

Innovations with Validation: An Ingenious Way Forward?

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Innovation is a process by which a domain, product, or service is renewed and brought up to date by applying new processes, introducing new techniques, or establishing successful ideas to create new value.¹ Innovations are thus alterations or modifications of the existing inventions to improve their efficacy at the site of application. As with all innovations, these are temporary and make-shift arrangements, at the level of the user to enhance ease of use, which over time gains widespread acceptance until it is formally recognized.

When it comes to the field of medicine, the ground-level challenges faced by the delivering clinicians are closely studied, and attempts at rectifying are made in the most pragmatic way with the least cost incurred. These challenges were most apparent during the recent COVID-19 pandemic, due to the wide dissemination of information through various digital media. We all know, the COVID-19 pandemic was predominantly a logistic crisis in many aspects rather than a pure medical crisis, where healthcare systems across the globe miserably failed to provide adequate logistics not only to the patients but also to the healthcare workers to deliver the required care in a safe manner.

In this issue of *IJCCM*, Mohamed Kamal et al. publish a before-and-after intervention study on 60 Australian healthcare workers in a Sydney hospital who had previously failed a quantitative fit test (QnFT) while using ProShield® duckbill N95 respirator.² They studied the difference in quantitative fit test failures before, and after donning a safety goggles with an elastic headband. They found a significant reduction in QnFT failures when safety goggles with the headband were added. Wardhan et al. published a pilot study in 2020 wherein a double-sided adhesive tape was applied to enhance the face and respirator interface fit thereby reducing the qualitative fit test failures.³ Investigators from the same Australian hospital (where the current study is from) had previously published an unpowered pilot study in 2020 wherein two different types of duckbill N95 respirators were used.⁴

These studies, conducted over a few months during a pandemic, bring the fear of the unknown into context and provide an actual sense of urgency. As a result, such innovations are important since they have the potential to avoid regulatory authorities and excessive time delays, ensuring rapid implementation.

During the pandemic, we have noted that the quality of personal protective equipment (PPE) affects the risk for COVID-19 infection, and N95 respirator is the crucial aspect of COVID-19 prevention. Eye protection (using goggles or face shields) is also an integral part of PPE in the prevention of air-borne pathogens. A recent prospective cohort study found that when compared with healthcare workers who donned optimal PPE, front-line healthcare workers who reused PPE had an increased risk of COVID-19 positivity with a HR 1.46, 95% CI, 1.2–1.76.⁵ The risk of COVID-19 positivity with

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inadequate PPE after a multi-variate analysis was 1.31, 1.10–1.56.⁵ This demonstrates that sub-optimal PPEs and PPE shortages were painfully real. Furthermore, in developing nations, the availability of fit tests to ensure safety may not be as widespread as in a more developed and advanced world with a sparse population.

In this context, the innovative concept by Australian authors promises to solve the logistic issues arising from failed quantitative fit tests, as this method ensures a more reliable mask-face seal in limited resource settings (it may be worthwhile to note that in a pandemic situation, even the most advanced nations will face acute shortages which will thereby mimic a low resource setting). Procurement of additional logistics may still be required for those who fail the quantitative fit test even with the safety goggles with the headband. Unfortunately, though innovative, this method is only to ensure improved fit and obviously cannot differentiate between those who have and do not have an adequate seal (without a quantitative fit test). But certainly, these numbers may be lower with the use of this technique.

Along with this, the other limitations of this study have been duly acknowledged by the authors themselves. Being a single-centre study in Australia, it needs external validation. The interpretation from this study may not be applicable universally at this stage since the types of masks/goggles commonly used vary across continents, countries, and regions within the same country. Apart from individual facial morphology and the presence and extent of facial hair; the mask fit is also affected by age, gender, and race. Randomization was not done in the order of before-and-after testing. The participants in this study happen to be predominantly females, and hence we are unable to predict whether any significant difference in the quantitative fit test failure rate will occur if the participants happen to be predominantly men or in an equally mixed population. We may not be able to assess the long-term effects (e.g., pain, irritation, local pressure effects, etc.) of the elastic band since it is studied only for a short period during quantitative testing. Finally, there could be variations in the interpretation of

quantitative fitness failure by various machines and technologies across the globe. Another interesting publication on 2022 from Australia noted a significant difference in QnFT failures between different types of N95 respirators which shows that optimally designed N95 respirators could drastically reduce QnFT failures.⁶ Hence optimally designed N95 respirators when freely available can negate the need for the safety goggles with the wrap-around elastic band technique.

As we conclude, it is interesting to note that though a “self-seal check” was commonly practiced after donning N95 masks, prior qualitative or quantitative fit tests were never done or were rarely practiced in most Indian hospitals or ICUs during the COVID-19 pandemic. This brings to light the scant regard given to occupational safety and health in the Indian (or in other developing or undeveloped countries) health systems, either before or after the pandemic. Would these simple innovations help to safeguard frontline workers with a ‘take charge of your own well-being’ attitude, and simultaneously, encourage policymakers to enhance safety at the workplace? It would be interesting to initiate studies at least in retrospect, to find out the extent of increased risk for COVID-19 in countries/ICUs where the fit tests were not done versus the countries/ICUs where it is mandatorily practiced. It would also be prudent to validate the innovation in various countries with the most common masks/goggles available in their settings.

Finally, in an era characterized by extensive travel and global connectivity in an environment of resurgent pathogens and pandemics, are fit tests alone adequate measures to ensure the health and safety of our frontline workers? Only time will tell.

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