Impact of the RCN independent critique (March 2021) of the evidence underpinning infection prevention and control for COVID-19 in the United Kingdom

Dr Edward Purssell
Professor Dinah Gould

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For further information:
Rose Gallagher, Professional Lead Infection Prevention and Control, Royal College of Nursing

SUMMARY

We assessed the impact of an independent critique of the methodology used to inform current UK infection prevention and control guidance for COVID-19 commissioned by the Royal College of Nursing in March 2021. We looked for any changes in the methodology that had been used to inform this guidance and evidence taken to underpin it.

Our assessment suggests that the UK draft updated respiratory guidelines do not meet expectations for a rapid review intended to support guideline development when a pandemic is progressing. Despite mounting evidence, the updated draft guidance from the IPC Cell (September 2021) does not yet acknowledge that airborne transmission of SARS-CoV-2 is likely (except in situations where aerosol generating procedures are undertaken). Failure to take account of this evidence means that health workers continue to be offered a level of respiratory protective equipment at variance with that available to their contemporaries in other developed nations. Guidelines in Europe, the US and Australia are based on recommendations from the European Centre for Disease Control and the Centre for Disease Control which have been updated in line with emerging evidence (CDC, 2021; ECDC, 2020). Consequently, health workers in these countries have routine access to FFP3. FFP3 is not routinely available to health workers in the UK when caring for patients who have or who are suspected to have COVID-19. We conclude that the situation regarding recommendations for the provision of respiratory protection for health workers has not changed since the first independent critique in March 2021.

KEY RECOMMENDATIONS

- The RCN should lobby for a rapid systematic review to be commissioned by the UK Health Security Agency (UKHSA) as a matter of urgency. It should be undertaken by an independent multi-disciplinary team and include full stakeholder involvement. This review should adopt recognised methodology developed especially for use with COVID-19 (Garrity et al., 2021) and used to develop new guidance adopting the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework to ensure transparency. Particular attention should be given to respiratory protection. The new review should be used to inform infection prevention and control (IPC) guidance and have the status of a 'living review' with monthly updating and full transparency of findings for the duration of the pandemic until the World Health Organization (WHO) declares it over.

- Until the new guidance is available the precautionary principle should continue to be advocated in view of the increased transmissibility of the Omicron variant and its implications for workforce absence in premises where health and social care are delivered.
- The RCN should commence a review of lessons identified as a result of the development of pandemic IPC guidance taking into account professional nursing and trade union components of its role based on its members'

experience. This review should inform RCN priorities and activity spanning the next 6-18 months as the UK moves to the management of COVID-19 as an endemic seasonal infection.

BACKGROUND

Health workers are at higher risk of acquiring COVID-19 than members of the general population (Mutambudzi et al., 2020). Throughout the pandemic the Royal College of Nursing (RCN) has continued to express concern over the lack of meaningful stakeholder and multi-professional engagement in the development of the COVID-19 UK Infection Prevention and Control (IPC) guidance for its members. The RCN has also raised concern about the ongoing failure of the UK IPC guidance to recognise the spread of SARS-CoV-2 via the air (except during aerosol-generating procedures) in enclosed spaces where health workers deliver care (e. g. hospital wards, domiciliary care, ambulances, hospices, nursing homes). Attempts by the RCN and other stakeholder organisations to influence the detail and inclusion of evidence supporting transmission of COVID-19 via the air throughout the pandemic, but specifically given the emergence of more transmissible variants of concern, were unsuccessful. This situation prompted the commissioning of an independent critique of the IPC COVID-19 guidelines published by Public Health England (PHE) in March 2021 and the evidence underpinning them (RCN, 2021).

Findings of the independent critique in March 2021

The evidence contained in the UK IPC guidance was based on a series of independently undertaken rapid literature reviews. We reported that:

- recommendations from the rapid review (March 2021) and the UK IPC guidelines did not draw sufficiently on the evidence relating to face-protection; glove use; and the importance of ventilation in premises where health care is delivered

- the methodology used to undertake the rapid review did not meet expectations for the conduct of rapid reviews appropriate in emergency situations.

THE SECOND INDEPENDENT CRITIQUE

The RCN has not altered its position regarding the level of respiratory protection that should be offered to its members when delivering care for patients known or suspected to have COVID-19. The RCN and other stakeholders were invited to review updated draft UK IPC guidance developed by the UK IPC Cell (September 2021). The RCN responded to the consultation invitation. However, RCN feedback specifically challenged the continuing definition of airborne infection or aerosol production only occurring in particles <5μm, drawing on wider international literature that reflect growing evidence on this issue and implications for the protection of health care workers. The RCN commissioned a second independent critique to examine any changes in the methodologies and recommendations suggested in this more recent guidance and the rapid review (November 2021) then informing it. The findings and recommendations of the second critique are presented below.

AIMS

1. Assess the impact of the first independent critique of the methodology used to inform current UK IPC guidance for COVID-19.

2. Assess any changes to the methodology used to inform the UK IPC guidance and sources of evidence quoted.

3. Compare the methodology to undertake the rapid review of evidence in March 2021 (as described in the UK IPC guidance) to any review in November 2021 and evaluate any changes in the breadth and depth of evidence considered and taken into account in the UK IPC guidance.

4. Identify whether any of the recommendations from the first RCN independent critique (March 2021) have been adopted and make further recommendations (if required) to improve the standards used to inform IPC practice and the use of personal protective equipment (PPE).

5. Make recommendations to support improvements in available guidance to inform safe IPC practice and the use of PPE to protect health care workers exposed to COVID-19 in the workplace.

METHODS

An open invitation for expressions of interest to undertake a review of impact of the original RCN Independent report in March 2021 was published in November 2021. Expressions of interest were evaluated by a three-member panel and the commissioned authors were appointed in December 2021.

The authors drew on the evidence of best practice used to generate clinical guidelines when a pandemic is well advanced (Schünemann et al., 2020). This information was used to critically appraise the methodology employed to compile the November 2021 ARHAI Scotland rapid evidence review and the recommendations it contains.

The UK guidelines also used alternative sources of evidence in the latest published guidance, but these could not be critiqued because of their generic nature.

FINDINGS OF THE SECOND INDEPENDENT CRITIQUE

The most recent guidance for the prevention and control of COVID-19 in the UK is included in a report entitled 'Infection prevention and control for seasonal respiratory infections in health and care settings (including SARS-CoV-2) for winter 2021-2022' (UK Health Security Agency, n.d.). These are general guidelines are meant to be customised by users to meet the needs of specific clinical and adult social care settings except for England which has separate

adult social care guidance (UKHSA 2021). Many of the recommendations are based on risk assessment and controls assurance.

We note that the most recent iteration of IPC guidance considers recommendations from two publications (PHE, 2016; Health Protection Scotland, 2015) and policy recommendations from the World Health Organization (WHO, 2021), Department of Health and Social Care Pandemic Influenza guidance and Scottish National Infection Prevention and Control Manual. In terms of evidence used to inform recommendations, a link at the time of investigation was provided to the November 2021 rapid review (ARHAI Scotland, 2021). No other literature review or evidence is presented.

Key findings of the critical appraisal of the most recent review of evidence underpinning the UKHSA IPC guidance (ARHAI Scotland, 2021) are summarised below.

- The methodology adopted to conduct the rapid review (November 2021) does not meet the standards that should be used to undertake a rapid review when a pandemic has reached an advanced stage.

- The methods used to develop both the recommendations in the rapid review (November 2021) and UK guidelines lack transparency.

- There has been no discernible attempt to include stakeholder feedback in IPC guidance. The RCN and other professional bodies were asked to respond to a stakeholder consultation but no stakeholder response to the IPC guidance consultation has been published, despite indications that this would be publicly available. It is therefore not possible to know what feedback, if any was considered by authors of the revised IPC guidance and how decisions were made on amendments to the guidance, including inclusions and omissions.

Responses to the questions posed by the RCN

1. Assess the impact of the original RCN report of the methodology used to inform current UK infection prevention and control guidance for COVID-19.

The first independent critique commissioned by the RCN in February 2021 has not influenced the methodology used to generate the UK guidelines for COVID-19.

2. Assess any changes to the methodology used to inform the UK IPC guidance and sources of evidence quoted.

There is little if any change in the methodology used to generate the UK guidance arising from the first independent critique commissioned by the RCN in February 2021.

3. Compare the methodology used in March 2021 by those developing UK infection prevention and control guidance with that in November 2021 and evaluate any changes in the breath of evidence considered and used.
The methodology adopted in November 2021 is not more rigorous than the methodology adopted in March 2021.

4. Identify if any of the recommendations from the original RCN independent critique (March 2021) have been adopted and make further recommendations (if required) to improve standards used to inform infection prevention and control practice and the use of personal protective equipment.

The recommendations suggested in the first independent critique commissioned by the RCN do not appear to have been acted on. The RCN and other stakeholders were invited to comment on the updated UK guidelines for respiratory infections in September 2021. To date there has been lack of transparency concerning what feedback was considered, acted on or included in the guidance. Of particular concern is the lack of any acknowledgement of the airborne route of transmission of SARS-CoV-2 and continuing omission of the use of PPE in the UK IPC guidance.

DISCUSSION

Methodology

The rapid review: 'Assessing the infection prevention and control measures for the prevention and management of COVID-19 in health and care settings' (November 2021) does not meet contemporary expectations for a review of the literature used to generate guidelines. Early in a pandemic when very little is known about a novel pathogen, it is considered permissible to draw on existing guidelines for other pathogens that might be similar but not when more information about the emerging infection becomes available (Garritty et al., 2021; Schünemann et al., 2020; Tricco et al., 2017). Updating is considered essential as a pandemic progresses and more is known.

Emergency guidelines should be considered 'living' guidelines and generated with pre-determined, transparent timelines specifying when they should be revised and amended and should involve the use of a transparent framework to balance the strength of the recommendations (e. g. Grading of Recommendations Assessment, Development and Evaluation) to enable users to understand how decisions were reached when certainty of the evidence might still be low or moderate (Dagens et al., 2020). The recommendations arising from the rapid review (November 2021) do not meet these criteria. Guidelines should be externally reviewed using a validated tool (e. g. AGREE II) (Brouwers et al., 2010) to highlight areas where recommendations are vulnerable to allow the authors to remedy any deficiencies in future revisions of their 'living guideline' (Dagans et al., 2020). It is not clear whether recommendations from the rapid review (November 2021) benefited from external review.

This second critique has demonstrated that:

1. The 'evidence' used in the November 2021 ARHAI Scotland rapid review depended heavily on old guidelines dating from much earlier in the pandemic when far less was known about SARS-CoV-2. These older guidelines applied to other respiratory conditions (usually severe acute respiratory syndrome (SARS), middle eastern respiratory syndrome (MERS CoV)), not specifically to SARS-CoV-2.

   By November 2021 the pandemic had been in progress for twenty months and much more about SARS-CoV-2 was known. At such a late stage in the pandemic, the focus of evidence should have been on SARS-CoV-2 with additional evidence drawn from those in other disciplines (e.g. aerosol science) to target the measures put in place to protect health workers.

2. Searches undertaken by the authors that the RCN had commissioned identified systematic reviews containing information about the efficacy of different types of face-covering offering respiratory protection not cited by ARHAI. Of these, six contained information directly relevant to new guidelines. These searches are shown in Appendix 1 as highlighted text.

The ARHAI Scotland review methodology employed in November 2021 can be further called into question over technical details relating to the way the searches were conducted. The review does not describe the methods used to undertake the searches in detail or explain how decisions were reached concerning which works were eligible for inclusion. It is apparent from publicly available information that the reviewers omitted to use the crucially important Mesh term n95 OR ffp2 AND surgical mask that would have identified the papers retrieved in PUBMED and shown in Appendix 1.

In the UK there is a preference for the procurement FFP3 masks in health care settings, but they offer little added protection to that provided by FFP2 masks and FFP2 masks can easily be purchased. Consequently, it is difficult to justify exclusion of this Mesh term in the searches. Whilst it is unknown if the inclusion of this search term would have resulted in any discernible change to the guidance, this omission reinforces previous concerns on the quality and value of the evidence based used by the UK IPC cell to develop national guidance.

Stakeholder involvement

All recognised guideline development methodologies emphasise the importance of stakeholder involvement (NICE, 2012). The RCN has raised concerns throughout the pandemic regarding the need and desire for wide stakeholder meaningful involvement in the development of guidance. The rapid review of evidence (November 2021) and the subsequent published UK respiratory guidance for winter 2021-2022 do not disclose whether stakeholders contributed to the development of their recommendations. The draft UK respiratory guidance for winter 2021-2022 was submitted to a number of groups

for consultation, including the RCN, but it is not possible to determine if any other stakeholder involvement occurred and there is lack of transparency on what, or if any, feedback was included in the development of the published UK IPC guidance.

Recommendations to support improvements in available guidance to inform safe infection prevention and control practice and the use of personal protective equipment.

Based on the March 2021 report and this subsequent review the following is recommended, taking into account the paucity of 'gold standard' evidence, to inform IPC guidance for COVID-19.

- The RCN should lobby for a rapid systematic review to be commissioned by UKHSA as a matter of urgency. It should be undertaken by an independent multi-disciplinary team and include full stakeholder involvement. This review should adopt recognised methodology developed especially for use with COVID-19 (Garrity et al., 2021) and used to develop new guidance adopting the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework to ensure transparency. Particular attention should be given to respiratory protection. The new review should be used to inform IPC guidance and have the status of a 'living review' with monthly updating and full transparency of findings for the duration of the pandemic until WHO declares it over.

- Until the new guidance is available the precautionary principle should continue to be advocated in view of the increased transmissibility of the Omicron variant and its implications for workforce absence in premises where health and social care are delivered.

- When WHO declares that the pandemic is over, finalised guidelines should be developed and agreed to support business as usual delivery of health and care and preparation for a future pandemic event. Uptake of the new guidelines and their impact should be assessed for the remainder of the pandemic.

- The RCN should commence a review of lessons identified as a result of the development of pandemic IPC guidance taking into account professional nursing and trade union components of its role based on its members' experience. This review should inform RCN priorities and activity spanning the next 6-18 months as the UK moves to the management of COVID-19 as an endemic seasonal infection.

- The RCN should consider how to communicate the findings of this review and how to influence actions to improve the standard of available guidance and evidence used to inform this.

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APPENDIX 1

Results of a rapid search of the literature for information on the use of face-coverings against SARS-CoV-2 conducted in PUBMED 6.12. 2021.

The report authors identified the absence of a key Mesh search term n95 OR ffp2 AND surgical mask. Six additional references contained information directly relevant to new guidelines. These searches are highlighted * for ease of identification.

Items 1-24 of 24 (Display the 24 citations in PubMed)

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