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Dr Jenny Harries, OBE
Chief executive of the UK Health Security Agency
39 Victoria Street
London
SW1H 0EU

8 July 2021

Dear Dr Harries,

We are writing to you on behalf of an alliance of healthcare professionals representing over 25 professional associations, trade unions and individual experts, to raise our concerns at on-going challenges in the development and content of UK IPC guidance and to request a meeting to discuss these. Specifically, our concerns relate to:

- Recognition of airborne transmission of covid-19 outside of aerosol generating procedures (AGP's) and the increasing evidence supporting this as a primary mode of transmission in all settings.
- The need for clarity of the UK IPC guidance to recognise airborne transmission of covid -19 and risks to health professionals in close proximity to patients with known or suspected covid-19 through short range aerosol transmission not mitigated via ventilation.
- The lack of stakeholder engagement and consultation in the development of UK IPC guidance, specifically those organisations represented in this letter.

We attach recent communication from Michael Dynan-Oakley who chaired a recent meeting between representatives of our alliance and the UK IPC cell and Public Health England and our response to him on issues highlighted above. We remain very disappointed at responses to our questions and request for a further meeting which has not been granted.

We understand that you have been commissioned to lead a review of the UK IPC guidance and would like to offer our assistance and help with this. The commission is a positive development and critical for learning to inform ongoing management of the pandemic as many of our members report a 'post code' lottery on access to PPE depending on the employers interpretation of the guidance and ability to undertake and act on risk assessment. We would value a meeting at your convenience to discuss this and how we might be able to support development of the terms of reference if not already confirmed.

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Pat Cullen

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We look forward to hearing from you.

Yours sincerely,

Jude Diggins
Interim Director of Nursing, Policy & Public Affairs

Dr Barry Jones BSc MBBS MD FRCP
Chair AGP Alliance

Attachments:

IPC Stakeholder Engagement post meeting letter (DHSC)23.06
Mr Michael Dynan-Oakley - Letter in response to MDO DHSC letter 23.6
Appendix to Letter IPC Cell

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Department of Health & Social Care

PPE Policy and Strategy
Directorate
39 Victoria Street
London
SW1H 0EU

Attendees
IPC Guidance Stakeholder Meeting

23 June 2021

Dear All,

PPE IPC GUIDANCE STAKEHOLDER ENGAGEMENT

1. Thank you for participating in the personal protective equipment (PPE) Infection Prevention Control (IPC) Guidance Stakeholder Engagement meeting on 3 June, which included senior representatives from the IPC Cell, the NHS, the Devolved Administrations, PHE and DHSC.

2. In bringing the open and positive discussion to a close on the day, I agreed to follow-up with a coordinated written response to the key questions that we focussed on during the meeting. Accordingly, the questions that follow are those you posed and the answers reflect the collective views and positions of colleagues.

Q1. How can we ensure the provision of guidance that is standardised across all four nations, is consistent with the latest evidence on airborne transmission, aligns with existing guidance on other airborne conditions such as measles or TB, and reinforces the need for all healthcare employers to undertake effective local risk assessments that reflect needs for flexibility in infection control?

3. The IPC Cell makes recommendations for IPC guidance based on inputs from various sources of scientific evidence. Information from the Hospital Onset COVID-19 Infection (HOCI) Working Group, Scientific Advisory Group for Emergencies (SAGE) and other working groups feed into the evidence that the IPC Cell considers. The Cell also reviews international guidance and published literature to inform improvements in IPC practice, specifically the prevention of transmission and management of COVID-19 in health and care settings.

4. The guidance document ‘COVID-19: Guidance for maintaining services within health and care settings infection prevention and control recommendation’, which was most recently updated on 1 June 2021, and published by PHE, took into

account the evidence presented by SAGE in their paper 'Masks for healthcare workers to mitigate airborne transmission of SARS-Cov-2'.

5. The levels of PPE recommended in the IPC Guidance remain the same. However, this latest edition has been amended to stress the importance of individual PPE requirements being based on local risk assessments, using the principles of the hierarchy of control. Specifically, that the use of airborne precautions and extended use of PPE/respiratory protective equipment (RPE) is required if an unacceptable risk of transmission remains after rigorous application of the hierarchy of controls.

6. The IPC measures recommended in the guidance are underpinned by the National Infection Prevention and Control Manual (NIPCM) practice guide and associated literature reviews. The manual can be found at: https://www.nipcm.scot.nhs.uk/. This has been available in Scotland and Wales for a number of years. An English NIPCM is being drawn-up as set out in the 'UK Five-year Tackling Antimicrobial Resistance National Action Plan (2019-2024)', with systems and processes in place to ensure stakeholder engagement as part of its development and implementation.

7. NHSE/I has not advised the step down or changes to advised IPC best practice guidance with organisms such as TB and Measles during the pandemic. NHS E/I continues to support all healthcare employers to undertake effective local risk assessments, recognising that the implementation of the IPC guidance may vary in different care settings.

Q2. What consideration has the IPC cell made of the provision of FFP3 or equivalent, reusable respirators, which are sustainable and can be manufactured in the UK, to ensure frontline health and care staff have airborne protection against COVID-19? How can we ensure provision of such PPE becomes "business as usual" for this and future pandemics?

8. In December 2020, the UK IPC Cell produced a consensus position statement based on the available scientific evidence/opinion on whether any changes are required to the current UK IPC guidance due to the identification of the new variants of concern. The Situation Background Action Recommendation (SBAR) summarises the evidence that underpins the UK IPC Cell's position to maintain the current recommendations for PPE, as set out in the UK IPC guidance, and was reproduced in Appendix 1 of the SAGE Environmental and Modelling Group (EMG) paper: Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2 (April 2021).

9. The IPC Cell understands the issues raised relating to airborne transmission. The evidence and guidance recommendations focus on following the 'hierarchy of control' and it is important to note that a range of risk-reduction control measures are available in various hospital settings to reduce the risk to as low as reasonably practicable before the need to consider the extended use of PPE.

10. The most recently updated IPC Guidance recognises the inclusion of hierarchy of controls will vary across different settings and therefore states "where an unacceptable risk of transmission remains following the hierarchy of controls risk

assessment, it may be necessary to consider the extended use of RPE for patient care in specific situations. The risk assessment should include evaluation of the ventilation in the area, operational capacity, and prevalence of infection/new variants of concern in the local area."

11. We are keen to build on and explore opportunities for innovation, such as in reusable PPE, particularly in UK manufacturing, while ensuring staff have the assurances they need that innovative products are safe and effective.

12. There is a PPE Decision Making Council (DMC), chaired by DHSC with membership from the IPC Cell, PHE, and representatives from the four Nations. The broad purpose of the DMC is to enable regulatory decision making, whilst ensuring that essential specifications standards are met, and PPE products are safe. The DHSC Reuse, Innovation and Sustainability (RIS) team has also been set up to improve the position relating to innovative and sustainable PPE. The focus of this is to ensure that the logistics for reusable, sustainable products is in place to facilitate safe use, as well as user engagement, usually through pilots for feedback and safe cleaning/decontamination between uses. UK Make has the remit to ensure resilience in its PPE manufacture and supply. The Hub and the national IPC teams are fully committed to the ambition of having more sustainable PPE.

13. The RIS team is in the planning stages of a largescale piloting of reusable P3 respirators in accordance with decontamination guidance that is being finalised from the decontamination specialists, headed by Dr Sulisti Holmes. The RIS team is planning to run pilots to test the logistics associated with reusable respirators, as well as reusable Type IIR masks, including collection, decontamination and return to users. The pilots may also explore manufacturer's instructions for use for a clinical setting and the suitability for returning a clean safe product back to the user. We welcome the opportunity to collaborate with Dr Gillian Higgins on this project going forward, as offered in the meeting, if she has the capacity to do so.

Q3. Improvements in the design and ventilation systems of healthcare environments will take time and even then will not effectively reduce risk of aerosol transmission within 2m of a patient. In addition, many frontline workers work in community settings where close proximity and ventilation is unpredictable e.g. homes, general practice, care homes and prison settings. In some of these settings, people may live in close proximity and the risk to professionals is higher. This emphasises that PPE remains a crucial mitigation measure that needs to be optimised. Does the IPC cell have other options if they do not agree with this?

14. Ventilation of healthcare premises is being looked at as part of the work to review and revise the current Health Building Notes and Health Technical Memorandums, led by the NHSE/I Estates/Facilities team, with IPC included within the advisory process.

15. IPC is a key element for the New Hospitals Project team, and both the IPC Cell and New Hospitals Project team are working closely together.

16. Where an unacceptable risk of transmission remains following the hierarchy of controls risk assessment, it may be necessary to consider the extended use of RPE for patient care in specific situations. The risk assessment should include evaluation of the ventilation in the area, operational capacity, and prevalence of infection/new variants of concern in the local area.

17. In response to the Government's Road Map for pandemic recovery, the effect of easing measures such as extended use of facemasks/coverings and the requirement of physical/social distancing within healthcare settings requires careful planning prior to the easing of these measures. This review will include working with stakeholders e.g. developing risk assessment tools that will support decision making in different healthcare settings.

Q4. How are the IPC cell ensuring that national guidance is coordinated with the HSE to ensure Infection Control and workplace Health and Safety regulation is consistent?

18. The Health and Safety Executive (HSE) does not determine the UK IPC guidance with respect to use of respiratory protection equipment but HSE expect that its specific guidance on how such equipment is used is followed (in the context of UK IPC guidance). Multiple interactions with HSE have taken place on the importance of the robust implementation of hierarchy of controls as set out in the existent IPC guidance.

19. HSE colleagues are regularly consulted on issues raised with the IPC cell and on the guidance to ensure the UK IPC guidance is consistent with HSE regulation. As outlined in the HSE Report of February 2021 (https://www.nhshealthatwork.co.uk/images/library/files/Bulletins/A21_Summary_of_findings_-_Hospital_COVID_inspections_-_24_February_2021.pdf), HSE did not note any issue with the IPC guidance but highlighted organisational approaches to local risk assessment and emphasised the need for triangulation in approach between health and safety, occupational health and IPC. These issues were highlighted and reflected on within the most recent IPC Guidance. The HSE are members of the PPE Decision Making Committee.

Q5. How can we secure greater future collaboration between policy makers and stakeholders in the development of policy and guidance?

20. The IPC Cell, PHE, NHSEI and DHSC are committed to ensuring a collaborative engagement approach is taken when developing IPC guidance.

21. There has already been collaboration with the Royal Colleges but there have also been times when, due to the nature of the pandemic, decisions have had to be made at pace, with limited opportunity for stakeholder engagement.

22. Nevertheless, the preferred approach is collaboration and the IPC Cell is working with stakeholders in the development of IPC guidance in response to the Government Road Map for pandemic recovery, including developing risk assessment tools that will support decision making in different healthcare settings.

23. Further to this, discussions are taking place between DHSC, PHE, NHSEI and UK IPC cell members regarding the approach to national IPC policy development in future, on which we shall seek stakeholders views. NHSE/I is also developing a stakeholder engagement strategy plan and will share this with stakeholders, in due course.

24. As the Chief Nursing Officer explained in the meeting, she and other senior members of the IPC Cell and DHSC are committed to hearing the views of clinical stakeholders and to working collaboratively.

25. Please do also continue to use the IPC Cell mailbox nhseandnhsi.ipc-cell@nhs.net when it comes to sharing any additional information.

26. I do hope this helps to explain the position. I am confident the channels of communication are open, and I am keen to do what I can to support any next steps.

Yours,

MICHAEL DYNAN-OAKLEY

Deputy Director, PPE Policy, Briefing and Engagement

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Michael Dynan-Oakley
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8 July 2021

Dear Mr Dynan-Oakley

Thank you for your letter dated 23 June in response to the questions posed at the meeting held on 3 June with stakeholders representing over 25 professional associations, trade unions and individual experts, all co-signatories to letters to the Prime Minister (16th February 2021) and the Chief Medical Officers (12th March 2021).

Given the depth of discussion at the meeting and evidence presented to aid this we are disappointed by your response, specifically non recognition of the critical issue of short range aerosol transmission of COVID-19. Crucial questions were not answered during our meeting and have not been addressed in your written response. This is essential to enabling the proportionate and accessible supply and use of respiratory personal protective equipment (RPE) for health professionals.

At this point in the pandemic with escalating infections and increased hospital admissions our focus remains the adequate protection of our members and patients in all care settings.

Our members continue to report a loss of confidence in the UK IPC guidance, dissatisfied by a lack of consultation with stakeholders, in particular those represented at the meeting on 3rd June. The level of respiratory protection advised for health professionals in the UK remains below that of other developed countries including the US and Europe. This continues despite the limitations of the evidence base clearly stated in the ARHAI Scotland rapid review of the literature and previous review of the evidence base by the Royal College of Nursing which identified significant inadequacies in the ARHAI methodology.

As stated in the meeting we remain keen to support the revision of future guidance and resources. We look forward to receiving clarity on what this process might involve. Likewise we await receiving detail on the governance arrangements for guidance development and expectations for consultation as previously discussed and agreed in May 2021.

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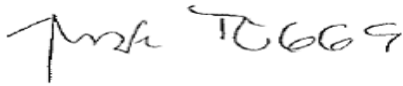
The attached appendix includes further detail on specific points included in your response which we hope you find informative.

Please do not hesitate to contact us if we can be of assistance on the matters raised.

Yours sincerely,



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Chair AGP Alliance

Attachment:

Appendix to Letter IPC Cell

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Appendix:

Please see below detail relating to other points raised in response to the reply of 23rd June.

1. Role of the Health and Safety Executive and local adaptation of guidance

Thank you for clarifying your understanding of the role and contribution of the Health and Safety Executive (HSE) in UK IPC guidance[i] development. The issue of how health and safety requirements and advice is reflected meaningfully in this remains an area of ongoing concern by our members. Specifically they report a desire for clarity on risk assessment to drive implementation of guidance in line with local need. The reality reflects apprehension on the implications of being seen to have 'moved away' from the UK IPC guidance. The inclusion of a disclaimer within the guidance is perceived as a major barrier to avoid risk of liability by the UK IPC Cell even with the recent addition of a statement on this (page 5) introduced without consultation with stakeholders as previously stated.

Specifically, our members report to us that locally the guidance is seen as a 'must do' rather than providing flexibility. For example, in current IPC guidance 1st June 2021 Page 20:

"Fluid resistant surgical face mask (FRSM Type IIR) masks must: ……• be worn with eye protection if splashing or spraying of blood, body fluids, secretions or excretions onto the respiratory mucosa (nose and mouth) is anticipated or likely • be worn when providing direct care within 2 metres of a suspected/confirmed COVID-19 case •"

The use of the word "must" in the above quote implies no flexibility after risk assessment has revealed a high risk of aerosol transmission within 2m of a suspected or confirmed Covid-19 patient, irrespective of any procedure being performed or its aerosol generating procedure (AGP) status.

2. Risk assessment and hierarchy of controls

We welcome reference to the use of hierarchy of controls and risk assessment however the issue of ventilation in particular, as stated in our presentation, is misleading as the ability to control risks associated with short range aerosol transmission experienced when in close contact with patients cannot be mitigated in this way. The recent additional paragraph on page 5 directing readers to a risk assessment resource is inadequate[ii]. The resource video 'Hierarchy of Controls' is not a guide to risk assessment and provides limited detail on how to implement the appropriate respiratory protection in different scenarios and settings. The Royal College of Nursing was engaged in the development of this resource in early 2021 and provided detailed feedback in its development on these issues which were not accepted. The RCN subsequently made the decision not to endorse the video based on its limitations and deficiency in recognition of respiratory PPE assessment and use based on the precautionary principle.

Within the UK IPC guidance there is no explicit mention of the possibility of close-range airborne transmission and the need for mitigation with FFP3 or similar. This represents a core inconsistency present throughout the current guidance. Ventilation is minimally protective when in close patient contact (within 2m) in a ward, ambulance, care home bedroom etc. Only enhanced respiratory PPE can mitigate this risk as the hierarchy of

controls does not address this. Inconsistencies and disparities in the latest UK IPC guidance 1st June 2021 are further highlighted by the following:

Page 43 9.4.1: "Critical care areas: Droplet precautions apply when within 2 metres and providing direct patient care. Airborne precautions are required when undertaking AGPs".

Page 36: 10.2.1: "Respiratory protective equipment (RPE)/FFP3 (filtering face piece or hood): Respirators are used to prevent inhalation of small airborne particles arising from AGPs".

In Table 10.2, Page 36 we observe that it is NOT made it clear how high risk is defined, nor does it mention close range aerosol transmission in the absence of AGPs except if too many patients are in one space and ventilation is poor.

Additionally as the AGP list remains unchanged despite multiple requests for it to be so, or abandoned altogether, there exists no flexibility within the current guidance to exhibit a flexible precautionary response when in close proximity to a patient even after risk assessment.

3. Personal Protective Equipment

We note that the UK IPC guidance states ' For the purpose of this document, the term 'personal protective equipment' is used to describe products that are either PPE or medical devices that are approved by the Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA) as protective solutions in managing the COVID-19 pandemic'. Our members are aware the FRSMs were not classified as PPE pre-pandemic and accept their role in preventing droplet and secretion contamination to the face. They are however acutely aware of the HSE published report on surgical masks and their effectiveness against bioaerosols[iii] and recommendation that 'they should not be used in situations where close exposure to infectious aerosols is likely'. This has, and continues to add to the confusion of our members regarding advice on their protection and use of PPE whilst at work.

This is particularly confusing given the focus in the IPC guidance on using higher levels of RPE such as FFP3 masks for AGPs, but not when providing care or interventions at close range. This messaging is further reinforced in the links to supporting resources and materials available on the gov.uk website where practice is predicated on AGPs. We are concerned that clarity regarding the appropriate use of FRSMs, is not provided in the context of the recent guidance revision (1st June) and highlighted to enable more effective local decision making. The recent paper from Ferris et al demonstrates the benefits of substitution of FRSM with FFP3 masks in reducing staff infections[iv] even with the inevitable limitations of undertaking such a study in a fast moving pandemic.

In summary, despite multiple attempts to engage with government bodies and teams by a number of professional stakeholder organisations, no significant changes to guidance and therefore the management of risk to our members has occurred. This includes attempts to redress this through our letters to the Prime Minister, Public Health England and Chief Medical Officer and our meeting with you on 3rd June. Our attempts to influence meaningful stakeholder inclusion and engagement in guidance development remain unsuccessful with the central issue of aerosols as a major route of transmission and management of close

proximity risk a major concern. We are disappointed not to be offered a follow-up meeting as this pandemic and the need for collaboration are needed for the foreseeable future.

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[i] COVID-19: Guidance for maintaining services within health and care settings Infection prevention and control Recommendations. June 2021 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/990923/20210602_Infection_Prevention_and_Control_Guidance_for_maintaining_services_with_H_and_C_settings__1_.pdf

[ii] Every Action Counts https://www.england.nhs.uk/coronavirus/publication/every-action-counts/

[iii] Evaluating the protection afforded by surgical masks against influenza bioaerosols. Gross protection of surgical masks compared to filtering facepiece respirators. HSE 2008

[iv] Ferris M et al (2021) FFP3 respirators protect healthcare workers against infection with SARS-CoV-2.