9-3-2021

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Infection Prevention in Practice 3 (2021) 100116

Available online at www.sciencedirect.com

Infection Prevention in Practice

journal homepage: www.elsevier.com/locate/ipip

Comparative analysis of N95 respirators fit testing with commercially available and in house reagent

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ARTICLE INFO

Article history:
Received 12 October 2020
Accepted 4 January 2021
Available online 15 January 2021

Keywords:
Fit testing
COVID-19
N95 masks
In house reagents

SUMMARY

Background: Due to COVID-19, thousands of healthcare workers have been affected and have lost their lives in the line of duty. For the protection of healthcare workers, WHO and CDC have made standard guidelines and requirements for PPE use. N95 masks are amongst the most readily used PPE by healthcare professionals and it is highly recommended by OSHA that every make and model of N95 should go through a fit test at least once in a year.
Method: A total of 30 randomly selected healthcare professionals (who were a regular user of N95 respiratory masks) were subjected to assess in-house (saccharin sodium benzoate) reagent for use for standard qualitative fit testing in our hospital. Threshold testing with the in-house reagent at three different concentrations was performed prior to establish participants' sensitivity to the reagent. After successful completion of threshold testing, fit test was performed on participants wearing an N95 mask.
Results: All the participants included in the study passed the sensitivity testing with three concentrations of the reagents, while it was concluded that the concentration of the in-house reagent that was well suited for the sensitivity testing was a concentration of 1g/dl saccharin with 10g/dl sodium benzoate. For fit testing 12g/dl was found to be more appropriate.
Discussion: Our study provided a low cost solution to ensure safety of healthcare workers who are regular users of N95 masks following guidelines implemented by OSHA and CDC.
Conclusion: The in-house test solution prepared was found to be equally sensitive to its commercially available counterpart.

Introduction

After the declaration of COVID-19 as a pandemic, extreme shortages and disruption of personal protective equipment

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https://doi.org/10.1016/j.infpip.2021.100116

(PPE) have been observed by the healthcare organizations.This supply demand gap is putting health care workers at risk of contracting COVID-19 and other infectious diseases. The World Health Organization (WHO) and Center for Disease Control (CDC) are emphasising the correct and rational use of PPEfor healthcare workers dealing with the outbreak [1].

Among all the essentials needed by healthcare professionals to combat the recent outbreak of COVID-19, N95 masks are amongst the most readily used PPE (which remove particles from the air when inhaled through it). They effectively filter out particles (including viruses and bacteria) measuring as small as 0.3 microns with a success rate of 95%. They significantly reduce the risk of exposure from airborne particles (from small particle aerosols to large droplets) [2]. According to The Occupational Safety and Health Administration (OSHA), it is directed that in order to protect from exposure; N95 masks should make a tight seal with a wearers' face. It is highly recommended by OSHA that every make, size and model of the respirator should go through the fit testing at least once a year [3].

Fit testing can be done by two methods, quantitative fit testing and qualitative fit testing. Quantitative testing is done by a machine that can evaluate actual amount of leakage into a face piece. There are three methods of quantitative testing approved by OSHA. These include generating aerosol, ambient aerosol and controlled negative pressure. It can be used for any respirator with a tight-fitting mask [3]. Quantitative fit testing removes the individual subjectivity and therefore is more robust; however the machine cost and availability of trained users to ensure proper use, limits its availability in the resource-limited countries.

Qualitative fit testing, on the other hand, is done by a method that depends on the individual's sense of taste or smell and does not assess the amount of leakage. OSHA approves four different testing methodologies for qualitative fit testing. These include reagents containing Isoamyl acetate, Saccharin, Bittrex and Irritant smoke. Qualitative testing is done using a commercially prepared fit testing solution of standardized strength that comes with the fit-testing kits, including plastic hood and nebulizer (see Figure 1). Although hood and nebulizers are reusable, the availability of fit test solution is quite a challenge (both from an expense point of view and ease of availability). Especially when used for fit testing large numbers; as was experienced during the global H1N1 influenza pandemic in 2009 [4].With global trade shut down during the early wave of the COVID-19 pandemic, procurement and shipment delays resulted in acute shortness of commercial fit test solutions.

Figure 1. Picture of hood and nebulizers used for Fit testing (commercially procured)

Due to the COVID-19 pandemic, the use of PPE has increased rapidly and therefore the need for fit testing has also surged.It is highly recommended by the CDC to have proper fit testing for all N95 respirators used by frontline healthcare workers, endorsing OSHA guidelines. [5]. Considering concerns about a shortage of fit-testing kits and test solutions, OSHA encourages employers to prioritize the use of fit-testing equipment to protect employees who must use respirators for high-hazard procedures [3].

In order to overcome this demand, we prepared an in-house fit test solution in our pharmacy compounding services and compared the results with the commercially available reagent to observe any difference in the performance of these reagents. We conducted fit testing through qualitative methodology, already in practice at our center. Numbers of tests had to be scaled up for mass-testing all hospital employees using N95 masks at COVID-19 dedicated units.

The main aim of the study was to test whether there is any difference in the performance between the in-house prepared reagent and a commercially available reagent for qualitative fit testing of N95 masks.

Methods

This was a single-blinded study conducted at the of Aga Khan University (AKU) main campus, Karachi Pakistan. The participants were healthcare workers aged $\geq$18 years and were regular users of N95 respiratory masks (who had previously been fit tested). More than 800 healthcare workers have been fit-tested at AKU using 3M™ FT-30 (bitter) Solution and their pass and fail tests were reviewed. Assuming the hypothesized frequency of passing sensitivity test to be 91.7% +/-10 (3), we estimated a minimum requirement of 28 participants. For the fit test: keeping a 2-sided confidence level (1-alpha) of 95% and Power of 80%, a ratio of those who passed fit-testing by commercial kit to those who failed it at 2:1, and assuming 25% pass fit-testing with an in-house reagent (out of those who failed by commercial), and 91% pass fit-testing with in-house reagent out of those who passed by commercial reagent (3), we required a minimum of 23 participants.

Thus, 34 randomly selected participants were enrolled. Enrollment was done on a voluntary basis and no compensation was given to study participants. Consent forms were administered to participants prior to testing. Participants failing to give consent were excluded from the study. Three different concentrations of the in-house fit testing solution was compounded in our pharmacy following preparation guidelines from CDC for in-house preparation of fit test solutions [6]. These solutions were placed in identical clean hospital grade plastic bottles labeled A, B and C: 1 gm, 8 gm and 12 gm Sodium benzoate/60 ml Saccharin solution in distilled water. All the solutions had identical consistency and color. Participants with a known allergic reaction to the contents of testing solutions were excluded from the study (common allergies may include eye and skin irritation). Saccharine and Sodium benzoate are compounds commonly used in food related items and drugs, hence they are safe to use.No occupational hazard and toxicological information have been reported in material safety data sheets [7,8]. Participants with facial hair interfering the N95 seal were excluded from the study. Those who had eaten, drank any flavored drinks or smoked 30 minutes prior to the study were also excluded.

Testing procedure

All the participants that were enrolled in the study had to go through two phases of study: threshold or sensitivity testing, and then the actual fit testing. The sensitivity test determines the participant's ability to taste the solution. This was done using all three concentrations of Saccharine-Sodium benzoate (in-house reagent). The sensitivity of the taste receptors of the participant being tested was checked by administering a puff of the lowest concentration of reagent through a hand-held nebulizer (provided in the fit-testing kit) while wearing a hood over their head. The reagent is expected to be sweet (saccharin) in taste. Each individual was asked if they could taste the reagent; if not, another puff was administered every 20 seconds till the person could sense the taste of the reagent or 20 puffs count was complete. Once the sweet taste was sensed, the person was instructed to remember the taste for the subsequent Fit-test procedure to follow. After gargle and rinsing mouth completely the next two concentrations were tested. Only those who could sense the taste were labelled as "sensitivity test pass" and furthered to the second part of the study. The proportion of participants who could sense the taste for each concentration of the reagents was calculated against the total number of participants.

The fit testing was performed for all three concentrations for each participant passing the sensitivity test. Each participant had to pass all four steps in order to be considered "Fit test" passed. The standard four steps of fit-testing procedure are described below.

Step 1 (at baseline)

The participant being fit-tested had to wear the N95 mask and seal test it, that is, no air should leak from any of the edges of the mask when the person exhales and negative pressure (vacuum) is built when inhaling. A hood was placed over the person's head and five puffs of the in-house fit-testing reagent were administered while the participant was asked to breath normally for 30 seconds. Participants were instructed to indicate if they could sense the taste they were sensitized with. If yes, the fit test has failed and they were asked to remove the mask, rinse mouth, repeat donning and seal test and the fit test was repeated. Two attempts were completed before declaring a fit-test failed. Participants who did not sense the reagent taste proceeded to next step.

Step 2 (with deep breath)

An additional five puffs of reagent were administered and participants were asked to take deep breaths for 30 seconds. If they could still not taste the reagent, the participant proceeded to next step. However, if they did feel the sweet taste, they were instructed to doff mask, rinse out taste, and repeat Step 1. Two attempts were made before declaring a "fit test" fail.

Step 3 (with exercise)

Another five puffs of reagent were administered and participants were asked to move their head side to side, up and down, to bend at the waist, reach up and to the side in measured movements. Participants were asked to continue these movements for 30 seconds. If they could still not taste the reagent, then proceed to Step 4. If participants could sense the taste, then he/she was asked to doff mask, rinse out taste, and repeat from Step 1. Attempt twice before declaring "fit test" failed.

Step 4 (with exertion)

Another 5 puffs of reagent were administered and participants were instructed to talk continuously for 30 seconds (a written passage shown to participants to read out). If they can still not taste the reagent, then fit test is passed. If they can, then doff mask, rinse out taste, and repeat from Step 1, to attempt twice before declaring failed.

Data analysis

A data collection form was developed to record the responses from each participant and reagents. This information was entered and analyzed into the Microsoft excel version 2010. Data collection variables included participant fail or pass status with commercial reagent, fit testing solution code, sensitivity testing response for each concentration (yes or no), and number of puffs at which sensitivity was achieved, pass or fail status of fit test for each concentration. Data is presented in percentages corresponding to the observations made after the sensitivity testing of each concentration of the reagents. Sensitivity, specificity, positive (PPV) and negative predictive value (NPV) for fit test with each concentration was calculated against commercial reagent.

Ethical consideration

Consent forms were administered to participants prior to the conductance of the fit testing. The study began after ethical approval from the ethical review committee of Aga Khan University, Karachi.

Results

All 34 participants passed the first phase, that is, taste sensitivity testing with all three concentrations of the in-house reagent. The average number of puffs administered to achieve sensitization of taste receptors for each concentration are given in Table I. Performance of each reagent against the 3M™ FT-30 (Bittrex) reagent is also shown as sensitivity, specificity, PPV and NPV. A high specificity and positive predictive value denoted a better ability of that concentration to detect failure of fit. The higher the specificity and PPV, the safer to use that concentration as reagent for fit testing (see Table I).

Looking at the results of the concentration of in-house reagent, we found 10 g/dl sodium benzoate in 1gm/dl Saccharin most suited for taste sensitivity test while for fit-testing the reagent with 12 g/dl sodium benzoate was found to be most suitable as it had the highest positive predictive value and did not miss any person who is likely to fail fit-test by a NIOSH approved kit.

Discussion

The main purpose of this study was to assess the efficacy of homemade solution for qualitative fit testing of N95 respirators in a healthcare setting. Our findings suggest that an in-house fit test solution can provide a valuable alternative, with performance comparable to a commercial solution. We tested

Table I
Performance of three concentrations of homemade reagent for fit testing of N95 masks compared to 3M™ FT-30 (bitter) reagent on 34 healthcare workers of a tertiary care hospital in Karachi

Composition of reagent	Mean no. Of puffs (95% CI) to achieve sensitization	Sensitivity: Passed in-house/passed commercial (%)	Specificity: Failed fit test in-house/failed commercial (%)	PPV: Passed commercial/passed in-house (%)	NPV: Failed commercial/failed in-house (%)
1 g/dl Saccharin + Na benzoate 8 g/dl	5.8 (4.5—7.0)	21/23 (91.3)	7/11 (11.8)	21/25 (84)	7/9 (63.6)
1 g/dl Saccharin + Na benzoate 10 g/dl	3.3 (2.7—4.0)	21/23 (91.3)	9/11 (81.8)	21/23 (91.3)	9/11 (81.8)
1 g/dl Saccharin + Na benzoate 12 g/dl	2.1 (1.8—2.5)	21/23 (91.3)	11/11 (100)	21/21 (100)	11/13 (84.6)

Note: PPV =positive predictive value, NPV: negative predictive value.

commercial grade saccharine alone in earlier phases of the study using a published protocol [4]. However, results were not reproducible. We modified our solution by adding Sodium Benzoate; a common food preservative to the saccharine solution that perhaps stabilized the solution, and produced consistent results following CDC guidelines [6]. Multiple solutions with varying concentrations of sodium benzoate were prepared, of which three concentrations (8, 10 and 12 gm) tested in the current study were most stable and workable.

All staff tested in this study used a 3M N95 model (NIOSH-approved with head bands) respirator for fit testing using the in-house as well as the commercial solution. Using 12 gm/dl sodium benzoate reagent as test solution we were able to detect all those who failed fit testing using a commercial solution; thus reaching the specificity of 100% with no false positive fit tests (i.e. falsely passed fit test), our benchmark for final approval of the test solution.

Fit testing using NIOSH approved kits is recognized as a tool that can ensure protection by assessing fit of a specific respirator model or size. However, due to a global shutdown, the supply and demand chain for respirators and fit test solutions has critically affected the functionality of many healthcare organizations. Health Care providers demand availability of appropriate PPE (especially fit tested face filtering respirators) for optimum protection.

To compensate for this global shortfall OSHA temporarily suspended its mandatory requirement of annual fit test of respirators for all healthcare workers and instead prioritized it for staff at highest risk. [9] Our study has practical implications as it provides the option of an uninterrupted supply of homemade fit test solution that is comparable to NIOSH approved kits; thus providing a reliable alternative during a global crises situation. Initial fit testing is essential to determine if the respirator properly fits the worker and can provide the expected level of protection. [4].

Our findings are of value to resource limited countries where the NIOSH approved kits are either not available or are prohibitively expensive. Resource allocation towards health care is extremely scarce in low-income and middle-income countries, which are already overburdened with communicable and non-communicable diseases. As the COVID-19 pandemic tightens its grip around the world and tough decision need to be made regarding the allocation of healthcare supplies, [10] our in-house solution provides a cheaper and reliable alternate to commercial fit testing solution.

We found our homemade sensitivity and test solution to be stable at room temperature with a shelf life of 30 days. There was no obvious crystal formation in the solution, however crystals developed on the nebulizer nozzle after multiple uses. Users were instructed to thoroughly wash the nebulizer chambers and nozzles at the end of sessions. Although in this study comparative analysis was performed using only one type/model of N95 respirator in principle, this should be applicable and useful for all makes and model of N95 respirators. Further studies using different model and style of N95 are however, required to make our findings more generalizable.

Conclusions

We successfully evaluated an in-house prepared reagent for fit-testing. The sensitivity and specificity of in-house fit testing reagent is comparable to the commercial solution and was found to be stable at room temperature with a shelf life of 30 days.

Authors contributions

EK. J.F, H.S: conceived, developed protocol and initiated activity.

K.K, B.A, SC, KI: conducted fit tests of the staff.

Z.R: coordinated the staff availability for fit testing.

S.S.R, SK: assisted in formulation of in-house solution.

E.K, J.F, H.S: participated in manuscript writing and result analysis.

AZ, H.Z and E.K: supervised the entire activity.

All authors reviewed the manuscript and provided valuable feedback.

Acknowledgement

Authors are thankful to office of research and graduate studies Aga Khan University, Stadium Road for providing logistic support. Especial thanks to Mr. Qurban and Mr. Zulfiqar for their prompt assistance in organizing of Fit test sessions.

Conflicts of interest

The authors have no conflicts to declare.

Funding sources

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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