EDITORIAL

Clearing the Fog on the Use of N95 Mask

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N95 respirator mask has become a household name due to the COVID-19 pandemic. In spite of the guidelines recommending its use only by healthcare workers in close contact with COVID-19-infected patients, during aerosol-generating procedures and environmental cleaning, it has been used extensively in the community during the pandemic.[1] As per regulatory standardization, the N95 mask should be able to filter 95% of particulate matter from the environment if properly designed and donned. Due to the extensive demand, N95 masks started becoming available in all shapes and sizes, sometimes without proper standardization and many times donned inappropriately even by healthcare workers who are not used to wearing these masks earlier.[2] In order to prevent the transmission of droplet and airborne infection like COVID-19, it is important that COVID-19 appropriate behavior like proper donning of a suitable mask is practiced universally.[3] Regulatory bodies like Occupational Safety and Health Administration (USA) requires a fit test before certifying N95 masks for public use . The fit test for N95 masks could be qualitative or quantitative. Qualitative fit test is based on the principle of whether the subject wearing the mask is able to smell or taste the test substances (gas, vapor, or aerosol), if it leaks inside the mask. The chemical substances that are used are Saccharin vapor (sweet taste) and denatonium spray (bitter taste). The use of Irritant smoke has been discontinued for this test. The test is conducted after verifying the taste of the challenge agent by the subject wearing an unfiltered mask. There is much subjectivity in this test as it is dependent on reporting by the wearer. Moreover, this test is not currently recommended for tight-fitting mask like N95, due to its low sensitivity to detect leaks.[4] Quantitative methods are more reliable and are based on the principle of measuring the concentration of the test substance (challenge agent) inside and outside the mask or determining the flow rate of air under the mask. The former is the most commonly used fit test. The challenge agent could be a natural atmospheric molecule like sodium chloride (particle size increased by a method of vapor condensation) or an artificially created chemical. The ratio of the concentration of the agent measured by the detection device (e.g., PortaCount, AccuFIT) that is capable of counting the test particle above 0.015 microns, by a laser beam technology, outside the mask as compared to inside is called as fit factor (FF). FF for a standardized N95 respirator is recommended to be more than 500 to compensate for the difference between static (test) and dynamic (workplace) conditions.[5]

In order to ensure the proper fitness of the N95 mask, it is advisable that the wearer should tightly press the mask flush against the face and at the bridge of the nose to seal any gaps. Moreover, a user seal check is recommended by the manufacturer for all wearers of the mask. This seal check is done by sharp inhalation and exhalation while wearing the mask and observing for an air leak around the nose and edges of the mask.[6] This maneuver does not guarantee a proper seal and has been found to be insensitive when compared with the quantitative fit test (QnFT). Apart from wearing a suitable mask, eye protection by wearing goggles is a part of personal protective equipment (PPE).[7] Frosting of the goggles is sometimes taken as a marker of an improper seal of the mask by the wearer. Moreover, the relative position of goggles over the mask can also impact the degree of leak around the mask. In the absence of a validated point of care test for the adequate seal of N95 mask, it is imperative that the subjective perception and practices should be tested against the gold standard method of QnFT for N95 mask. This issue of the journal have two articles on pragmatic studies to address this issue.

In the first study conducted in 70 healthcare volunteers donning standard N95 respirator masks, after a satisfactory user seal check, the participants donned eyeglasses and checked for fogging by self-reporting , QnFT by aerosol particle count method was carried out in all participant and a FF of <100 was considered to be the indication of poor fit.[8] Fogging of eyeglasses as an indicator of poor fit was found to be 71% sensitive and 46% specific with a wide confidence interval. The receiver operating curve for fogging of eyeglasses as a marker of poor fit when compared to gold standard quantitative test was 0.59, which is almost equal to the results that can be predicted by tossing a coin. The reasons for the poor performance of fogging as a measure of good fit may be multifactorial: (1) Leakage around the edges of the mask rather than the nasal bridge; (2) PortaCount technology in the study may not be sensitive to detect minor leaks enough to cause fogging that can be detected by other technology like infrared camera;[9] (3) fogging was based on reporting by the test subject, which could have varied sensitivity; (4) fogging also depends on the ambient temperature and breathing pattern of the subject, which is variable; and (5) proper tightening of N95 mask band and proper size eyeglasses may also be confounding variables in the interpretation of test results in this study. Thus, we need a more robust, point of care validated surrogate method apart from the user seal check or eye glass fogging to confirm the absence of leakage from the N95 mask.

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The second study also utilizes similar QnFT of N95 mask to ascertain the fitness of N95 mask with the use of safety goggles.[10] Safety goggles have become an integral part of PPE but is usually donned when coming in contact with aerosol-generating procedures in an infected patient. This paper studied an additional role of safety goggles as an added protection by increasing the fitness of the N95 mask and decreasing the leakage around the mask. In their analysis, FF ascertained by QnFT (PortaCount) increased from 69.4–169.1 (mean increase of 99.7) in 76% of participants, which was considered to be significant. Moreover, most of the participants felt more comfortable in wearing safety goggles along with a PPE mask. This study concluded that the use of safety goggles increases the proportion of users who pass the QnFT. Extrapolation of these results in patients with beards, other facial abnormalities, ill-fitting goggles, and N95mask should be done with caution.

Acceptance and publication of these kinds of pragmatic studies in a peer-reviewed national journal are indicative of a growing trend among researchers to address the clinical problem by pragmatic trials. We have realized over years that many large multicenter randomized trials, though considered gold standard, are not able to influence clinical practice due to their inconclusive results. On the contrary, small studies conducted and analyzed in a standardized manner addressing a clinically relevant issue may impact our clinical practice. This should also encourage young clinicians with an aptitude for clinical research to identify daily clinical problems and design small trials to address the problems. Astute editors will welcome such manuscripts of clinical relevance similar to the studies published in this issue of journal. This might be the way forward in "clearing the fog" on many misty clinical issues like ones addressed in these trials.

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