Masks for healthcare workers to mitigate airborne transmission of SARS-CoV-2

Summary

We have summarised the evidence on SARS-CoV-2 transmission and mitigation in UK health and care settings, with a specific focus on small particle aerosols and healthcare worker (HCW) facemasks.

Throughout we refer to FFP3/N95 masks as Respiratory Protective Equipment (RPE). Personal Protective Equipment (PPE) is used as a generic term to refer to a broad range of personal measures, which may include gowns, gloves, type II fluid resistant surgical facemasks (FRSM) and face visors.

- Transmission risks apply to multiple locations across healthcare settings and associated (clinical and social) activities (high confidence).
- Transmission risks should be managed to be as low as reasonably practicable without unintended consequences. Reducing transmission requires the risk from all activities to be assessed for all areas, and the hierarchy of control should be used to identify appropriate controls with “elimination”, “substitution”, “engineering controls” and “administrative controls” considered (including in combination to build strength in depth) before PPE or RPE is considered (high confidence).
- There is variation in nosocomial COVID-19 rates across NHS trusts and there are multiple factors that may explain this variation. It is not currently possible to identify whether any of this variation is related to RPE use (high confidence).
- Inspections of acute hospital trusts have identified clear variability in compliance with the full range of ‘COVID-secure’ guidance recommended to mitigate virus transmission risk (high confidence).
- The optimal management of transmission risks from patients with possible or proven COVID-19 requires actions based on a risk assessment accompanied by effective organisational leadership and support (high confidence). In the healthcare setting, this system is most effective with strong support from the Trust management, and when the Infection Prevention and Control (IPC) and Health and Safety teams work in close and effective partnership (high confidence).
- Improved understanding of aerosol risks supports the need for a greater consideration of this route of transmission within risk assessment and IPC strategies, including ensuring compliance with wearing of FRSM as source control by staff and patients (as far as possible) and paying specific attention to the effectiveness of ventilation in both clinical and non-clinical areas (medium confidence).
- If an unacceptable risk of transmission remains after rigorous application of the hierarchy of control it may be necessary to consider the extended use of RPE for patient care in specific situations (medium confidence).

- This approach should be considered in the context of the operational requirements of implementing the effective use of RPE as a component in any risk management system, and recognising that it would need to accompanied by training, supply chain management, face-fit testing, monitoring and management oversight (medium confidence).

Overview of current guidance

Current UK COVID-19 infection prevention and control (IPC) guidance for healthcare is produced jointly by the Department of Health and Social Care, Public Health Wales, Public Health Agency Northern Ireland, Health Protection Scotland/National Services Scotland, Public Health England and NHS England.[1]

UK infection prevention guidance [1] and that issued by the World Health Organisation (WHO) [2] both recommend that HCWs routinely wear surgical face masks (that are correctly fitted/worn) while COVID-19 is endemic, and that FFP3 and similar types of respirator masks 'are recommended for use where aerosol generating procedures (AGPs) are in place for a suspect/confirmed COVID-19 patient.'[2] This guidance has not changed since new virus variants have been described. The current advice is that the mechanisms of transmission of recent novel variants of concern are likely to be the same as the wild-type SARS-CoV-2 and other variants in circulation.[3] The reason for the increased transmission of such variants are unclear; it is possible that the infectious dose could be lower and/or viral load higher, so altering the relative importance of some transmission routes.

The most recent update (Version 1.0 published 20 August 2020; Revised Version 1.1 published 21 January 2021)[1] of the UK IPC guidance states:

> 'Sessional use of single use PPE/RPE items continues to be minimised and only applies to extended use of facemasks (all pathways) or FFP3 respirators (with eye/face protection) in the medium and high risk pathway for healthcare workers where AGPs are undertaken for COVID-19 cohorted patients/individuals.'

The WHO defines an AGP as a medical or care procedure that creates the potential for airborne transmission of infections that may otherwise only be transmissible by the droplet route.[4] The WHO considers droplets as being larger than 5 μm; a 5-10 μm micron droplet can remain in the air beyond 2m and may only be partially stopped by a facemask. It should be recognised that as well as producing aerosols, AGP procedures produce larger droplet particles.[5-7] During AGPs, there may be an increased risk of aerosol spread of infectious agents, irrespective of the mode of transmission (contact, droplet, or airborne), and airborne precautions (FFP3 respirator and facial protection) must be implemented.[8]

It important to emphasise that those responsible for healthcare settings should ensure that all current infection prevention and control measures, including with respect to respiratory measures, are fully implemented. A hierarchy of risk approach to enable mitigation measures is required (discussed in more detail below), both in terms of how they impact on the

transmission routes and the level at which they are implemented within an organisation; PPE is the lowest tier in such a hierarchy (Eliminate, Substitute, Engineering/environment, Administrative, PPE).[9] As such, multiple measures should be in place to minimise virus transmission, including good ventilation to mitigate aerosol transmission. Current guidance recommends that appropriate PPE should be readily available and worn correctly by staff at all times. Cleaning and ventilation protocols should be followed and optimised, particularly in communal areas such as toilets, and patients and visitors should wear facemasks/coverings at all times, unless it is clinically impossible to do so.[1,3]

The risk of SARS-CoV-2 acquisition by healthcare workers

HCWs worldwide appear to be at increased risk of acquiring COVID-19 compared with members of the public.[10] It is important to note that such observations may be affected by multiple factors and behaviours. The Health Protection Scotland (HPS) Antimicrobial Resistance and Healthcare-Associated Infections (ARHAI) group has recently published a rapid review of the literature on the risk of SARS-CoV-2 acquisition by healthcare workers (HCWs).[11] This was driven by growing concerns surrounding the potentially increased risk of COVID-19 acquisition by HCWs, including open letters and correspondence from professional bodies. Specifically, the review aimed to determine the risk of COVID-19 acquisition in healthcare workers providing care to suspected/confirmed COVID-19 patients in health and care settings. The noted major limitation of the studies included in its review was that it was not possible to determine the exact source of infection or direction of transmission in the groups analysed. Thus, it generally remains unclear how much PCR positivity in HCWs is directly related to the workplace or indeed to patient care, and how much is a result of acquisition outside of the workplace in the community. The review concluded that 'there is a distinct paucity of rigorous research regarding the risk of SARS-CoV-2 infection amongst HCWs in the UK'.[11]

A multivariable analysis from Oxford, which controlled for factors including hospital-based COVID-19 exposure, role, specialty and ethnicity, found that household contact with known (adjusted odds ratio 4.82, 95% CI 3.45–6.72, $p<0.001$) or suspected (1.75, 1.37–2.24, $p<0.001$) cases remained important risk factors for acquisition of COVID-19.[12] There is evidence that transmission of COVID-19 between HCWs can occur in the work place not during healthcare delivery, while travelling to/from work, and outside of the workplace setting.[12,13] Indeed, one of the settings where SARS-CoV-2 RNA can be most commonly detected in the hospital environment is in areas where HCWs congregate and socialise,[14] There is some feedback that HCW compliance with distancing, respiratory protection wearing, etc is non-optimal; again, this is particularly in those areas where HCWs congregate and socialise, and guidance has been emphasised around such issues.[15] In addition, working outside the home is an important risk factor for acquisition of COVID-19.[16]

Higher frequency of use of FFP3 masks by HCWs in intensive care units has sometimes been suggested as evidence that this element of PPE is a key determinant of HCW COVID-19 infection risk. HCWs working in intensive care units may be at reduced risk of acquiring COVID-

19. This is likely to be influenced by multiple factors, including the higher staff to patient ratios, and a more controlled environment including few patient-patient interactions, no toilets and (usually) higher room ventilation rates. While the risk of COVID-19 in HCWs may vary according to speciality, increased risk has been seen in 'unexpected' specialties such as orthopaedics and haematology; this reflected the occurrence of staff-based outbreaks in wards with very few COVID-19 patients.[12] This study also found that, after controlling for working in a COVID-19 patient facing area, the greatest risk of infection by role remained for porters and cleaners (2.06, 1.34–3.15, p=0.001).[12] This emphasises that direct clinical exposure *per se* may not be the greatest risk factor for acquiring SARS-CoV-2 in the healthcare setting, although it is likely that it is one of the risk factors.

Hierarchy of controls

Whilst SARS-CoV-2 is present in the community, there will always be a risk of transmission by the three routes (person to person, air, surface) in any setting and the interfaces between them. In workplaces, including hospitals, the risk assessment process is used to identify the mix of control measures required to reduce the risk from any work activity in any location to as "low as reasonably practicable". This approach is further informed by the hierarchy of controls, which provides a structure to select the most effective control measures to eliminate or reduce the risk from hazards that have been identified during the risk assessment process.[17] The hierarchy of controls includes the following principles:

- Controls higher in the hierarchy are more effective than those lower in the hierarchy;
- Controls should be practical to implement and should be able to be maintained/sustained over time;
- The use of multiple different independent controls can give defence in depth through different layers of protection;
- Provision and effective use of personal protective equipment is the final choice in this hierarchy after all other control measures have been exhausted. Indeed, it is a common observation by HM Inspectors of health and safety, that organisations which have not implemented controls higher up the hierarchy have little chance of effectively implementing the reliable and effective use of PPE, which is notoriously difficult to do well.

It is important to note, therefore, that a whole range of risk-reduction control measures is available in various hospital settings to reduce the risk to as low as reasonably practicable before the need to consider the extended use of personal protective equipment.

Risk Decision making Frameworks

In the risk assessment process, terms such ‘so far as is reasonably practicable’ (SFAIRP) or “ as low as reasonably practicable” (ALARP) are used in order to avoid the imposition of controls that are not practically feasible to deliver while acknowledging that absolute safety cannot be guaranteed, and in order to ensure that preventive and protective actions are commensurate with the risks. Critical to this process is the need to differentiate between a “hazard” and a “risk”. A hazard is anything that can cause harm, damage or adverse health effects to people or plant in the work environment. A risk is the likelihood of a person or plant being injured/damaged or an individual receiving an adverse health effect following exposure to a hazard.

The precautionary principle has been defined, for example, by the United Nations Conference on the Environment and Development (UNCED) in 1992 as: ‘where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent degradation.’ Thus, the precautionary principle describes an approach that should be adopted for addressing hazards subject to high scientific uncertainty, and rules out lack of scientific certainty as a reason for not taking preventive action. Although invoking the precautionary principle means taking action when scientific uncertainty rules out sufficient information for risk assessment, it does not mean that a risk-based approach is abandoned – decisions continue to be informed by the best available scientific advice, taking into account the uncertainties. A risk-based approach is preserved by establishing credible scenarios to be considered. Applying the precautionary principle is essentially a matter of making assumptions to establish credible scenarios, and then using standard procedures of risk assessment and management to inform decisions on how to address the hazard. Nevertheless, this situation still enables the use of the hierarchy of controls that follows established good practice in risk reduction. For example, good risk management practice in health, safety and environmental protection starts from the position that, wherever practicable, it is better to avoid hazards by substitution or careful process/equipment design than to 'bolt-on' measures to reduce the risks (e.g. the immediate use of PPE). This would be particularly true for hazards where there are considerable uncertainties in the estimates of the risks attached to these.[18]

In the case of SARS CoV-2 in the hospital setting, there are three key hazard areas:

- Exposure to SARS-CoV-2 from surfaces (contact transmission);
- Exposure to SARS-CoV-2 at close range (short range aerosol and droplet transmission);
- Exposure to SARS-CoV-2 from the air (aerosol transmission).

For each of these hazard areas, there are a significant number of potential control approaches that can, and have been used for all hospital work activities and settings (as demonstrated by the good practice observed by the HSE inspections), based on the hierarchy of controls. The value of these control measures is demonstrated by the differential rates of nosocomial infection across trusts (see **HSE inspection of hospitals** and **National data review and modelling**).

Estimating the importance of different routes of SARS-CoV-2 transmission in hospital settings

SPI-M has summarised (December 2020) the key routes likely to be responsible for the transmission of SARS-CoV-2 in hospital settings and so resulting in patient or HCW nosocomial infection, as follows:

Patient nosocomial infection

- Models using national data from the first wave (between 1st March and 29th July 2020) suggest that most nosocomial infections in hospital inpatients resulted from indirect transmission from other patients.
- Modelling using detailed data from four Oxford hospitals (12th January to 2nd October 2020) suggested exposure to patients suspected of acquiring nosocomial SARS-CoV-2 was associated with a substantially greater risk of suspected nosocomial infection than exposure to patients who likely acquired SARS-CoV-2 in the community.

HCW nosocomial infection

- Models using national data from the first wave suggest the most likely source of nosocomial transmission to health care workers (HCWs) was other infected HCWs.
- This finding was supported by modelling using Oxford hospital data, which found exposure to other infected healthcare workers on the same ward was strongly associated with an increased daily risk of infection for healthcare workers, while exposure to other infected patients showed only a weak positive association.
- While more uncertain, the model also suggested the risk of a HCW acquiring COVID-19 from another HCW was similar to the risk of acquisition in the community.

Between group transmission

- Modelled estimates suggest current strategies (e.g. widespread PPE usage) mitigate the risk of transmission between patients and HCWs and HCWs and patients.
- This is also supported by the Oxford data where universal application of FRSMs after 1 April 2020 was associated with reduced transmission from staff to patients.
- Modelling from national data indicates that while the risk of patient to HCW transmission is currently low, this may plausibly increase (if IPC guidance were to be relaxed for example) and in this case patient to HCW transmission would likely play a key role in the number of infections in HCWs (through seeding HCW to HCW transmission).

Evidence for (small particle) aerosols and infectivity

SARS-CoV-2 is well recognised to be present in respiratory particles; however, there are not yet good data on which sizes of particles carry virus, the levels of infectiousness associated with these, and how setting and/or activity affects such issues. Evidence so far suggests significant

variability in transmission risks with some people presenting almost no risk, and a small number able to transmit to multiple people within a short period of time.

- Data from healthy volunteers show respiratory particles (measured as particles, not virus) range from less than 1 μm in diameter to >100 μm, and that compared with breathing activities such as coughing and singing can produce considerably more particles (over 20 times more).[18,19]
- Exhaled breath of 66 COVID-19 patients using facemasks detected viral RNA from 37%; 21 patients were asymptomatic at the time. Results suggest the amount of virus exhaled varies over 5 orders of magnitude. There is no evidence relating to particle size from this data.[21]
- Community evidence consistently shows that virus transmission is greatest when people are in close proximity and increases with duration of exposure. There are indications that outbreaks with high secondary attack rates are more likely to be associated with activities that produce more aerosol, poorly ventilated spaces and cases where the individual is mildly symptomatic,[22,23] suggesting transmission through particles small enough to remain suspended in air over distances greater than 2 m (likely <10 μm diameter).
- Recent evidence from quarantine hotels in Australia and New Zealand suggests the potential for aerosol transmission, including between two rooms onto a common corridor. Poor ventilation and positive pressurisation of rooms has been cited as a contributing factor.[24]
- The physics of aerosol behaviour means that if small particles can be generated in sufficient quantity to cause infection at longer distances, they will be also present at close proximity to the infectious person and at much greater concentration. Modelling studies suggest that in close proximity inhalation (of a wide range of aerosol sizes) may be a more likely exposure route than deposition of large droplets on the mucous membranes.[25] Discussion of the behaviour of different aerosol sizes is given in a previous paper.[26]
- In a healthcare context, robust evidence for any particular transmission route is very difficult to obtain. Outbreak investigations have limitations and are confounded by multiple factors, but most cite proximity of beds/patients and/or healthcare workers as key risk factors. There is no clear evidence for transmission via small aerosols from published outbreak reports; however, given the complexity of the healthcare environment this does not rule out transmission via small aerosols.
- A number of studies have sampled air in hospitals to establish the presence of the virus. A systematic review published in late 2020 reported 24 studies, in which 17% of air samples from close patient environments were positive for SARS-CoV-2 RNA.[27] Air sampling typically measures particles smaller than 10 μm diameter. Significantly higher positivity was found in ICUs and there were no differences according to distance (<1 m vs >1-5 m). Positive samples were found in toilet, clinical, staff and public areas, with higher concentrations in the non-clinical areas. 81 viral cultures were performed in 5 studies; 7 samples from 2 studies in the close-patient environment contained viable virus. Further studies have since added similar evidence.

- It should be noted that an air sample reflects a snapshot at the time of sampling, and will only be positive if viral RNA is being emitted in aerosols at the time or a short time before the sample was taken (i.e. before the ventilation can remove it). By contrast, RNA on a surface can remain for several days or even longer if the surfaces is not cleaned. Sample positivity is likely to depend on the type of sampler used.
- Evidence for the risk associated with aerosol generating procedures (AGPs) is limited and several studies are ongoing to understand the likelihood of enhanced exposure. Early data from studies suggest that coughing can produce more small aerosols than some AGPs including CPAP and HNFO;[28] however, this is based on measurements of inert particles from healthy volunteers in controlled settings. Viral aerosol measurements during patient care show mixed results with no clear relationships between procedures and the likelihood of detecting viral RNA in air.[29]

Infection prevention approaches and transmission routes

Transmission of respiratory diseases are conventionally classed as either airborne or droplet in a clinical context, and this determines the infection prevention measures. Pathogens classed as airborne require negative pressure isolation rooms with high ventilation rates and strict PPE controls including FFP3 masks, while those classed as droplet focus on barrier precautions including FRSM when within 1m. Single rooms are recommended where possible for diseases spread by droplet transmission, but there are no special requirements for ventilation.

Evidence to date suggests that SARS-CoV-2 transmission falls between these two conventional categories, with transmission possible through inhalation and mucous membrane exposure to a range of particle sizes, as well as potentially via fomites. Airborne transmission via very small (<5 μm) particles has not been shown to be the primary transmission route. Evidence from aerosol measurement in hospitals suggests the virus could be present in very small (<5 μm) aerosol particles , and evidence from community settings suggests airborne transmission can happen in some circumstances where ventilation is poor.

Approaches to infection prevention therefore need to recognise the uncertainty around transmission routes and build on the hierarchy of control approach to better consider the spectrum of risks in both clinical and non-clinical areas. This includes:

- Openly recognising that airborne transmission can occur but that evidence suggests it is most likely in poorly ventilated spaces and that applying full conventional airborne precautions throughout a hospital is neither practical nor likely to be necessary;
- Improving engineering controls including ensuring good ventilation across all clinical and non-clinical spaces that are shared by people, including consideration of airflows between spaces and ensuring that staff are aware of the actions they need to take to ensure ventilation remains effective;

- Ensuring FRSM are routinely worn by all staff and patients as far as possible to provide source control;
- Addressing risks in shared staff areas including maintaining social distancing, ventilation and restricting occupancy if necessary;
- Application of appropriate testing regimens to reduce the likelihood of undiagnosed asymptomatic staff or patients;
- Using effective and supportive approaches to continue to encourage high levels of compliance with measures, whilst recognising the significant pressures that exist for HCWs;
- Using a local risk-based approach to determine when additional controls such as enhanced PPE are needed that takes into consideration the likelihood, duration and proximity of exposure to a COVID-19 case and what other measures have been applied in the setting.

Considerations for implementing the use of FFP3

The effectiveness of PPE / RPE policy and implementation depends on equipment availability, proper physical environmental controls, adequate staff training, strict adherence to hand hygiene and appropriate human behaviour.[30]

Where an unacceptable risk of transmission remains after rigorous application of the risk assessment process (including application of measures higher in the hierarchy of controls) it may be necessary to consider the extended use of appropriate RPE (such as FFP3 masks) for patient care in specific situations. The decision to implement FFP3 respirators for the care of patients with suspected/proven COVID-19 should be based on an IPC risk assessment of the care area with effective leadership and organisational support. In particular, this should consider the likelihood of interaction with an infectious COVID-19 patient, the duration and proximity of exposure, and the application of other IPC measures.

In terms of PPE and RPE, the risk assessment should also reflect on: whether there is good adherence to appropriate fitting and use of FRSM and/or FFP3 masks, as inappropriate use can increase the risk of hand contamination and onward infection transmission (see later); whether staff are routinely wearing eye protection (important to reduce risk to eyes including inadvertently touching them); and whether patients are routinely being asked to wear masks whenever this is possible.

As above, other factors that need to be considered is whether the care area is considered high risk because of poor ventilation and/or over-crowding - can these risks be addressed, or a more suitable area used? Are there other measures under the hierarchy of controls that can be taken e.g. improving air flow and dilution by opening windows or enhancing mechanical ventilation systems? Administrative controls, as outlined in the IPC guidance [1] such as screening, triaging, testing, and isolation enable the highest risk patients to be identified and support application of the hierarchy of controls.[2]

Extending the use of FFP3 across care areas has operational implications; for example, it would require sufficient supplies of FFP3 to maintain stock and not compromise supplies for HCWs

undertaking AGPs who are at recognised increased risk. Such a decision would also need to consider whether the same principles of sessional use would apply and whether HCW traffic in specific areas is increased resulting in much higher usage.

If a decision were taken to enhance precautions in an area to include FFP3, then there needs to also be a clear strategy for how and under what circumstances the change would be stepped down.

Fit testing and checking

Following wave 1 of the COVID-19 pandemic, NHS hospitals have generally been organised into green (elective surgery/low risk), amber (possible COVID-19) and red (COVID-19 cases) pathways. At the peak of wave 2 the maximum number of COVID-19 inpatients at one point in time was typically <15% of the total bed base. Thus, we estimate that typically less than ~10% of a HCWs in hospitals wear FFP3 masks as recommended in existent UK IPC guidelines. Moving to a universal or substantial majority of HCWs wearing FFP3 would be a major organisation requirement particularly considering the need for a very large increase in fit testing capacity. Fit checking (user seal-check, self-check), refers to the process whereby the HCW assures their own correct wear and good facial seal. It should not be confused with fit testing, which is a mandatory HSE requirement prior to FFP3 use by UK HCW.[33] Fit testing should be conducted by a competent/trained person, and this may be rate limiting factor. Qualitative fit testing is a pass/fail test based on the wearer's subjective assessment of leakage through the face seal region by detecting a bitter- or sweet-tasting aerosol as a test agent.

Initial fit pass rates vary between 40% and 90% and are especially low in female and in Asian healthcare workers; fit testing is recommended to ensure a proper fit of respirators for the individual healthcare worker so that alternative respirators can be selected if required.[34,35] In a UK pandemic healthcare setting, of 583 people fit tested with an FFP3 respirator, 19% failed the test.[35] Some individuals require multiple fit tests with different facemasks until a pass result is obtained. Assuming that FFP3 supply can be maintained overall, the availability of individual facemask models may be less robust, which can be a challenge for individuals for whom only a limited range of suitable options exist.

Behaviour, compliance and comfort

The factors that influence HCW behaviours are complex and not well studied. A recent Cochrane review found that HCWs believed that they followed IPC guidance more closely when they saw its value.[36] Some HCWs found it difficult to use masks and other equipment when it made patients feel isolated, frightened or stigmatised. In addition, the workplace culture may also influence whether or not HCWs follow IPC guidelines.[36]

There is a paucity of evidence around assumptions and practices associated with use of IPC precautions by HCWs. A small number of studies looking at use of gloves have found around 17% of use was unecessary[37] and despite intense promotion of hand hygiene, excessive use of non-sterile clinical gloves was common and had the potential to cause cross-contamination in 50% of care episodes.[38] A key risk identified is failure to doff gloves when moving from a high

to low risk area; it is not known whether this is generalisable to other PPE.[39] The risk of noncompliance events with respiratory PPE has been highlighted, (adjustments, respirator or face touches, under-the-respirator touches, and eye touches) which could lead to self-contamination.[32]

Compensatory behaviour or inappropriate use associated with respiratory PPE and RPE is particularly poorly studied. In one study in a community setting, face coverings may have been associated with risk compensation behaviour, for example with the public spending less time at home, more time in moderate to high-risk locations, and social distancing fatigue when living with a face mask mandate.[40] However, extrapolating such findings to healthcare settings is not possible. A number of other studies have shown no evidence for compensatory behaviour,[41] with neither hand washing nor physical distancing reduced in those wearing face coverings.[42]

RPE is intrusive and can be uncomfortable to wear. A previous SAGE paper identified a number of possible adverse effects associated with the prolonged use of FFP3 e.g. facial dermatitis from the respirator, increased work of breathing, respiratory fatigue, impaired work capacity, increased oxygen debt, early exhaustion at lighter workloads, elevated levels of CO2, increased nasal resistance.[31] RPE may interfere with communication and vision. The HSE notes that RPE can give a sense of false protection, especially when not worn in accordance with the manufacturer's instructions.[33]

Although there is a lack of good evidence surrounding behaviours, compliance and comfort it is important to recognise that any increase in use of FFP3 would need to be accompanied by clear guidance and training for staff to minimise any of the risks highlighted here.

Key evidence sourcing / review groups regarding respiratory protection use by HCWs

We have highlighted below key information sources (sections 1-5), with additional information provided in Appendices 1-4. The key findings/outputs relevant to the decisions regarding respiratory protection usage by HCWs are summarised in bold text at the end of each section.

1. **UK IPC Cell**

Established in January 2020, the UK IPC Cell (membership includes senior IPC representatives from Public Health Wales, Public Health England, the ambulance service, NHS Scotland (ARHAI), Public Health Agency Northern Ireland and NHS England/Improvement) aims to:

- review international guidance and the published literature (national and international) to assess the learning and scientific evidence base to inform improvements in IPC practice, specifically the prevention of transmission and management of COVID-19 in NHS settings
- receive recommendations/ outputs from the Hospital Onset COVID-19 Infection (HOCI) Working Group including other SAGE subgroups and other expert groups e.g. New and Emerging Respiratory Threats Advisory Group (NERVTAG), and consider for inclusion in operational guidance

- advise on updates and revisions to IPC operational guidance ensuring alignment with the phase of the pandemic.

The UK IPC cell produced (in December 2020) 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 SBAR summarising the evidence that underpins the UK IPC cell position to maintain the current recommendations for PPE, as set out in the UK IPC guidance, is reproduced in Appendix 1.

SBAR sets out the rationale for current position regarding respiratory protection usage by HCWs.

2. ARHAI Scotland

ARHAI Scotland has produced 12 rapid reviews, based on extensive literature reviews, assessing the IPC for the prevention and management of COVID-19 in health and care settings (summarised in Appendix 2). The most recent review was published on 12/02/21.[29] The objectives for the rapid reviews were to establish the epidemiology of COVID-19; personal protective equipment (PPE) requirements; requirements for hand hygiene; environmental survivability of COVID-19; and requirements for cleaning/decontamination of the care environment.

In its most recent update,[29] the ARHAI Scotland rapid review concluded:

- Airborne precautions (FFP3 respirators) are required when performing AGPs on patients in the medium risk (amber) and high risk (red) pathways.

- HCWs may choose to wear an FFP3 respirator rather than an FRSM when performing an AGP on a low-risk pathway patient; this is a personal PPE risk assessment.

The Royal College of Nursing commissioned a recently published independent review of guidelines for the prevention and control of COVID-19 in UK health care settings.[40] The review was critical of the process followed in assessing the evidence pertaining to reducing the risk of virus transmission, particularly airborne transmission, and thus of the existent IPC guidance. The review recommended that 'the evidence relating to airborne transmission, the ventilation of health care premises and implications for the use of face-protection need to be re-considered and included in UK guidelines.'[43]

The most recent of a series five updated evidence reviews (published in the Annals of Internal Medicine, Impact Factor 21.3), which post-dates the RCN commissioned review, concludes 'On the basis of these limitations and because of inconsistent results across studies, evidence for N95 versus surgical mask use and other comparisons involving mask use and risk for SARS-CoV-2 infection in health care settings remains insufficient.'[44]

There is an evidence base, which is subject to regular update and review, to support the existent recommendations for respiratory protection for HCWs. Repeated evidence reviews should continue.

3. The Hospital Onset COVID Working Group (HOCWG)

HOCWG, a sub-group of the Scientific Advisory Group for Emergencies (SAGE), was established in April 2020 to provide scientific advice on minimising the transmission of COVID-19 within hospital settings. As Wave 1 subsided, SAGE advised that the functions of the group should in future be picked up by the organisation responsible for operational delivery i.e. become a primarily NHS facing effector group, whilst retaining a link to SAGE. Thus, HOCWG transitioned to the **Hospital Onset COVID-19 Infection (HOCI)** group in August 2020. HOCI was set up to be an operationally focused oversight group, with four nations representation, supporting implementation of good IPC practice on a day-to-day basis and the receipt of data on local outbreaks.

Data review and modelling

The relevant evidence and SitRep data (available on a daily basis for each hospital trust in England since summer 2020) on nosocomial infection have been continuously reviewed by HOCI. The longitudinal trends of nosocomial COVID-19 infection rates clearly follow community infection levels, most obviously seen as the latter evolve across regions. Notably, SitRep data, in addition to results from Wave 1 (COCIN) demonstrate a marked heterogeneity in probable nosocomial COVID-19 infection rates across trusts and within regions.

Such heterogeneity has been explored further in modelling of potential drivers of nosocomial infection risk. This modelling demonstrates that the rate of community infections is a significant driver of nosocomial infections; the proportion of beds occupied by COVID-19 patients (itself a result of high levels of transmission in the community) is by far the dominant, significant driver of nosocomial infection risk. An association between COVID-19 related HCW staff sickness and community prevalence of infection was also clearly seen during Wave 2. Modelling has also identified patient age, patient length of stay and organisation CQC rating as being significantly associated with nosocomial COVID-19. CQC rating is a broad measure of how well organisations are managed and tends to reflect performance levels over a wide range of areas, including operational nosocomial infection prevention measures.

Local management and best practice

Trusts with relatively higher rates of nosocomial infection and/or COVID-19 infections in HCWs are identified and followed up to interrogate and provide further input where necessary. Conversely, trusts with lower nosocomial rates or where marked improvements in rates have occurred are investigated to provide data on apparently effective IPC interventions to HOCI and for dissemination.

Examples of such trusts with marked improvements in nosocomial/HCW COVID-19 rates

Examples from three acute hospital trusts where marked improvements in nosocomial/HCW COVID-19 rates have been achieved, are provided in Appendix 3. Whilst these are effectively before and after datasets, taken together with the wide variation in nosocomial infection rates across NHS trusts, the examples illustrate that a range of different interventions can be effective when applied consistently as part of a bundle of IPC measures.

HCW COVID-19 infections

While there are caveats around the completeness of reporting of NHS HCW lateral flow device (twice weekly) testing in England, results from ~0.5 million tests per week between December 2020 and February 2021 show a SARS-CoV-2 positivity rate of <1% (Table 1). This positivity rate increased through December, likely reflecting the very large increases in community prevalence and spread of the more transmissible B.1.1.7. variant. The data show a decrease in positivity from mid-January, which likely reflects the effects of roll out of HCW vaccinations (rolling from late December). By contrast, from December 2020 until early February 2021, the community positivity rate in England was estimated to be >1%.[45] Given the record/substantial numbers of COVID-19 patients in NHS hospitals during this key Wave 2 period, these data do not suggest that HCW hospital-acquired COVID-19 increased.

Table 1.

Weekly (from December 2020 to February 2021) Test and Trace positivity results of lateral flow device tests for NHS HCWs.

w/c	NHS week	Positive	Negative	Voids (& indeterminate)	Number of tests	% Positivity Rate
01 Dec 20	27	1,458	293,018	1,686	296,162	0.50%
07 Dec 20	28	2,869	491,963	2,569	497,401	0.58%
14 Dec 20	29	4,326	600,539	3,333	608,198	0.72%
21 Dec 20	30	5,264	573,860	3,848	582,972	0.91%
28 Dec 20	31	5,906	597,541	3,278	606,725	0.98%
04 Jan 21	32	5,919	657,589	3,236	666,744	0.89%
11 Jan 21	33	5,333	622,814	2,577	630,724	0.85%
18 Jan 21	34	3,872	608,366	2,191	614,429	0.63%
25 Jan 21	35	2,447	545,605	1,738	549,790	0.45%
01 Feb 21	36	1,573	524,221	1,539	527,333	0.30%
08 Feb 21	37	1,023	474,626	1,349	476,998	0.22%
15 Feb 21	38	767	407,868	1,070	409,705	0.19%
22 Feb 21	39	245	131,825	241	132,311	0.19%

Positivity rate is number of positive tests as a proportion of all positive & negative tests (excl voids). Based on total tests and not deduplicated by individuals.

Provisional data - not fully cleaned and incomplete with respect to the total numbers of LFDs provided to HCWs.

4. HSE inspection of hospitals

HSE inspected 17 acute hospitals, in 13 NHS Trusts in England and 2 NHS Health Boards in Scotland and Wales respectively, as part of the national HSE COVID-19 spot check inspection programme between 18 November 2020 and 27 January 2021. Each inspection checked the arrangements in place to manage risk arising from COVID-19 as required by published government guidance, and specifically in the following seven areas:

- Management arrangements
- Personal protective equipment
- Hygiene and cleaning regimes
- Dealing with suspected cases
- Risk assessment
- Social distancing
- Ventilation

There was a range of compliance both between and within the hospitals inspected: five of the seventeen (29%) showed compliance; four were given verbal advice to support improvement (24%) and eight required formal letters requiring remedial actions to be taken (47%).

In the 17 acute hospitals, higher levels of compliance were seen where the leadership team were visible to staff on the front line and the IPC leads worked alongside health and safety teams. Lower levels of compliance were generally found where there were limited or no monitoring arrangements in place to ensure the necessary control measures identified by each hospital's risk assessments were implemented and/or maintained.

Increased levels of compliance were seen in patient-facing clinical areas across most of the 7 areas inspected. Arrangements for staff who were displaying COVID -19 symptoms were well established. Lower levels of compliance were frequently found in in non-clinical areas, even when adjacent to clinical areas. Reasonably practicable control measures were often available but not implemented in a variety of non-clinical areas.

Given these findings a number of specific actions can be taken within the hospital environment at levels above the use of PPE in the hierarchy of control to improve COVID control measures. These include:

- Ensure risk management and control arrangements are reviewed to ensure they are adequately resourced;
- Consider how well those involved in the risk management system coordinate with each other, including the hospital leadership team, health and safety team, departmental managers, Infection Prevention and Control leads, and occupational health colleagues and whether this could be improved;
- Ensure compliance with their legal obligations to consult with trade unions and employee- representatives by ensuring they are engaged in the risk assessment process. Worker engagement in this process is critical to establishing effective control measures;
- Review whether, for all non-patient facing areas, a suitable and sufficient risk assessment has been carried out and the control measures identified have been implemented – in line with relevant guidance. Consider how well the risk assessments

for these areas have applied the hierarchy of control. For example, has the risk assessment:

- Identified the maximum room occupancy numbers and the optimum layout and seating arrangements in all areas? For example, in canteens, libraries, the laundry, porters lodge, clinical records, rest rooms, toilets, locker rooms, post rooms, changing rooms, offices, training rooms, doctors' common rooms.
- Considered how ventilation could be improved in all areas? Could some windows be unsealed to allow partial opening, could some doors be left open where appropriate, how are rooms with no windows or air conditioning being ventilated?
- Identified mitigating control measures where it is not possible to maintain social 2m distancing? For example, by providing physical barriers (screens), one-way systems or rearranging /modifying layout.
- Considered the adequacy of their cleaning regimens in non-clinical areas? Does it consistently consider high touch surfaces, for example printers, vending machines, kettles, photocopiers, door handles etc?
- Considered the provision of lockers and welfare facilities to ensure they can accommodate the number staff on shift in a COVID secure manner?

- Establish routine monitoring and supervision arrangements to ensure control measures identified in their risk assessment are implemented and are being maintained, are kept under review to ensure they remain valid, and act on any findings.

5. The Senior Clinicians' Group (SCG)

SCG is chaired by the CMO England with CMO and senior medical and nursing clinician representation from all four nations; it provides a forum for four nation discussion and advice but does not sign off decisions. The SCG has been consulted on several occasions regarding HCW risk of acquiring COVID-19, including the rationale for the current UK COVID-19 IPC guidance with respect to respiratory protection for HCWs.

CMO guidance in response to the threat of new SARS-CoV-2 variants was issued as an alert in late December 2020.[3] This noted that existent IPC guidance to control the virus was appropriate and stressed the importance of compliance with these measures, including the use of personal protective equipment by HCWs.

Research evidence gaps

In carrying out this review, we wish to highlight several key areas on which research on RPE for HCWs should usefully focus.

- There are few (especially controlled) data on the application of mitigation measures across different hospitals, the successes or challenges in applying them, and the interplay between behavioural aspects, administrative and environmental measures. A more in-depth analysis of data would be valuable for both clinical and non-clinical spaces.
- There are not currently robust data on the potential for risk compensation behaviour. It would be valuable to understand the response of healthcare workers to different measures, especially relating to PPE in terms of whether enhanced PPE changes their perception of risk and actions that they take. This information would be helpful for a range of infections not just COVID-19.
- While there is guidance on ventilation for hospitals there are very few data on the efficacy of ventilation outside of specialist spaces (isolation rooms, operating theatres) where measurement is carried out as part of commissioning. Current ventilation guidance focuses on risks in clinical spaces, with little consideration of locations such as corridors, nursing stations, offices and HCW communal areas / break-rooms.
- Application of air cleaning strategies such as HEPA filtration units and upper-room UV-C devices have been suggested as measures to improve poorly ventilated spaces, including in the ARHAI review. Studies to measure robustly the impact of such interventions and their utility would be beneficial.

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Appendix 1.

UK IPC Cell Position Statement on current IPC guidance and use of PPE for new COVID-19 variant strains

This statement reflects the position in December 2020

Situation

The identification of SARS-CoV-2 virus new variants of concerns: VOC122020/01, lineage B1.1.7, first identified in Kent on 20/09/2020; and VOC122020/02, lineage B1.351 or 501Y.V2 first identified in South Africa in October 2020, across parts of the UK, has necessitated a review of the current Infection Prevention and Control (IPC) guidance, in particular, the Personal Protective Equipment (PPE)/ Respiratory Protective Equipment (RPE) requirements and whether there is any evidence or expert opinion that would change the current recommendations.

The UK IPC cell has been asked to provide 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.

This paper summarises the evidence which underpins the UK IPC cell decision to maintain the current recommendations for PPE as set out in the IPC guidance[1]

Background

Current IPC guidance[1] for management of COVID-19 individuals within healthcare settings recommends patients to be managed in one of three COVID-19 pathways (High, Medium or Low risk) with extended use of facemasks for staff and face coverings for patients/visitors in both clinical and non-clinical areas. These are examples of how organisations may separate COVID-19 risks but must not impact the delivery and duration of care for the patient or the individual. Pathways will be determined by epidemiological data and underpinned by local risk assessment.

The identification of new SARS-CoV-2 variants of concern including VOC 202012/01, (lineage B1.1.7), first identified in Kent on 20/09/2020 and VOC 202012/02 lineage B1.351 or 501Y.V2 first identified in South Africa in October 2020 have been considered in regard to whether the recommended level or PPE/RPE should change. This is based on the following technical reviews:

- ECDC Threat Assessment Brief: Rapid increase of a SARS-CoV-2 variant with multiple spike protein mutations observed in the United Kingdom[2].

- ECDC. Rapid Risk Assessment. Risk related to spread of new SARS-CoV-2 variants of concern in the EU/EE[3].

PHE Technical briefing: Investigation of novel SARS-CoV-2 variant: Variant of concern 202012/01[4].

Assessment

An IPC cell meeting was held on 22/12/2020 (this includes membership from the devolved administrations) to review two papers[10,11] on the transmissibility of the new SARS-CoV-2 variants of concern. The aim was to provide a consensus opinion as to whether current guidance for PPE/RPE should be amended to include the use of FFP3 respirators as a recommendation for all patient pathways.

The extant IPC guidance advises IPC precautions based on the transmission route for this pathogen. Droplet precautions are advised for direct clinical care within 2 metres of suspected/confirmed cases (unless undertaking an AGP). This is consistent with international guidance with regard to the principle mode of transmission of SARS-CoV-2 as detailed in CDC Scientific Brief[9] and WHO Scientific Brief[6].

The UK IPC Cell were asked to consider other circumstances published in CDC Scientific Brief[9] WHO Scientific Brief[6] where aerosol transmission of SARS-CoV-2 appears to have occurred these include; enclosed spaces, prolonged exposure and inadequate ventilation and are associated with outbreaks in non-healthcare facilities The WHO Scientific Brief[6] consider that in poorly ventilated spaces, transmission through an airborne route cannot be ruled out, however *'detailed investigations of these clusters suggest that droplet and fomite transmission could also explain human-to-human transmission.'* This includes inconsistencies with other IPC measures such as adherence to mask use, maintaining physical distancing and hand hygiene.

SAGE[12] advise "*close-range transmission may be due to a combination of droplets and aerosols, as well as contaminated surfaces, and it is not yet possible to determine which mechanisms are dominating this transmission"* and that "*there is no evidence of long-range airborne transmission.*

An ARHAI Rapid Review of Literature[10] concluded "*there is currently insufficient evidence to ascertain if infection control precautions need to be altered in response to the emergence of the new COVID-19 strains".*

SAGE*[12]* agree that whilst fit-tested FFP3 respirators provide a higher level of protection to the wearer against aerosol/ airborne transmission, *"the evidence that aerosol transmission is significant compared to other routes is not sufficiently strong to recommend that these are used in locations other than high risk clinical areas where aerosol generating procedures take place*".

The MHRA Central Alerting System (CAS)[13] supports the position of maintaining current IPC recommendations and states: "*current advice is that the mechanisms of transmission of both the novel variants of concern are the same as the wild-type SARS-CoV-2 and other variants in circulation. Therefore, it is extremely important that healthcare settings ensure that all current infection prevention and control measures are fully implemented, that appropriate personal protective equipment is readily available and worn by staff at all times, cleaning and ventilation protocols are followed and optimised".*

The following ECDC Rapid Risk Assessment[2] states that in countries where containment is no longer an option, action should include pursuing aggressive mitigation strategies and the stringent implementation of NPIs. The selection of NPIs should be determined based upon the overall levels of SARS-CoV-2 transmission, current healthcare capacity usage and careful assessment of the transmission dynamics of the new variant.

Recommendations

The UK IPC Cell agreed the following;

1. A review of current, available evidence has not identified a change in the mode of transmission between this variant strain and previous circulating strains of SARS- CoV-2
2. No change to the PPE recommendations i.e. wider use of FFP3 respirators when AGPs not being performed.
3. Support for the sessional use of FFP3 respirators (with eye/ face protection) in the medium and high-risk pathway for healthcare workers where AGPs are undertaken for COVID-19 cohorted patients/individual.
4. To continue to review emerging evidence/science and data and update the IPC guidance if required
5. To strengthen the UK IPC guidance; reinforcing for example:
   - wearing of facemasks by all inpatients, at all times, across all care pathways, providing this is tolerated by the patient and not detrimental to medical/care needs.
   - highlighting adherence with the guidance must be considered across all Trusts/areas.
   - where possible (and not detrimental to care) limit patient movement in hospital settings.
   - highlight the need for rapid testing particularly in high or increasing prevalence areas for staff and patients.

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13. MHRA Central Alerting System (CAS) Immediate Actions in response to SARS-CoV-2 virus new variants of concerns. Dec 2020

Appendix 2.

ARHAI Scotland Rapid Reviews of the literature: Assessing the infection prevention and control measures for the prevention and management of COVID-19 in health and care settings

Version history

Version	Date	Summary of changes
1.0	19/3/2020	Assessment of the emerging COVID-19 evidence base, includes literature identified up to 16 March 2020.
1.1	3/4/2020	Assessment of the emerging COVID-19 evidence base, includes literature identified up to 30 March 2020.
1.2	20/4/2020	Assessment of the emerging COVID-19 evidence base, includes literature identified up to 13 April 2020.
3.0	15/5/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 11 May 2020.
4.0	24/6/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 15 June 2020.
5.0	23/7/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 20 July 2020
6.0	2/9/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 31 August 2020
7.0	2/10/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 28 September 2020
8.0	05/11/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 02 November 2020
9.0	04/12/2020	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 30 November 2020
10.0	15/01/2021	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 05 January 2021
11.0	05/02/2021	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 01 February 2021
12.0	12/03/2021	Monthly assessment of the emerging COVID-19 evidence base, includes literature identified up to 01 March 2021

https://www.hps.scot.nhs.uk/web-resources-container/rapid-review-of-the-literature-assessing-the-infection-prevention-and-control-measures-for-the-prevention-and-management-of-covid-19-in-healthcare-settings/

Accessed 24 March 2021.

Appendix 3.

Examples of measures associated with large reductions in nosocomial / HCW COVID-19 infection rates

Trust A

Introduced universal visor use for patient care across the hospital in mid-December 2020 and this was associated with an almost immediate termination of hospital outbreaks in both patients and staff (Fig 1c, d) in green pathway areas. Typically, IPC interventions represent a 'bundle' of measures; in this case, rapid enhanced staff testing (using a combination of PCR and lateral flow tests); regular rescreening of all hospitalised patients; in house contact tracing; dashboards to allow rapid case and specimen tracking; universal use of fluid resistant FRSM across the hospital; eye protection for care of patients with COVID-19; increased use of masks by patients; and FFP3 masks for all aerosol generating procedures had been introduced across 2020.

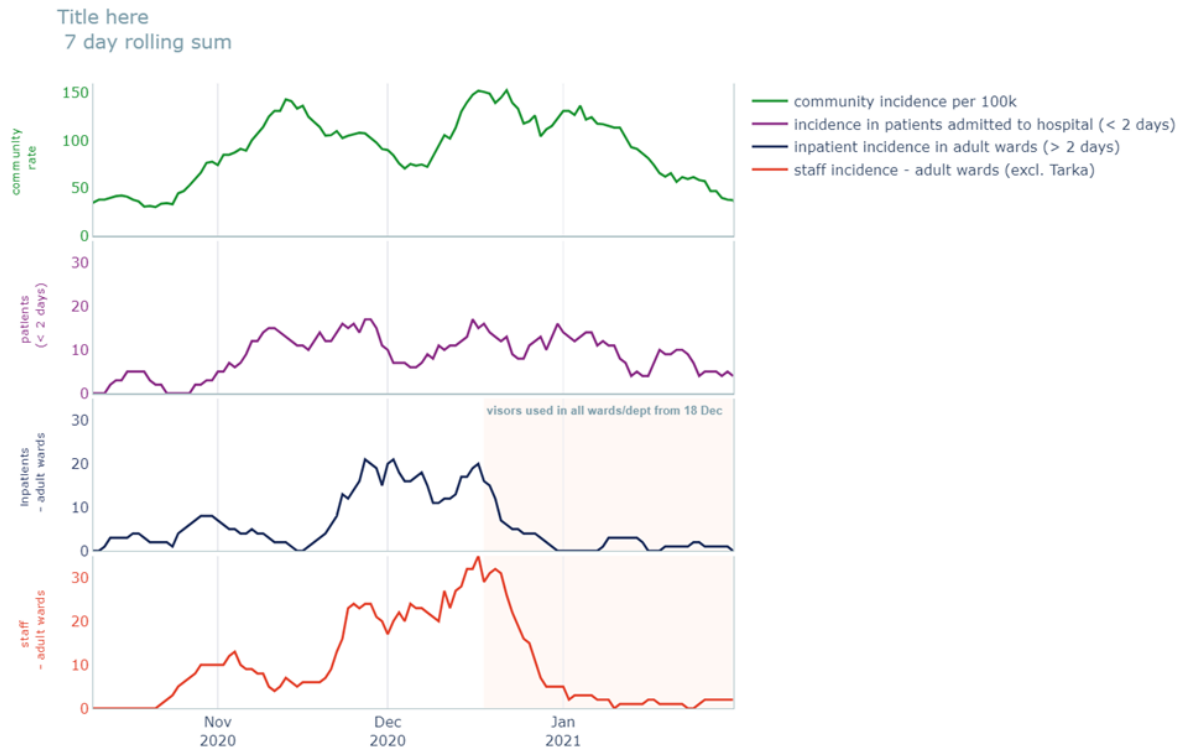


Fig 1.

a) Community incidence per 100000 population

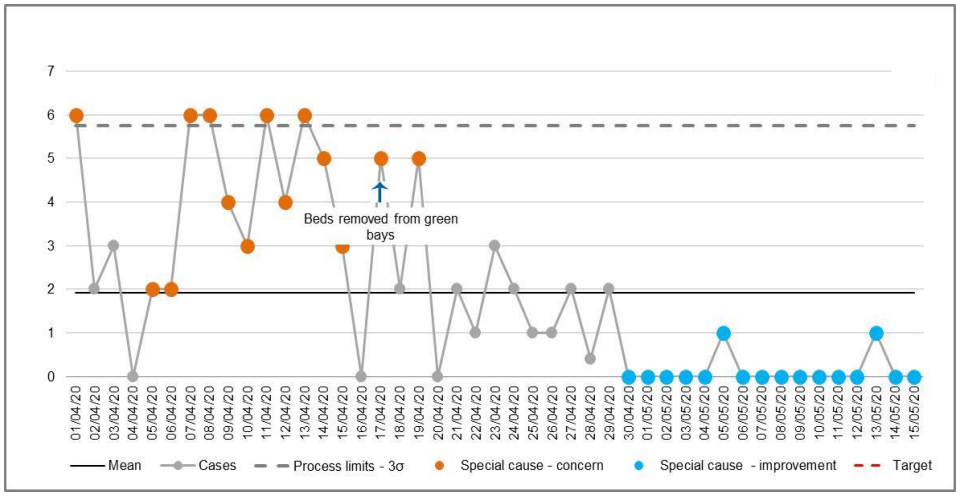
b) Daily ED admissions

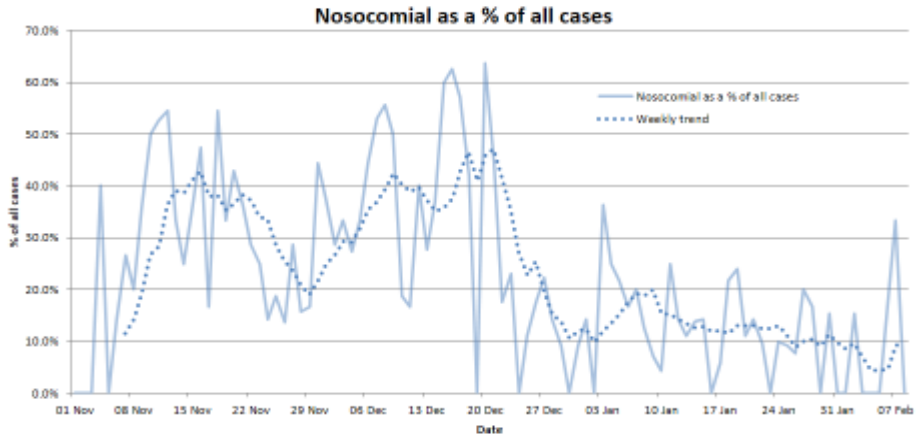
c) Daily positive tests in patients in Green areas

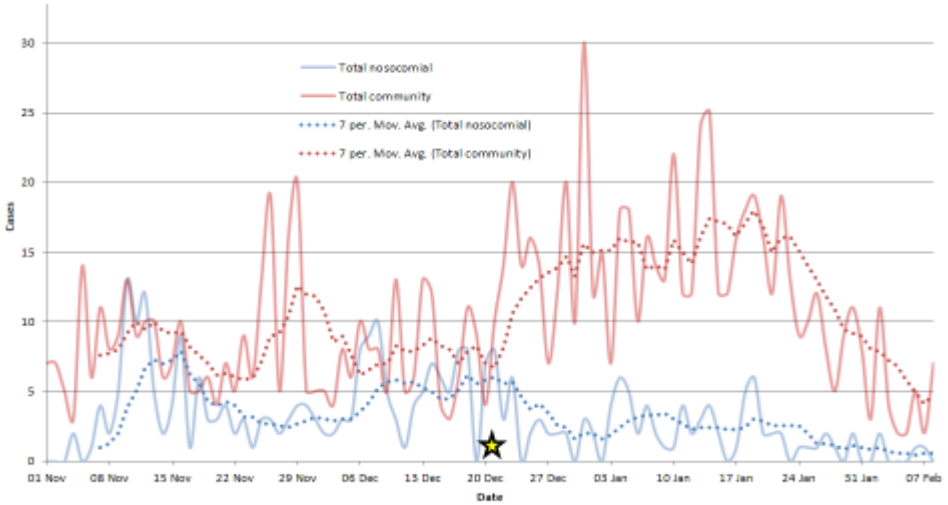
d) Daily positive tests from staff in Green areas

Trust B

Following a successful trial of bed removal to increase bed spacing during Wave 1 (top figure), COVID-19 admission pressures in Wave 2 led to a reversal of this intervention. Screens were then trialled unsuccessfully, with a subsequent increase in nosocomial infection (middle figure). In late December, bed removal was reimplemented, which was followed by a 50% sustained reduction in nosocomial COVID-19 cases (despite increasing community prevalence).







Trust C

Introduction of rapid testing for SARS-CoV-2 in A&E in December 2020 was associated with large reduction in rates of probable nosocomial COVID-19.