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Probability of fit failure with reuse of N95 mask respirators

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Editor—The 2019 coronavirus pandemic (COVID-19) has created a worldwide shortage of disposable N95 mask respirators that has led to extended use and reuse.[1–3] Multiple healthcare organisations[4] have implemented reuse of disposable N95 respirators designed for 8 h of use, for up to 20 days.[5] However, the durability and fit of respirators after multiple days of clinical reuse are unknown. A seal to the face is necessary to ensure that small aerosolised droplets are filtered. We conducted a cross-sectional pilot study to determine the effects of reuse and hydrogen peroxide vapour decontamination on the effectiveness of N95 respirators by qualitative fit testing.

This study was a voluntary, non-randomised, and low-risk quality improvement project; Institutional Review Board review and formal written consent were not required per institutional policy. From April to May 2020, a convenience sample of anaesthesiology clinical staff at an academic tertiary care centre who had within the past year passed fit testing of the same model of N95 mask respirator were included. Individuals who had worn their respirator for less than 1 day were excluded. All anaesthesiology clinical staff are trained yearly on performance of a self-performed user seal check and appropriate respirator use.

Before the start of the study, department management instructed clinicians to continuously record the number of days worn, times decontaminated with Food and Drug Administration approved Bioquell Z-2 vaporised hydrogen peroxide (Horsham, USA),[6] and times the N95 was donned. Before testing, participants self-reported the same information and if they believed the respirator provided a good fit. The participants were screened for COVID-19 risk by asking if they had any of the known symptoms and if their unprotected respirator was directly exposed to COVID-19 patients without subsequent decontamination. Exposed respirators that were not decontaminated were not tested. All six testing staff members were trained on appropriate fitting and testing directly by the Environmental Health and Safety Department. Qualitative fit testing was performed with denatonium benzoate (Bitrex®) in accordance with the Occupational Safety and Health Administration standard 1910.134 App A (3M, St. Paul, USA).[7] On a subset of participants (based on respirator availability) with fit failures, testing was repeated with a new N95 respirator of the same model. The data were analysed with logistic regression of binary fit failure using the R package cgam (R Foundation for Statistical Computing, Vienna, Austria) for flexible monotone increasing failure probabilities (Online Appendix).

Of 74 anaesthesia providers who participated in repeat fit testing, 46 were females and 28 were males. The females were more likely to fail fit testing (63% *vs* 29%; P=0.008). Ten participants wore the 1860 and 64 wore the 1804 VFlex™ (3M, St. Paul, USA). Figure 1 displays the estimated failure probability by number of days worn. The failure rate was 46% after 4 days (95% confidence interval [CI]: 31–63%), 50% after 10 days (95% CI: 36–63%), and 55% after 15 days (95% CI: 37–71%). Of respirators that passed fit testing, the median numbers of days worn were 7 (n=37; inter-quartile range [IQR]: 5–12) and 8 (n=37; IQR: 5–12) in the group that failed fit testing. The number of sterilizations had a modest association with

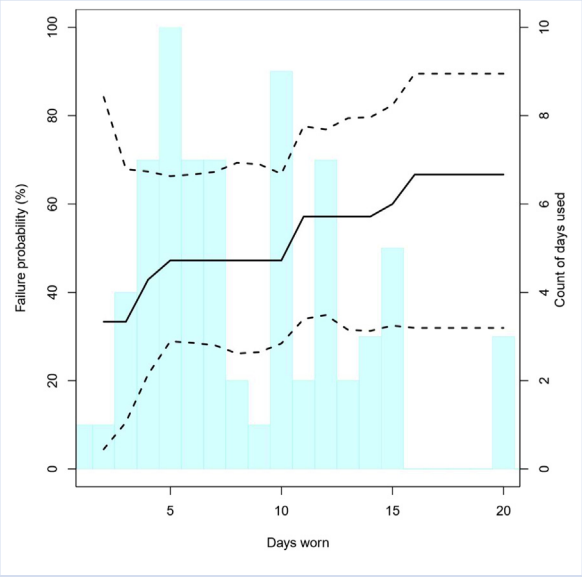

Fig 1. Risk of N95 mask respirator fit failure relative to number of days worn (n=74). The black line represents a monotone semi-parametric logistic regression with dashed lines representing the 95% confidence interval. Blue bars represent a histogram of respirators tested. Each respirator was tested only once.

modest precision (odds ratio [OR]: 1.5; 95% CI: 0.9–2.8) relative to fit failure, adjusting for the number of days worn. Each respirator was sterilised a median of one time in both groups (pass IQR: 0–1; fail IQR: 0–2; P=0.12). The number of days worn and number of uses were correlated (r=0.63; P<0.001). The number of times used per day had a negligible association with modest precision (OR: 0.8; 95% CI: 0.6–1.0) with fit failure. Of respirators that passed fit testing, the median numbers of use were 20 (IQR: 15–40) and 18 (IQR: 12–35) in the group that failed fit testing. Only 7% (one/15) of participants who repeated testing with a new N95 failed. Users with failed fit tests were more likely to state their mask fit poorly (OR: 6.5; P=0.02); however, 73% (95% CI: 57–85%) of users with N95 masks that failed testing believed their respirator fit well. Testers believed 89% (95% CI: 75–96%) of N95 with failed fit tests were of good or like new quality.

Our findings suggest that risk of N95 mask fit failure is high after 4 days of clinical use. We do not have adequate data to make predictions of the failure rate before 4 days of clinical use. Degesys and colleagues[8] reported 23% of respirators failed fit testing after three shifts (days), and this increased to 67% after more than three shifts. A strength of both of our studies relative to older studies is that reuse of the respirators was not simulated; our subjects were clinicians caring for real patients, and thus, the results we obtained are representative of actual use scenarios.

Potential limitations include qualitative testing, respirator donning, and cross-sectional design. Quantitative testing was not possible in this study as it necessitates irreparable damage to the respirator to allow sampling of air within the respirator. Our design of allowing repositioning after an initial failure should alleviate bias attributable to improper donning. As all participants passed fit testing in the past, it is unlikely that our results reflect respirators that never worked or individuals who were unable to don masks correctly. The markedly higher rate of passing with a new respirator also suggests that improper donning or lack of test reproducibility is not driving these results.

Longitudinal data collection with repeated measures would address some of the potential sources of bias in this study. Based on these and other results, we recommend that organisations follow the Centers for Disease Control and Prevention recommendations and limit reuse to five individual uses as supply allows.[5] If the local supply of disposable N95 mask respirators is insufficient to allow replacement more frequently, then alternative more durable elastomeric solutions or measures to restrict need should be considered. Despite training on user seal checks, the participants were unable to reliably identify if their respirator fit poorly before testing.

Declarations of interest

The authors declare that they have no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.bja.2020.06.023.

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The SARS-CoV-2 effect: an opportunity to reduce general anaesthesia rates for Caesarean section?

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Keywords: Caesarean section; COVID-19; general anaesthesia; neuraxial anaesthesia; quality improvement

Editor—Caesarean section is the most commonly performed surgical procedure in obstetrics. Evidence from the Hospital Episode Statistics and anaesthetic survey of the National Health Service activity collected as part of the accidental awareness during general anaesthesia (5th National Audit Project [NAP5]) suggests that 8–10% of all Caesarean sections performed in UK utilise a general anaesthetic.[1,2] The WHO declared a global pandemic of coronavirus disease 2019 (COVID-19) in March 2020.[3] Since the onset of COVID-19, recommendations suggest the use of neuraxial anaesthesia if possible over general anaesthesia for Caesarean section to avoid the risks of aerosolisation associated with tracheal intubation and extubation.[4,5] General anaesthesia for Caesarean section in the current pandemic poses risks for all healthcare staff and can impact utilisation of personal protective equipment for the hospital. We investigated whether general anaesthesia rates at our tertiary obstetric unit (10 000 deliveries and 2600 Caesarean sections annually) had changed since March 2020 with the emergence of COVID-19.

Anaesthetic information for all Caesarean sections undertaken at our unit between April 1, 2020 and May 31, 2020 was reviewed from electronic records. We specifically looked to determine the general anaesthesia rate for different categories of Caesarean section (proposed by the Royal College of Obstetricians and Gynaecologists) within that period.[6] We then compared the general anaesthesia rates with the similar period in the preceding 2 yr (2018 and 2019). No ethical approval was needed as the review was classed as an audit as per the Royal College of Anaesthetists (RCoA) standards.[7] Data are presented as frequency (%) and analysed using χ^2 independence, Fisher's expanded exact *P*-values, percentage difference, and 95% confidence interval (CI) with $P<0.05$ (two sided) as significant.

The number of Caesarean sections increased by 4.3% (95% CI: 1.3–7.4; $P=0.015$) during the 2020 period (Table 1). There was a change in rates of general anaesthesia ($P=0.0042$). The rate for the previous 2 yr was 7.5%, and this decreased significantly to 3.3% in 2020, representing a reduction of 4.2% (95% CI: 1.7–6.6; $P=0.0016$) during the pandemic. There was a change in the distribution of general anaesthesia rates in categories with respect to the total number of Caesarean sections ($P=0.022$). There was also a change in the distribution of categories for Caesarean section with respect to delivery rates ($P=0.037$). General anaesthesia rates stratified by category suggest reductions for Categories 2 and 3 Caesarean sections ($P<0.05$). Nine of the 459 Caesarean sections tested positive for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (1.96%), and all of them had neuraxial anaesthesia. Our hospital met all the RCoA suggested standards for general anaesthesia rates, both before (2018–9) and during the SARS-CoV-2 pandemic.

Our single-centre audit is one of the first to highlight a reduction in the frequency of administration of general anaesthesia for all categories of Caesarean section during the pandemic. The significant change in distribution of general anaesthesia rates for Caesarean section possibly suggests greater awareness of risks posed by an aerosol-generating procedure amongst multidisciplinary obstetric team members, thereby influencing obstetric and anaesthetic decision-making for Caesarean section.

The reduction in general anaesthesia for Caesarean section during the pandemic could also be attributed to staffing changes introduced in our tertiary unit. Since the pandemic began, a 24/7 on-site anaesthetic consultant was established to support on-site anaesthetic trainees. A previous national survey of anaesthetic activity in obstetrics (NAP5) revealed that anaesthesia for 23% of Category 1 Caesarean sections in the UK was delivered by trainees out of hours with distant supervision possibly contributing to the high 'avoidable' general anaesthesia rates.[2] We feel that the staffing changes introduced have led to: (i) enhanced situational awareness, team working, and communication with obstetricians, leading to appropriate and timely decision-making for Caesarean section; and (ii) improved direct and indirect supervision of anaesthetic trainees providing them with more educational and training opportunities to improve both their general