National Patient Safety Alert

NHS

Infection risk when using FFP3 respirators with valves or Powered Air Purifying Respirators (PAPRs) during surgical and invasive procedures

Date of issue:	25-Aug-21	Reference no:	NatPSA/2021/009/NHSPS

This alert is for action by: Organisations undertaking surgical and invasive procedures, including acute and specialist hospitals and independent hospitals providing NHS-funded care, and any general practices or community hospitals whose staff undertake surgical and invasive procedures.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in infection control and surgery.

Explanation of identified safety issue:

The purpose of wearing a type II fluid resistant surgical mask (FRSM) during surgical and invasive procedures is to minimise the transmission of pathogens in the nose, mouth and throat of staff to patients. They also protect staff from splash or spray of blood/body fluids onto their respiratory mucosa (nose and mouth).

A wide range of FFP3 respirators have been used as protection by staff across healthcare settings during the COVID-19 pandemic, including FFP3 respirators with and without exhalation valves. The exhalation valves do not filter exhaled breath, even when of a 'shrouded' type.

Current infection control guidance states that: "Valved respirators **should not** be worn by a healthcare worker/operator when sterility directly over the surgical field is required, eg in theatres/surgical settings or when undertaking a sterile procedure".[1] Powered hoods (also known as powered air purifying respirators or PAPRs) have been provided as respiratory protective equipment (RPE) for staff unable to achieve a tight fit with an FFP3 respirator(s). The air exiting PAPR hoods is not filtered.

Incident reports received since March 2020 identified five incidents describing dripping of condensation from the exhalation valve of an FFP3 respirator, potentially compromising the sterile field; one cerebral abscess involving an oral bacterium linked to the use of a valved FFP3 respirator during brain surgery; and three cases of endocarditis linked to PAPR use during cardiac surgery.

These incident reports and feedback from services suggest that the risks of valved respirators and PAPRs for surgical and invasive procedures is not well-recognised, and that their use may have become routine in some theatre environments.

Actions required

Actions to be completed by 25 Nov 2021

Revise procedures, purchasing processes, stock supply, checklists, and stock labelling to ensure:

1. Type II FRSMs and non-valved FFP3 respirators are available for departments undertaking surgical or invasive procedures. [1,2]
2. Valved FFP3 respirators/PAPR are removed from any areas that do not need them.[1,2]
3. Staff whose only respiratory protection equipment option is a PAPR or valved FFP3 respirator are informed that these should not be worn when undertaking a sterile procedure or directly over the surgical field,[1] except when Note A applies.
4. In areas where valved and non-valved FFP3 respirators need to be stocked, clear point of use warnings are attached that the valved FFP3 respirators should not be worn when undertaking a sterile procedure or directly over the surgical field,[1] except when Note A applies.

This Alert can only include brief abbreviated reference to IPC guidance. The Alert actions are focused solely on systems that will support staff to comply with IPC guidance and the full version of relevant guidance should always be consulted when implementing this Alert.

While this Alert links to the IPC guidance advice current at the time of its issue, organisations should always base their implementation of the Alert on any subsequently updated versions of IPC guidance.

For further detail see: https://www.england.nhs.uk/2021/08/infection-risk-when-using-ffp3-respirators-with-valves-or-powered-air-purifying-respirators-paprs-during-surgical-and-invasive-procedures

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Note A:
Surgical interventions are only undertaken when essential for patients with a known/suspected infectious agent/disease that is spread wholly or partly by the airborne route (for example, confirmed/suspected COVID-19). This makes it unlikely that circumstances where RPE is required by a staff member working directly over the sterile field will arise. In these circumstances the National Infection Prevention and Control Manual[2] (NIPCM) advises: "*Where it is not reasonably practicable to prevent exposure to a substance hazardous to health (as may be the case where healthcare workers are caring for patients with suspected or known airborne [transmissible pathogenic] micro-organisms) the hazard must be adequately controlled by applying protection measures appropriate to the activity and consistent with the assessment of risk. If the hazard is unknown the clinical judgement and expertise of IPC/HP staff is crucial and the precautionary principle should apply. Respiratory Protective Equipment [eg FFP3 respirators or PAPRs] must be considered when a patient is admitted with a known/suspected infectious agent/disease spread wholly by the airborne route and when carrying out aerosol generating procedures (AGPs) on patients with a known/suspected infectious agent spread wholly or partly by the airborne or droplet route*". Although the NIPCM guidelines are Scottish guidance, page 6 of the UK IPC Guidance[1] states: "*The IPC measures recommended are underpinned by the NIPCM practice guide and associated literature reviews. NHS England is using this as an opportunity to introduce and adopt the NICPM as set out in the 'UK Five-year Tackling Antimicrobial Resistance National Action Plan (2019-2024)".*[3]

Current UK-IPC guidance[1] provides advice on the nature of sterile procedures where valved respirators should not be worn in Section 10.2.1.

Note that manufacturers advise against using a fluid resistant mask over a valved FFP3 respirator or under a PAPR.

Patient safety incident data
The National Reporting and Learning System (NRLS) was searched for incidents reported as occurring since 1 March 2020 and uploaded by 26 March 2021 using a combination of words related to valved/vented masks and respirators and drips or condensation (our reference PSI616). Serious Incident data on StEIS was searched using similar terms and dates (our reference 5365). All incidents were reviewed. One report linked to use of a valved FFP3 respirator described an extensive cerebral abscess. A report submitted to StEIS at a later date described three cases of endocarditis after cardiac valve replacement surgery linked to the use of powered hoods with unfiltered exhalation ports. While the other 'dripping' incidents were reported as no harm or low harm, valved masks or powered hoods may not have been considered as a potential source of infections. For some surgeries (eg joint replacements) and invasive procedures (eg central line insertion), surgical site infection can have severe consequences of disability and risk of death.

References

1. UK-IPC Guidance. COVID-19: Guidance for maintaining services within health and care settings – Infection prevention and control recommendations. Version 1.2 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
2. NHS National Services Scotland. National Infection Prevention and Control Manual. April 2017. Chapter 2, Sect 2.4 RPE https://www.nipcm.scot.nhs.uk/
3. HM Government. Tackling antimicrobial resistance 2019-2024. January 2019. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/784894/UK_AMR_5_year_national_action_plan.pdf

Stakeholder engagement
- NHS England and NHS Improvement IPC cell and their partners in Public Health England, and the Health and Safety Executive
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel see https://www.england.nhs.uk/patient-safety/patient-safety-alerts/

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to co-ordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.