negligence then, under the 'protocol for liaison', the police will investigate alongside the HSE to determine whether offences have been committed by individuals (gross negligence manslaughter) and/or by organisations (corporate manslaughter). There is sufficient evidence to warrant such a referral to the police.

Annex 2: Unethical/illegal research project commissioned

The UK-HSA has commissioned a research project involving a Randomised Clinical Trial named '*WIPPET'.* I have noticed that, since it appeared on the NIHR website, the project descriptionhas been updated and the text 'discontinued' has been added). I shall nevertheless continue my observations since it is anticipated that UK-HSA may try proceeding with the project, this time funded by themselves. I, together with a number of medical practitioners, view the details of this research project with considerable alarm, based on the details which were published on the NIHR website.

The reasons for concern are as follows:

- It is unnecessary. A wealth of published evidence already exists including, just by way of example:
  - A study which, through Whole Genomic Sequencing convincingly demonstrated patient-to-HCW transmission whilst wearing FRSMs; and
  - A comparative study of Trusts which do use RPE vs those that don't.

  Other commentators will no doubt identify further similar research when they submit their own concerns/complaints about this ill-conceived study;
- It is unethical to put people in harm's way to prove a point (particularly a point which has already been satisfactorily been proven). The harm in question is infection with COVID-19 through wearing FRSMs with the associated risk of illness, severe disease, long-term disability and death.
- A key ethical consideration is that the individuals involved in any such trial must give informed consent. This begs the question of the accuracy and integrity of the information they would be given upon which to base their decision. Given that the research team preparing that information are clearly very aligned to the (mistaken) concept that FRSMs are safe to wear and protect against airborne disease, it is foreseeable that the information provided to the participants will be erroneous and misleading. This would be no basis upon which to provide "informed consent".
- As previously discussed, it is illegal under various sections of the HSW Act and COSHH Regulations to provide surgical masks for protection against microbiological airborne hazards.
- It is interesting to note that a number of investigators who will be conducting this research are the self-same individuals who have been heavily involved in dictating, directing, approving, preparing and publishing the 4-nations IPC guidance. It is these same individuals who have steadfastly clung to the principle that FRSMs are suitable respiratory protection despite all the evidence to the contrary. This gives rise to some interesting considerations:
  - Being well-respected scientists and medical experts in their field I am sure that they can be trusted to approach the investigation in a totally impartial, objective, unbiased way without any preconception of what the outcome might be, although some commentators may see it as a publicly-funded 'back covering' exercise.
  - Indeed some might raise an eyebrow at some of the statements in the summary information published by NIHR i.e.
    - "FFP3 masks are thought to be better than FRSM at filtering out small aerosols" – a misleading statement because they are not 'thought to be' they are 'known to be'.
    - There is a statement in the Abstract/Background which is patently untrue:
      "*At present both UK and the WHO guidance recommend use of FRSM for routine exposure to confirmed COVID-19 patients, and FFP3 (or equivalent) masks for aerosol-generating procedures (AGPs)".*

      This statement might possibly have been true at the time when the applicants submitted their application to NIHR (there is no indication online as to when that was). However it is most certainly untrue now on both counts. This may have been an influential factor in NIHR's decision to discontinue the project:
      - The UK changed its guidance on 17 January 2022 and section 6.5.6 stipulates that an FFP3 respirator (or equivalent) must be worn when caring for patients infected with an airborne disease. The Government have officially confirmed that COVID-19 is an airborne disease. QED.
        The applicants/investigators for this project will know this since several investigators were involved with issuing the revised IPC guidance on 17 January. If the trial goes ahead then the research team will be actively encouraging the participants to breach the very IPC guidance which they themselves have set out in section 6.5.6. This is bizarre and highly unethical.
      - The WHO guidance was changed on 22 December 2021 and includes provision for FFP3 masks to be worn when in a room with COVID patients

The key point that I expect you, the HSE, might like to investigate upon reading the very first line (i.e. the title) of the "WIPPET" summary is the competence of the applicants/investigators who submitted this project to NIHR. Personally I have no knowledge of their competence, though I believe there are professors and even a Director of IPC in NHS England/Improvement involved.

One would hope that people in these elevated positions would understand what is classified as "Respiratory Protective Equipment" and what is not. So I draw your attention to the title: "*The impact of different grades of respiratory protective equipment on sickness absence due to respiratory infections including SARS-CoV-2 in HCWs*". The research project is only looking at FRSMs and FFP3s, and the authors are therefore referring to FRSMs as Respiratory Protective Equipment (which, of course, they are not).

As mentioned above, the HSE is the competent authority on matters of health and safety and, in particular, the respiratory protection of workers. You may wish to send them a copy of your excellent publication "HSG53: Respiratory protective equipment at work – A practical guide" from which they may learn a little more about the subject. They will not find one single reference to surgical masks therein.

It would appear from the abstract provided, that the researchers intend to study 3,000 HCWs who will be knowingly and deliberately put in the position of working with COVID patients whilst wearing FRSMs. This not only contravenes H&S Regulations but it now contravenes UK-HSA's own IPC guidance. It matters not whether they are already working in this way – they should not be working in this way.

May I respectfully point out to you that the "activity will involve a risk of serious personal injury to the health of those 3,000 people" (i.e. infection with COVID-19). You will immediately recognise this wording as having been drawn from section 22(2) of the HSW Act which empowers you to issue a 'Prohibition Notice' which, if not complied with, may result in a jail sentence for the individuals concerned. In the event that this ill-conceived project goes ahead, you should issue a prohibition notice to stop it in its tracks. I do not know the status of UK-HSA, but if they enjoy Crown Immunity then you should issue a Crown Censure and issue Prohibition Notices on any NHS Trusts which are selected by UK-HSA to participate in the trial.

I would like to draw attention to NIHR's policies and guidelines as they should serve as an exemplar to the project management team in UK-HSA.

I refer, in particular to the topic of "Research culture and integrity". NIHR is a signatory to the "Concordat to support research integrity" through which it commits to:

- upholding the highest standards of rigour and integrity in all aspects of research; and
- ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards

UK-HSA should review compliance of their proposed project against some of these parameters.

I would also draw attention to the NIHR policy for "use of animals in research" (again as an exemplar) where they recognise the need for "animals to be replaced with non-animal alternatives wherever possible. Whilst not in any way wishing to offend healthcare workers by the analogy, the point is surely still valid for homo sapiens?

To experiment with human beings in the manner proposed, where exposure to a pathogenic and potentially lethal virus is concerned, amounts to an absolute insult and gross affront to the thousands of healthcare workers who have already experienced the disease first-hand and continue to suffer with Long Covid as a result of workplace exposure arising from the lack of RPE. These are wonderful people with feelings, who have made incredible sacrifices and lost colleagues during this pandemic. I referred earlier to a perception of HCWs being seen as 'cannon-fodder' back in March 2020. This proposal brings that term back to mind. It is frankly preposterous and shameful.

Research projects such as HSE's RR619 have long-since been used to evaluate the protection afforded by surgical masks against bioaerosols and there is a host of other evidence that RPE should be worn to protect workers against hazards of this nature.

Annex 3: Ongoing failure to protect healthcare staff with Respiratory Protective Equipment

This annex is divided into 4 sections:

1) Evolution of IPC guidance into the current version issued 17 Jan 2022
2) Confused guidance for General Practice and the Ambulance Service
3) Statutory Requirements (Information for Employees and Risk Assessment)
4) Recommendations in respect of future pandemics (or worsening of COVID-19)

1) Evolution of current IPC guidance into the current version (17 Jan 2022)

In order to understand the current predicament that the healthcare sector finds itself in, we need to consider the three most recent editions of the 4-nations IPC guidance. It should be noted that a step-change in the scope of this guidance occurred between the versions 1st June 2021 and 17th December. It moved from being specific only to COVID-19 to cover a range of "winter seasonal respiratory viral infections". The scope is extended to include influenza (flu) and respiratory syncytial virus (RSV) as well as COVID-19.

1.1) Issued: 1 June 2021

This contained the imperative statement "Fluid Resistant Surgical Masks must be worn when providing direct care within 2 metres of a suspected/confirmed COVID-case". This has already been adequately covered in annex 1 and needs no further discussion.

It also introduced the concept that RPE may be worn if, after a local risk assessment, an "unacceptable risk of transmission remained" which, as discussed, is virtually impossible for the HCW 'on the ground' to determine, since there is no practical way of quantifying the amount of these invisible particles in the air being inhaled, nor the level of viral contamination within them. This will be discussed in section 3 below.

1.2) Consultation document issued: 22 September 2021

The IPC Cell issued a consultation document outlining new IPC guidance that they proposed to introduce (*No URL link is available to this document*). This contained an appendix specifying whether FRSM or RPE should be worn for various respiratory infectious agents. See figure 1 below:

Respiratory Infection/ Infectious agent	TBPs required (Contact/droplet/airborne)[1]	Recommended Patient placement[2]	Fluid-resistant surgical mask (FRSM) or respiratory protective equipment (RPE) required	Period of infectivity	Duration of precautions whilst patients is in hospital (where reported in the evidence)[3]
Coronavirus (SARS-CoV-2/COVID-19)	Droplet	Single en-suite room or /cohort if two or more patients	Fluid-resistant surgical facemask (FRSM) for direct patient care >1 metre and RPE for AGPs	From 2 days prior to symptom onset until 10 days after symptom onset.	Whilst symptomatic and/or 14 days after first positive PCR test.

Fig 1: Draft IPC guidance September 2021 : Entry for COVID-19

There are two points to note:

- The transmission route is still defined as 'droplet' despite the wealth of evidence that COVID-19 is transmissible via the airborne route (see annex 1, section 3 above);
- FRSMs are apparently only required to be worn if performing patient care at a distance greater than 1 metre. Either the authors believe that healthcare workers all have extraordinary arms capable of reaching a distance greater than one metre, or they are insufficiently trained in rudimentary mathematics to be able to determine the correct orientation of the sign "<" (less than) and ">" (greater than). This does not inspire confidence.

1.3) Issued: 17 December 2021 (*re-issued on 21 December, but with no significant changes*)

There are two key points to note:

Firstly, the appendix with the table of diseases (fig 1 above) had been removed, leaving the reader completely in the dark as to whether COVID-19, RSV or influenza were now considered 'airborne' or 'droplet'. This was particularly confusing given that Government videos (previously mentioned) were being broadcast to the public at the time demonstrating that COVID-19 particles are airborne "hanging in the air".

The section which dealt with RPE (6.5.6) contained the most bizarre, unclear and ambiguous criteria imaginable as to when RPE should be worn. It stated that RPE must be worn when "caring for patients with a suspected or confirmed infection spread **wholly by the airborne route**, such as tuberculosis".

The key word here was "wholly" and the reader was left wondering whether COVID-19 was now considered airborne or was it not? Because tuberculosis had been given as an example and not COVID-19, it was presumed that COVID-19 must still be considered by the age-old dogma of "droplet" and so FRSMs continued to be the recommended protection in most hospitals, the ambulance service and other healthcare settings.

This peculiar "wholly airborne" guidance needs some further consideration. Everyone agrees that there are 3 principle routes of transmission:

- fomites (contaminated surfaces);
- droplets (landing directly on the eyes or the mucosa in nose/mouth); and
- "airborne" (inhaled).

So if a disease is not "wholly airborne" then it must be "partially airborne". In other words one of the following 3 conditions must be true. Either it is transmissible by:

- the airborne route and the droplet route; or
- the airborne route and the fomite route; or
- all three (airborne and droplet and fomite).

There are no other combinations for something that is partially airborne.

So the IPC authors appeared to believe that if a disease is partially airborne there must be some feature of the droplet or fomite routes of transmission which in some strange way nullifies the airborne route such that it no longer presents a threat to health. This is most peculiar and defies all logic. If a disease is airborne then it is airborne and it will remain so – even it is also transmitted by fomites or droplets as well. It is difficult to see how anyone with a modicum of scientific knowledge could think that the existence of a fomite or droplet route in some way negates the airborne route.

As if to reinforce the debatable competency underlying this statement, even the example given of a "wholly airborne" disease (i.e. tuberculosis) was, strictly speaking, technically wrong. According to the "Green Book" for immunisations at chapter 32 it states that "*Almost all cases of TB in the UK are acquired through the respiratory route by breathing in infected respiratory droplets* ". The key words here are "Almost all" (i.e. not "wholly"). This is presumably a reference to gastrointestinal tuberculosis (where the route of entry may be via ingestion, not inhalation). So, with this logic, and taking the IPC guidance at its word, if we take paragraph 6.5.6 absolutely literally, RPE would not be worn with TB patients because it is not "wholly airborne".

Another point to note, is that the 'Green Book' description for TB refers to the disease being acquired by breathing in "respiratory droplets" in the context of a disease which is recognised as airborne. The authors of that document in 2018 clearly did not see the need to make any fine theoretical distinctions between 'aerosols' and 'droplets' as seem so important to today's IPC Cell. I recommend they have a discussion with the eminent scientists who author the "Green book" and learn from the acknowledged experts. We might then at last get some coherent and cohesive guidance.

We can actually learn quite a lot about transmission from TB. It is universally accepted that transmission of TB us 'airborne'.

The TB bacillus (a form of bacterium) measures between 2,000 to 4,000 nanometres in length with a radius between 100 and 250nm The SARS-CoV-2 virus has a sphere diameter of approximately 100nm with spikes or about 23nm. An average-sized bacillus is therefore approximately 260 times the size of the virus. The ability of a microbe to become entrained in an aerosol or respiratory droplet is largely governed by its physical properties such as its size and weight. So if a lumbering great TB bacillus can readily become aerosolised then so can a tiny SARS virus – indeed the latter is more likely to do so.

As I pointed out to PHE (29 Jan 2021) the process of aerosolisation of viruses is well described in an article "Breathing is Enough: For the spread of influenza virus and SARS-CoV-2 by breathing only" (Journal of Aerosol Medicine and Pulmonary Drug Delivery vol.33, N°. 4, 28 July 2020). It read:

- "*Coughing produces aerosol particles of size greater than 5 microns. However ordinary gentle breathing produces smaller aerosols less than 5 microns which, in the majority of cases will even escape through a surgical mask being worn by the patient.*"

- "*The lungs produce aerosol particles with a size of about 0.4 microns in diameter*";
- "*These are generated in the very small airways deep in the lung through the reopening of collapsed small airways. They are then expelled during exhalation and remain airborne in a room for several hours.*

The PHE in their response (2 Mar 2021) politely thanked me for the reference and said they would pass it on to their Scottish colleagues – presumably ARHAI. However, a search of the ARHAI 'rapid reviews' revealed that they never even mentioned it in any of their documents which inform IPC guidance. Perhaps it did not peak their interest. It certainly fits well and supports the airborne/aerosol theory of transmission. It would not, however, have fitted comfortably with the droplet theory of transmission.

1.4) Issued: 17 January 2022

In this, the latest issue of the guidance, the authors have presumably realised (or been told) of the idiocy of the "wholly airborne" phrase and have removed it. It now reads:
"*A respirator with an assigned protection factor (APF) 20, that is, an FFP3 respirator (or equivalent), must be worn by staff when caring for patients with a suspected or confirmed infection spread by the airborne route (during the infectious period)"*

This is a small step in the right direction but incredibly there is still no statement anywhere in the document that COVID-19 is 'airborne' and requires RPE for their protection. Neither is there any indication regarding the 'droplet/airborne' status of respiratory syncytial virus, nor influenza – both of which were defined as 'droplet' in the consultation document for this version of the guidance.
Confusion continues.

The only official document I can find is the National IPC Manual which, in its 'A-Z of pathogens' still states that COVID-19 is 'droplet'. This flies in the face of the Government's (Cabinet Office) view, EMG's view, the Respiratory Evidence Panel's view, the HSE's Chief Scientific Advisor's view etc. It still says that FRSMs are to be worn with infectious patients, directly contradicting the 4-Nations IPC guidance.
Confusion continues.

Then, if we look in that same NIPC manual for endemic flu, we see that it too is 'droplet transmission', whilst the authoritative 'Green Book", chapter 19 confirms that it also includes 'aerosol transmission'.
Confusion continues.

Seeming to be helpful in giving the reader a better understanding of "airborne transmission" the glossary of terms was amended from the June 2021 version, which had been a nice simple definition:

"*The spread of infection from one person to another by airborne particles (aerosols) containing infectious agents*"

to a more complex and less comprehensible:

"*The spread of infection from one person to another by airborne particles (aerosols) containing infectious agents. Airborne particles are very small particles that may contain infectious agents. They can remain in the air for long periods of time and can be carried over long distances by air currents. Airborne particles can be released when a person coughs or sneezes, and during AGPs. 'Droplet nuclei' are aerosols formed from the evaporation of larger droplet particles (see droplet transmission). Aerosols formed from droplet particles in this way behave as other aerosols. Airborne precautions are measures used to prevent, and control infection spread without necessarily having close patient contact via aerosols from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another individual. Aerosols can penetrate the respiratory system to the alveolar level."*

I am not quite sure how this adds to the reader's comprehension. The penultimate sentence (which I have underlined) reveals a possible conceptual flaw in the IPC authors' thinking about what is really important in this matter. They make the point that aerosols can float in the air beyond "close patient contact", which is absolutely true. However, what it abjectly fails to do is to emphasise the increased risk that aerosols present to workers in close patient contact. Whilst there is no harm in recognising that aerosols present a risk in the wider environment of a room or a ward (hence the need for good ventilation), it is patently obvious that it is "close patient contact" where the most extreme degree of risk exists, because that is where the concentration of the aerosol plume will be the greatest and the highest level of respiratory protection is needed to keep people safe. This is rudimentary science.

It may help the members of the IPC Cell to take note of the Government's oft-used phrase "follow the science" the detail of which was given in annex 1, section 3 above. It may be summarised as follows:

- The Government's scientists' collective view that:
  - 'Aerosols' are of a size approximately 100μ (microns) or less;
  - Any liquid particles larger than that are considered to be 'ballistic droplets' (which can impinge directly on the mucosa if they should be within close range);
  - Within the aerosol fraction there are 3 sub-fractions:
    - Nasopharyngeal aerosols (15-100μ); (nasopharyngeal = nose and throat in layman's terms)
    - Thoracic aerosols (5-15μ); (thoracic = chest in layman's terms)
    - Respirable aerosols (less than 5μ). (will pass deep into the lungs i.e. the 'alveoli', which is the name given to the tiny structures which enable oxygen to pass into the blood)
  - Two of the main targets for the SARS-CoV-2 virus are:
    - the epithelial cells in the nose (likely to be impacted by the larger nasopharyngeal aerosols);
    - alveolar cells known as 'Alveolar Type 2' (only likely to be impacted by the respirable aerosols)

    In other words, aerosols of <u>any</u> of these sizes can trigger the COVID-19 disease. The only difference is where the disease actually starts (nose or lungs in layman's terms). To the victim it makes no difference whatsoever where the virus first takes hold. Whether it starts in the nose, throat or lung, once it has taken hold the disease spreads and may cause serious illness and death.

- The key point is that the inhalation of <u>any</u> sized aerosol, including the larger ones that settle in the nose and throat can initiate the disease – and these are still categorised as 'airborne'. It is not just the respirable fractions.

For the avoidance of doubt, let me make this quite clear. The beliefs and understanding of the IPC Cell are conceptually flawed, plain wrong and therefore dangerous. I shall try and explain this in very straightforward terms in the hope that they, and everyone else, will understand what is really a very simple matter. Each and every edition of the IPC guidance since the start of the pandemic has described "Droplet transmission" in this way:

"***Droplets (>5μ) spread from the respiratory tract of one individual directly onto a mucosal surface or conjunctivae of another***". In layman's terms :

- "mucosal surface" = nostrils, lips, tongue, cheek, throat.
- "conjunctivae" = eyes

The key word to note here is "directly".

A droplet, in the true sense of the word, projected from the mouth or nose will, broadly speaking, travel forward in a straight line, other than falling downwards towards the ground due to gravity. This is where the '2-metre rule' comes from. This sort of droplet is what the EMG/SAGE experts refer to as a 'ballistic droplet'. It is certainly the case that if such a droplet happens to land on the eyes, nostrils or lips of a person it can cause disease. However, it will neither divert sideways nor upwards, being only drawn downwards by gravity. The dictionary definition of 'ballistic' is '*moving under the force of gravity only* ".

Now, consider the situation as droplet size becomes smaller (e.g. less than around 100 microns, which the EMG/SAGE experts refer to as 'aerosols'). The smaller the droplet size the lighter it is in terms of its weight, so it's path of travel through the air will not only be determined by gravity, but also by air movements. That is why they are described as "airborne". The dictionary definition of 'airborne' is '*transported by air*'). Aerosols will travel wherever the air travels.

Air movements happen when a person breathes in. Aerosols entrained in the air will be drawn inwards towards the person's mouth or nose as they breathe in. Moving air will always take the path of least resistance and will follow the easiest route. Unless the person is wearing a tight-fitting filtering mask (e.g. a CE-marked 'Filtering Face Piece' (FFP) with a good seal to the face, the air (and any aerosols entrained within it) will readily get inside the mask via the leaks around the edges. Surgical masks do not provide a seal to the face and this is why they are no good for safeguarding HCWs from airborne virus-laden aerosols breathed/coughed out by infectious patients.

Had this fairly simple concept been taken on board by the IPC policy-makers early in the pandemic then I believe that the rates of hospital-acquired infection and deaths would have been far lower than we have seen. The recently published numbers of COVID deaths arising from hospital-acquired infections are truly appalling (e.g. 11,600 in England and 2,000 in Wales).

The fatality rate amongst HCWs in the UK is believed to be amongst the highest in the world. The toll it has taken on HCW health in terms of Long-Covid is awful, with some crippled with neurological damage which can be caused by the disease, others with debilitating gastrointestinal problems and many other symptoms. The severity of the disease upon HCWs is most likely connected with the high viral load encountered day after day during their work caring for infectious patients without adequate RPE. Of course this nosocomial (hospital-acquired) infection is not limited to HCWs themselves, but the infection has passed along countless transmission chains via patients (and HCWs) to others beyond the hospital walls. This is why the Right Hon Jeremy Hunt MP is on record as saying that up to 40% of all deaths in the UK may be attributable to infections originally acquired in hospital.

We should therefore ask ourselves how this shocking state of affairs has come about.

1) Do we really believe that this is due to 'fomites'? Are the standards of hygiene, cleaning and disinfection really so abysmally poor in UK hospitals that so many people are touching surfaces and then transferring the virus into their eyes, nose or mouth? Many scientists now believe this 'hand-to-face" route of transmission to be far less significant than in the early days of the pandemic, though good hand-hygiene of course remains very important.

2) Do we really believe that this is due to 'droplets' happening to land on a person's mucosa? Given the practice of "universal masking" in hospitals, is it really likely that droplets of spittle, cough, or sneeze landing directly into patients' faces by infectious staff or other patients to such an extent as to account for the spread of infection on this astronomical scale?

3) Or is it more likely that the following chain of transmission is the cause:
    a. Infectious patients are constantly emitting infectious aerosols with every breath, every word they say or with every cough or sneeze;
    b. These invisible aerosols form a 'plume' around the patient's head – even if they are wearing a surgical mask as "source control". A study shows that surgical masks provide less than a 4-fold reduction in shedding of aerosols – the remainder escaping into the air around them. Of course, when eating, drinking and having various medical procedures performed upon them, patients cannot wear masks at all. This escape can occur through the mask material itself or via gaps between the mask and the face. As a person exhales, particularly if breathing heavily, the increased air pressure inside a loose-fitting mask can cause it to lift slightly away from the face, making it more likely that aerosols can escape (as many people who wear spectacles with their masks will appreciate).
    c. Healthcare workers, inappropriately protected by surgical masks then inhale these and the viruses take hold in the nose, mouth or the alveoli in the lungs.
    d. The healthcare workers in turn develop the disease and, as confirmed by Government sources, one in three of them will show no symptoms of the disease, so may still be working without even realising they are infectious to others.
    e. One might argue that staff are regularly tested for COVID-19. However research shows that PCR tests return almost 1 in 10 'false negatives'. Taking this figure, together with point (d) above, this means that approximately one in 30 HCWs may still be caring for patients whilst they, and everyone else, is unaware that they are infectious to others.
    f. There is also a consideration that those staff will be wearing surgical masks as 'source control' but, as mentioned in (b) above, their infectious aerosols will still escape into the air around them, with potential to infect yet more patients and other staff.
    g. And so the cycle goes round and round and round:
        i. Patient to HCW (and other patients) ; then
        ii. HCW to patients (and other HCWs);

    It is therefore easy to see from this scenario how the clusters of outbreaks occur that are seen in hospitals. Also, of course, the disease can travel beyond hospital walls via outpatients, inpatients being discharged and HCWs carrying the disease home and out into the community.

2) Confused guidance for General Practice and the Ambulance Service

Although the 17th January edition of IPC guidance, in itself, brought no clarity as to whether RPE should be provided to all HCWs working in close contact with patients, when considered alongside other Government guidance updated the same day, it did bring the clarity we need.

As mentioned above, once the peculiar "wholly airborne" phrase had been removed, we are left with a clear, unambiguous statement that "*RPE must be worn by staff when caring for patients with a suspected or confirmed infection spread by the airborne route*". Since the IPC Cell failed to identify whether COVID-19 is spread by the airborne route, happily the Government did. Its guidance page "Coronavirus: How to stay safe and help prevent the spread" unambiguously explains that COVID-19 is airborne: *"Airborne transmission is a very significant way that the virus circulates".*

So, when we put these two statements together, we have a definitive statement that "***RPE (i.e. FFP3 or equivalent) must be worn by staff when caring for patients with a suspected or confirmed COVID-19 infection***".

2.1 Confusion in respect of guidance for General Practice

On 18th January, immediately following the publication of the latest guidance, the DHSC wrote to GPs informing them that FFP3 respirator masks were now going to be made freely available to them via the PPE portal for circumstances where they assessed they would be at risk. The letter explained which types of mask could be obtained and how many would be allowed to each practice per week (based on the number of patients they served).

This will have been good news for Practices which have seen GPs and other HCWs falling ill with COVID-19 in their droves. However, until the DHSC letter on the 18th January, FFP3 masks were not available to them from the Government.

However, an inappropriate statement made by a member of the IPC Cell at a webinar on 13th January, just prior to the launch of their latest guidance was reported in Pulse (a journal for General Practitioners) just added to the confusion. She reportedly told the attendees at the webinar that "*Surgical face masks give you very much good protection, there's some good evidence*". This demonstrates that members of the IPC Cell really do actually believe that FRSMs provide good respiratory protection for a disease that is known to be airborne and for which FRSMs are, as previously discussed wholly inappropriate and unlawful. Anyone making such incorrect, misleading and dangerous statements should be included in your investigation into the Section 36 offence.

2.2 Confusion in respect of guidance for the Ambulance service

Shortly after the publication of the revised guidance which, as discussed, confirms RPE to be used for close-contact care of patients infected with an airborne disease such as COVID-19, the Association of Ambulance Chief Executives (AACE) issued a 'position statement' which referred to "subtle changes" in the guidance and an acknowledgement by the IPC Cell that their guidance had unintentionally given rise to misinterpretation. At least this is some sort of admission on the IPC Cell's part that they do publish confusing and ambiguous guidance. So say we all !

The Chief Executives then went on to stress that "There is no new evidence to support any further changes to the levels of PPE used in the ambulance service." This statement is wrong since there is an abundance of 'new evidence', such as:

a. the Government (Cabinet Office) confirming that COVID-19 is airborne;
b. the evidence provided by HSE's Chief Scientific Advisor's evidence to the Commons Select Committee, together with that of his colleague, the Professor from Pavia;
c. the evidence provided by the UK-HSA Respiratory Evidence Panel
d. the evidence from quarantine hotels, ferrets etc etc

For further details refer back to Annex 1, Section 3

It is difficult to know how much more 'new evidence' the ambulance Chief Executives require to accept the fact that COVID-19 is airborne and therefore the requirement of section 6.5.6 can only be interpreted as RPE (not FRSMs) for direct patient care. At times when there are high rates of community transmission, every call-out to an injured or unwell patient in an indoor setting represents an "unacceptable risk of transmission" and RPE should be provided without any quibbles. Our paramedics, being at the sharp end of the 'front-line' deserve no less.

3) Statutory Requirements (Information for Employees and Risk Assessment)

Throughout the pandemic information has been provided to employees in the healthcare sector that has been misleading and simply plain wrong. This misinformation has put their health and their lives at risk. The most glaring examples of misinformation have already been discussed (i.e. that FRSMs will protect them from this disease and the wholly confusing saga of 'droplet' vs 'aerosol') so I need not cover that again. Suffice it to say that such ambiguity and confusion over what RPE should be used should not be allowed to exist at any time, but especially not during an emergency such as a pandemic. Apart from anything else it is illegal under health and safety legislation.

HSWA section 2(2)(c) and COSHH Regulation 12 requires that employees must be given accurate information about the nature of hazardous substances that they face at work.

The PPE Regulations 1992 Regulation 9 requires that employees must be given accurate and "comprehensible" information concerning the PPE required to protect them.

Since the health authorities are not doing either, I call on HSE to step in and pronounce, unambiguously that "RPE (not FRSMs) must be worn when providing direct care within 2 metres of a suspected/confirmed COVID-case unless local risk assessment can demonstrate otherwise".

So the default would be the wearing of RPE at all times when exposed to a high risk of contracting coronavirus i.e. when:

- testing or diagnosing whether a person has been infected with coronavirus (COVID-19)
- caring for or treating a person who has, or is suspected of having, coronavirus
- involved in any type of service that is provided directly within the environment or facilities where diagnosis or care is occurring

Note, this definition of 'high risk' is not mine. It is the Secretary of State for Health and Social Care who has prescribed these criteria as 'high risk'. This may be found displayed on the NHS Business Services Authority's website. One wonders what further sort of risk assessment is needed when such clear-cut criteria are set out by the highest authority in the land, unless of course these criteria only apply after the worker has died and not whilst still living.

I mention "unless a risk assessment can demonstrate otherwise" (i.e. that RPE need not be worn). This takes account of the fact that there may be times when wearing PPE can actually increase the risk to the employee wearing it (HSE Guidance Legal 25 paragraphs 32 and 35). Such circumstances might, for example, be adjudged to exist if:

- the employee suffers from a respiratory complaint such as asthma and cannot tolerate tight-fitting RPE because of the increased burden on the lungs; or
- the working environment (e.g. high ambient workplace temperature) is not conducive to wearing tight-fitting RPE and causing health problems
- The wearing of tight-fitting masks is causing other health problems such as dermatological complaints.

Under any of the above circumstances, consideration should be given to the provision of powered respirators to protect the employee. Alternatively, if that is not a suitable solution and no other engineering options such as perspex barriers or local forced air ventilation are practical for the tasks to be undertaken then redeployment to a lower risk activity or job-rotation may be the only answers.

However, in practice the situation is that we are not permitted to simply take the Secretary-of-State's definition of 'high risk' as a basis for determining RPE requirements. Neither is there any agreement that the default for close-contact care is RPE as opposed to FRSMs. So in practice HCWs will need some sort of risk assessment method to work with. NHS England provides, via its 'Every Action Counts' facility, two documents setting out the criteria for completing a local risk assessment – one is for primary care, community care and outpatient settings. The other for acute inpatient settings. These were updated on 2 February 2022. Whilst these contain some reasonable guidance for the higher elements in the 'hierarchy of control' they are of no help whatsoever in respect of close-contact care within 2 metres of infectious patients for 2 reasons:

1) It relies upon the Transmission Based Precautions (TBPs) specified in the National IPC Manual (NIPCM) and refers the reader to these via hyperlink. These TBPs are of no use unless you know whether you are following 'airborne' or 'droplet' precautions for the disease in question. NHS-England follows the 4-nations IPC guidance which says 'airborne', in the NIPCM it says 'droplet'.
Even the definitions for 'airborne' are different. In the NIPC Manual, for the purposes of deciding whether RPE should be used, they still define 'airborne' (at section 2.4.4) with this ridiculous criterion of "disease spread **wholly** by the airborne route" (as previously discussed) whereas, the 4 nations IPC guidance has dropped the nonsensical "wholly" qualifier and now specify RPE for any disease which is airborne (whether wholly or partially).

   Since the two documents are directly interlinked and say different things they cannot be relied upon.

2) The two NHS England risk assessment criteria documents do not, themselves, provide any guidance as to what to do in terms of deciding the RPE requirements for close-quarter care. They just end up with the rather wearisome 'cop-out' which states "*If transmission remains following this risk assessment, it may be necessary to consider the extended use of RPE (FFP3) for patient care in specific situations*". As mentioned, the HCW has no way of determining whether 'transmission remains' or whether it doesn't given that the aerosols are invisible and the viral content cannot be quantified.

However, there is a solution for healthcare workers who need a practical, easy to follow risk assessment method. This facility, the COVID-19 workplace risk assessment toolkit, has been developed by the Royal College of Nursing in conjunction with Professor K Bampton (CEO, British Occupational Hygiene Society {BOHS}), drawing in guidance from Professor R Agius (co-chair BMA Occupational Medicine Committee) and other experts in microbiology. As with the NHS England risk assessment method, the facility also approaches risk assessment using the hierarchy of control (as required by the COSHH Regulations). However, unlike the NHS-England method it is useful in that it actually helps you to determine when RPE (such as FFP3 masks, reusable respirators or powered respirators) are appropriate for your protection without any confusing references to 'droplet', 'aerosols' or 'airborne'. It is written in plain language, is easy to follow and contains good practical advice for managers, employees, safety reps.

Another feature of the RCN toolkit is that it comes with an excellent resource explaining all about RPE, what it is, how to select the right RPE, explaining about filters and the right sort of RPE for protecting against harmful microorganisms such as the virus which causes COVID-19. I commend it to anyone with responsibility for care of infectious patients.

One final point on the topic of risk controls. Much emphasis has been placed on "Aerosol Generating Procedures" (AGPs) with these being singled out as a reason for wearing RPE. This is now considered by many an outdated concept as RPE should be worn when caring for patients suspected or confirmed to have COVID-19 under all circumstances (including AGPs). This is the opinion of a wide range of medical practitioners.

4) Recommendations in respect of future pandemics (or worsening of COVID-19)

4.1) Forthcoming Public Inquiry

A public inquiry is soon to begin and the appointment of Lady Hallett as Chair is very welcome news indeed. In the event that Lady Hallett happens to see this letter, my advice would be two-fold:

4.1.1 Scientific representation on the Inquiry Panel

When appointing the inquiry panel, give consideration to inviting an eminent scientist such as Sir David King. As the Government's Chief Scientific Advisor some 15 years ago, the 'Universal Ethical Code for Scientists' was published under his leadership. The Government and all policy-makers have needed accurate, clear, open and honest scientific advice. This phrase "follow the science" has been widely used – and indeed that it the right path to take.

The Inquiry Panel may find the 'Ethical Code' would be an informative base-line against which to review and assess not only the quality and clarity of the scientific advice provided, but the manner it which it has been used and applied in practice (or distorted, as the case may be).

I recall that, back in 2006, Sir David also set in motion a plan to better prepare the UK (and the rest of the world) for future pandemics. A report was prepared by 340 scientists from all over the world in preparation for a global pandemic which was predicted as almost certain to happen within the next 25 years. Sadly, his vision was not carried into practice and the UK appears to have been ill-prepared for Coronavirus when it struck. (I say "appears to have been" as this will clearly be a matter for the Inquiry to determine).

Since the primary purpose of the Inquiry will presumably be to set out a clear path in terms for preparations for future pandemics (or a worsening of the current one through the evolution of a vaccine-resistant variant) I am sure that the panel would find Sir David's knowledge, foresight and wisdom very helpful.

4.1.2 Regulation

I am reminded of a previous public inquiry into a major disaster, the Piper Alpha accident in 1988. One of the key recommendations made by Lord Cullen was that responsibility for health and safety offshore should be transferred away from the Department of Energy to the Health and Safety Executive which he considered more suited to the task.

If there is just one thing that I dearly hope will come from the Public Inquiry, it is that a recommendation will be made for responsibility for making policy in relation to the respiratory protection of healthcare workers to be transferred away from the UK-HSA, DHSC and the NHS IPC Cell to the Health and Safety Executive who are far more suited to the task, given their unquestionably greater expertise in this area.

This would, I suggest, be in the form of an "Approved Code of Practice" made under section 16 of the Health and Safety at Work etc Act 1974. Responsibility for implementation of the ACoP would still rest with the NHS and other employers, but they will be compelled to follow the guidance given in the ACoP. Both the HSE and the Care Quality Commission would oversee a satisfactory implementation in the workplace. In the event of the CQC discovering significant non-compliance, they would be required, through an amendment of Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, to report the facts to the HSE for enforcement.

The HSE have understandably desisted from interfering in medical matters within the health service, deferring to the other Government Departments. However, they do undoubtedly have the capability in terms of medical knowledge to be able to draw up such a code and would, in any event, be able to draw upon further medical advice from medical professionals, their governing bodies, professional institutions, colleges and trade unions.

One of the things that HSE is very good at doing is consulting with stakeholders prior to issuing new regulations, codes of practice and guidance.

4.2) A cautionary note from the World Health Organisation

As COVID-19 restrictions relax across the UK and there seems to be a general perception (including at Government level) that we are now reaching the point where we are nearing the end of the pandemic and "just have to live with it", we need to reflect on the wise words of the Director General of the World Health Organisation, Dr Tedros Adhanom Ghebreyesus. His message to the world on 1st February which may be viewed on the UN website and I would urge everyone reading this to spend 3 minutes watching his speech which begins:

> *We're concerned that a narrative has taken hold in some countries that because of vaccines, and because of Omicron's high transmissibility and lower severity, preventing transmission is no longer possible, and no longer necessary.*
>
> *Nothing could be further from the truth. More transmission means more deaths. We are not calling for any country to return to so-called lockdown but we are calling on all countries to protect their people using every tool in the toolkit, not vaccines alone.*
>
> *It's premature for any country either to surrender or to declare victory. This virus is dangerous and it continues to evolve before our very eyes. WHO is currently tracking four sub-lineages of the Omicron variant of concern, including BA.2.*
>
> *This virus will continue to evolve, which is why we call on countries to continue testing, surveillance and sequencing. We can't fight this virus if we don't know what it's doing and we must continue to work to ensure all people have access to vaccines.*

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4.3) Recommendations to the Parties involved in policy-setting

In the hope that this letter will be read by the members of the IPC Cell and those also involved in dictating, directing, approving and publishing the IPC guidance I have just one message.

I regret that it is not very original and is adapted from the words of Oliver Cromwell, Sir Amery and more recently the Right Hon David Davis MP. Nevertheless it is apt:

Leave matters of respiratory protection of workers to the acknowledged experts, the HSE

Healthcare workers have, for too long now, felt “expendable” or “cannon-fodder”

You have sat there for too long for all the harm you have done. In the name of God, GO!