### Accepted Manuscript

Title: The effectiveness of respiratory protection worn by communities to protect from volcanic ash inhalation; Part II: Total inward leakage tests

Authors: Susanne Steinle, Anne Sleeuwenhoek, William Mueller, Claire J. Horwell, Andrew Apsley, Alice Davis, John W. Cherrie, Karen S. Galea

PII: DOI: Reference: S1438-4639(17)30802-7 https://doi.org/10.1016/j.ijheh.2018.03.011 IJHEH 13205

To appear in:

Received date:	22-11-2017
Revised date:	19-3-2018
Accepted date:	27-3-2018

Please cite this article as: Steinle S, Sleeuwenhoek A, Mueller W, Horwell CJ, Apsley A, Davis A, Cherrie JW, Galea KS, The effectiveness of respiratory protection worn by communities to protect from volcanic ash inhalation; Part II: Total inward leakage tests, *International Journal of Hygiene and Environmental Health* (2010), https://doi.org/10.1016/j.ijheh.2018.03.011

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.



# The effectiveness of respiratory protection worn by communities to protect from volcanic ash inhalation; Part II: Total inward leakage tests

Susanne Steinle<sup>1\*</sup>, Anne Sleeuwenhoek<sup>1</sup>, William Mueller<sup>1</sup>, Claire J. Horwell<sup>2</sup>, Andrew Apsley<sup>1</sup>, Alice Davis<sup>1</sup>, John W. Cherrie<sup>1, 3</sup>, Karen S. Galea<sup>1</sup>

- 1. Centre for Human Exposure Science, IOM, Research Avenue North, Riccarton, Edinburgh, EH14 4AP, UK.
- Institute of Hazard, Risk & Resilience, Department of Earth Sciences, Durham University, Science Labs., South Road, Durham, DH1 3LE, UK.
- 3. Institute of Biological Chemistry, Biophysics and Bioengineering, Heriot-Watt University, Edinburgh, EH14 4AS, UK.

\*corresponding author

### ABSTRACT

Inhalation of ash can be of great concern for affected communities, during and after volcanic eruptions. Governmental and humanitarian agencies recommend and distribute a variety of respiratory protection (RP), most commonly surgical masks. However, there is currently no evidence on how effective such masks are in protecting wearers from volcanic ash. In Part I of this study (Mueller et al., Submitted), we assessed the filtration efficiency (FE) of 17 materials from different forms of RP against volcanic ash and a surrogate, low-toxicity aerosol, Aloxite. Based on those results, we now present the findings from a volunteer simulation study to test the effect of facial fit through assessment of Total Inward Leakage (TIL).

Four different disposable RP types that demonstrated very high median FE ( $\geq$  96% for Aloxite;  $\geq$  89% for volcanic ash) were tested without provision of training on fit. These were an industry-certified mask (N95-equiv.); a surgical mask from Japan designed to filter PM<sub>2.5</sub>; a flat-fold basic mask from Indonesia; and a standard surgical mask from Mexico, which was also tested with an added medical bandage on top, as an additional intervention to improve fit.

Ten volunteers (6 female, 4 male) were recruited. Each RP type was worn by volunteers under two different conditions simulating cleaning-up activities during/after volcanic ashfall. Each activity lasted 10 minutes and two repeats were completed for each RP type per activity. Dust (as PM<sub>2.5</sub>) concentration inside and outside the mask was measured with two TSI SidePak aerosol monitors (Models AM510 and AM520, TSI, Minnesota, USA) to calculate TIL. A questionnaire was administered after each test to collect perceptions of fit, comfort, protection and breathability.

The best-performing RP type, across both activities, was the industry-certified N95-equiv. mask with 9% mean TIL. The standard surgical mask and the basic flat-fold mask both performed worst (35% TIL). With the additional bandage intervention, the surgical mask mean TIL improved to 24%. The PM<sub>2.5</sub> surgical mask performed similarly, with 22% TIL. The N95-equiv. mask was perceived to provide the best protection, but was also perceived as being uncomfortable and more difficult to breathe through.

This study provides a first objective evidence base for the effectiveness of a selection of RP types typically worn around the world during volcanic crises. The findings will help agencies to make informed decisions on the procurement and distribution of RP in future eruptions.

Key Words: facemask, PM<sub>2.5</sub>, ash, volcano, total inward leakage

#### **INTRODUCTION**

Around the world, governmental and humanitarian agencies recommend and distribute respiratory protection (RP) to communities to reduce personal exposure during airborne particulate pollution crises. These scenarios may involve human-made crises (urban pollution or biomass burning), or natural sources, such as volcanic eruptions, wild fires, and dust storms. The specific pathogenicity of the particles in these exposures is rarely known (e.g., Horwell et al., 2013), so agencies tend to take a precautionary approach (McDonald and Horwell, 2017).

Evidence for the effectiveness of different forms of RP relevant for community exposures to airborne particles is lacking. Whilst such protection is heavily-regulated in industry (e.g., HSE, 2013; NIOSH, 1996), for the most part, such regulations are not available for the public. This gap is partly because industry standards incorporate a requirement for 'fit testing' to ensure that exposed workers have masks which fit their individual facial shapes. Workers are also trained on how to wear the mask and cannot have features which may compromise fit, such as facial hair (Bolsover, 1992). Fit testing and training is not a realistic prospect for public use, although some advice is possible through accompanying information.

There are few published studies which have assessed the effectiveness of RP, through the assessment of 'total inward leakage' (TIL), in non-occupational settings. Unlike filtration efficiency (FE), which only indicates the pentration of particles through the filter medium, as done in Part I of this study (Mueller et al. Submitted), TIL represents the total effectiveness of the RP, taking into account both filter penetration and faceseal leakage (Brown, 1995; Grinshpun et al., 2009; Lee et al., 2008; Rengasamy and Eimer, 2012; Rengasamy et al., 2014a; Rengasamy et al., 2014b).

Jung et al. (2014b) determined the TIL for three certified anti-yellow sand masks (KF80 = FFP1<sup>1</sup>) and two certified guarantine masks (KF94 = FFP2) that, in previous experiments, showed a high FE. Overall, all masks satisfied the TIL criterion according to their certificate (25% for KF80 and 11% for KF94) except one guarantine mask which had a mean TIL of 22.4%. A similar approach was taken by Cherrie et al. (Accepted) who also ran FE experiments as the basis for a simulation study with volunteers using masks commonly used by the public in Beijing against a diesel exhaust challenge. Results showed the best-performing mask to be a disposable respirator designed for occupational purposes (3M9322 with median TIL of 1.8%), with consumer masks having TILs in excess of 60%. Van der Sande et al. (2008) investigated the efficiency of professional and home-made masks (made from a tea towel) and found that the protection provided by all types of masks appeared to be relatively stable over time, though a high degree of individual variation was observed. The results of this study indicate that industrycertified masks are likely to cause less TIL than surgical masks or other forms of ad hoc protection (TIL measured while talking for adults: 1.5%, 19%, and 31%, respectively for a FFP2 mask, surgical mask, and tea cloth), and that variability in facial shape will also impact TIL, including poorer protection for children versus adults. Lee et al. (2008) found that the protection factors of N95 masks were, on average, 8-12 times greater than those of surgical masks when tested in a human volunteer study against NaCl particles in the bacterial and viral size range (0.04 – 1.3  $\mu$ m). Most masks performed worst against particles in the smallest size range ( $\sim 0.04 - 0.2 \mu m$ ).

Major volcanic explosions can generate substantial amounts of volcanic ash, smothering the environment for great distances in a blanket composed of fine-grained mineral and glass particles. Such ash can stay in the environment for months or even years, remobilizing with wind and human activity (Horwell et al., 2003). In terms of exposure reduction for volcanic ash, the World Health Organization/Pan American Health Organization (WHO/PAHO) recommends that people stay indoors or, if they must go outdoors, that they wear a light-weight, disposable mask (Pan American Health

<sup>&</sup>lt;sup>1</sup> FFP1 (low efficiency), FFP2 (medium efficiency), FFP3 (high efficiency) where FFP = Filtering Face Piece. The US N95 standard is roughly equivalent to FFP2, and N99 is equivalent to FFP3.

Organization, 2017). No further information is available on the types of mask which might be effective in such circumstances, and this is the case for all advice offered around the world (see summary of advice at: www.ivhhn.org/resources/global-ash-advice.html; IVHHN, 2017).

The Health Interventions Volcanic Eruptions (HIVE; in project http://community.dur.ac.uk/hive.consortium/) has identified that surgical and basic, flat-fold masks were distributed by agencies in Yogyakarta, Indonesia to both adults and children with no accompanying information, following ashfall from Kelud volcano in 2014 (Horwell et al., 2017). The researchers observed that many people were not wearing their RP properly (e.g., not correctly opened up, fitted and tied), and glasses, in particular, impacted on the seal to the face. In addition, there was plentiful evidence that some masks were not going to offer effective protection due to obvious gaps between the mask and the face. This was particularly evident for surgical masks, 'fashion' masks, and cloth materials.

In our current study, we present the first evidence on the effectiveness of the range of forms of RP worn by communities exposed to volcanic ash. In the first part of this study (Mueller et al., Submitted), we presented the FEs of materials of 17 different forms of protection challenged with volcanic ash sourced from Sakurajima (Japan) and Soufrière Hills (Montserrat) volcanoes and Aloxite (the surrogate, low-toxicity dust to be used in the present study) in an exposure chamber.

For the study presented here, we chose four from the six best performing masks as reported in the FE tests (Mueller at al. Submitted) for testing on human volunteers. By quantifying TIL, the impact of fit on overall effectiveness was determined. No training was provided on fitting the mask.

#### Methods

#### **Respiratory protection selection**

The masks selected for testing were 1) an industry-certified (EN 149: 2001 standard; European Committee for Standardization, 2001) 3M Aura 9322 FFP2 respirator (N95-equiv.); 2) a surgical mask from Japan which purports to filter particles sub-2.5 µm in diameter and is readily available from stores (PM<sub>2.5</sub> Surgical (J)); 3) a basic, flat-fold mask, distributed in bulk quantities by the Red Cross in Yogyakarta, Indonesia (PMI) during eruptions of Kelud/Merapi volcanoes (Basic flat-fold (I)); and 4) a standard surgical mask from Mexico, available from pharmacies (Surgical (M)).



Figure 1: Masks chosen for volunteer study as shown by human volunteers (top row) and alone (bottom row)

Masks 1-3 were chosen because they all had median  $FEs \ge 98\%$  for both volcanic ash and Aloxite. The Mexican surgical mask had a FE of 89% and 96% for volcanic ash and Aloxite, respectively, and was chosen because surgical masks are distributed and used commonly around the world. In addition, because of the likely poor-fit of surgical masks and the fact that many people add additional layers to their RP in an attempt to provide extra protection (Horwell et al., 2017), the Surgical (M) mask was also tested with a bandage (Boots Pharmacy Stretch bandage, 7.5 cm x 4 m) tied over the mask (Figure 1 (image 4+)). Mueller et al. (Submitted) provide details of the composition of the four types of RP.

#### **Volunteer recruitment**

Ethical approval for the volunteer tests was given by the Ethics Board of the Department of Earth Sciences, Durham University (Ref: ESE20170523CH).

Volunteers were recruited through word of mouth, social media, and a marketplace website. Interested individuals were asked to fill in a health questionnaire to ensure that they met the inclusion criterion of falling in the 18-65 age range. Potential volunteers were subsequently excluded from participation if they had cardiovascular or respiratory problems (e.g., asthma), suffered from claustrophobia, and, in the case of female volunteers, were pregnant or breastfeeding. We adopted a precautionary approach, due to potential participant attrition, and recruited four male and five female volunteers for part A (we aimed for eight volunteers with a range of face shapes and including some with facial hair). All volunteers finished part A; however, two female volunteers were unable to participate in part B and so an additional female volunteer was recruited for part B only (Supplementary table A1).

During an initial visit, volunteers were familiarised with the experimental set-up and test procedures. They provided informed, written consent and were informed that they could leave the study at any time without giving a reason.

### **Experimental setup**

Before the testing, 10 facial dimensions of each volunteer were measured and each volunteer was classified based on the five-size face-sizing system by Zhuang et al. (2007).

When TIL is assessed according to the European Standard (EN149:2001; European Committee for Standardization, 2001) measurements are collected during the inhalation phase of the breathing cycle, with clean air being fed to the photometer during the exhalation phase. In the current study, TIL was assessed during both the inhalation and exhalation phases. A sampling probe was inserted through the material of the mask at a location that was close to the peri-oral area, comfortable for the volunteers, and, where possible, resulted in minimal contact with the skin. This was secured to prevent leakage through the hole. The probe was a 20 mm aluminium disc (to prevent static) with eight equidistant 1 mm inlet points on the outside of the disc to prevent impaction of the inlet points with the face, based on BS EN 140:1999 (European Committee for Standardization, 1998). This was attached to a SidePak (SP) aerosol monitor (Models AM510 and AM520, TSI, Minnesota, USA) via Tygon<sup>®</sup> tubing supported by a head harness, in order to prevent distortion of the mask and kinking of the tubing (Figure 2A). The exception was the Basic flat-fold (I) mask where the material of the mask was too thin and flimsy to support the probe, so the tubing was fed through the top of the mask, down the side of the nose and without the sampling probe attached (Figure 2B). The mask remained intact; however, despite all effort taken to minimise the leak size due to the experimental set-up, a small gap remained where the tubing entered the mask. Each volunteer was photographed before the probe was fitted to the masks and prior to each test with all equipment fitted.



**Figure 2:** Attachment of sampling tube and probe A) PM<sub>2.5</sub> Surgical (J) as an example for all masks except B) Basic flat-fold (I) mask which had a slightly different arrangement for the measuring tube

Volunteers were asked to don a coverall, wellington boots, and a belt with the two SPs attached. The mask was prepared by a researcher with the probe and connected to the tubing that was already secured on the headgear. Volunteers were not trained on the wearing of RP but were helped with donning the RP and headgear (which was now connected to the RP), and the researcher ensured that the RP and tubing was not twisted or compromised during donning due to the experimental set-up. The researcher then connected the tubing to the SPs and checked the whole set up to ensure that the headgear and sampling probe was correctly and securely positioned. If requested by the volunteer, help to adjust the RP was given. Volunteers put on goggles and gloves. Although the goggles may have slightly altered the fit of the mask around the nose, any impact was considered minimal compared to the gaps observed elsewhere around the faceseal. In order to prevent contamination, on completion of the activity, volunteers were instructed to remove gloves and other Personal Protective Equipment (PPE) before removing their mask.

Dust concentrations inside the mask (penetration) and outside in the breathing zone (challenge) were continuously measured with two SP instruments fitted with PM<sub>2.5</sub> impactors, factory calibrated to Arizona road dust, running at 1.7 l/min, logging every 10 seconds. The order in which masks were worn by each volunteer was randomised; however, due to issues with attaching the probe and tubing to the Basic flat-fold (I) mask and associated timing, during the brushing activity, this mask was tested last for each volunteer apart from one.

Tests were conducted in a purpose-built exposure chamber (2.5m × 2.5m × 2.4m). In addition to a general ventilation system, two small fans were installed to keep the dust suspended. A researcher was in the chamber at all times to check the dust concentrations. If only one volunteer was available, a researcher conducted the same activities as the volunteer, to ensure that the challenge concentration was within the acceptable range. The researcher was wearing a face-fitted rubber half mask respirator fitted with a particle filter due to their extended work durations in the exposure chamber.

The challenge dust used in this study was Aloxite, a low-toxicity surrogate dust for volcanic ash, which had been tested in the preceding FE study (Mueller et al., Submitted).

Each mask was tested under two different conditions designed to mimic cleaning-up activities during/after volcanic ashfall:

- A) Continuous brushing of tables 10 ml of dust was placed on a small table and volunteers brushed the dust into a dustpan and emptied it back onto the table.
- B) Continuous sweeping of the floor 5 ml of dust was placed on the floor and volunteers swept the floor with a long-handled brush.

Two repeats of each test were conducted using the same mask on the same day. Each test lasted for 12 minutes: one minute standing, 10 minutes brushing/sweeping, and then an additional one minute standing. After five minutes, volunteers swapped sides in the chamber. The chamber was ventilated between tests.

During the volunteer study, the maximum PM<sub>2.5</sub> concentration permitted was approximately 2.5 mg/m<sup>3</sup>. This was based on ensuring that volunteers were not exposed to concentrations above the 8 hr time weighted average respirable low-toxicity dust limit of 1 mg/m<sup>3</sup> recommended by the IOM (Institute of Occupational Medicine, 2011). If the SP concentration approached 2.5 mg/m<sup>3</sup>, the volunteer was asked to stop brushing /sweeping until the level fell to around 2 mg/m<sup>3</sup> or below.

Start and stop times were recorded by a researcher outside the chamber. Volunteers left the chamber between tests for at least 10 minutes, during which time they were provided with refreshments and completed the questionnaire survey. Volunteers were together throughout preparation and testing and therefore could discuss aspects related to the RP and the study. It is considered that they may

have learnt from each other throughout the study through these discussions and observing each other's behaviour whilst donning and fitting the RP.

#### **Questionnaire survey**

To identify the volunteers' perceptions and opinions on the masks, a structured questionnaire was administered between and after tests. It included questions on comfort, need for adjustments whilst being worn, ease of breathing and perception of protection provided. The questions included closed and open responses, including ranking questions (1=best, 5=worst), where the volunteers were provided with a set of the masks to physically place in order.

#### **Data analysis**

The TIL of each face mask was calculated by dividing the penetration concentration ( $C_{Pen}$ ) within the mask by the challenge concentration ( $C_{Chal}$ ) outside the mask using Equation 1.

Equation 1: Total Inward Leakage (TIL) = 
$$\frac{C_{Pen}}{C_{Chal}} \times 100\%$$

TIL values can be in excess of 100% where the  $C_{Chal} < C_{Pen}$  in situations, e.g. where there is accumulation of particles within the mask, with particles being potentially exhaled from the lungs, and/or in the SP. Only the readings from the 10 minute time interval during the volunteers brushing/sweeping activities were used for analysis. There were 214 readings with very high TIL (as defined by TIL > 200%), of which 83% were associated with very low  $C_{Chal}$  values. Since TIL is sensitive to such low concentrations,  $C_{Chal}$ readings below the 5<sup>th</sup> percentile (0.122 mg/m<sup>3</sup>) were excluded. After exclusion of these data, there remained very few (n = 36) measurements with very high TIL.

Prior to calculating the TIL for each mask, a Correction Factor (CF) was applied to the C<sub>Chal</sub> and C<sub>Pen</sub> values to adjust for measurement differences between the SP units used to measure concentrations. Data were collected from SP units measuring different levels of ambient concentrations inside and

outside the experimental chamber, from which mean values were calculated for each unit. A CF was calculated for each unit based on the ratio of means in the reference and a given SP (Equation 2), which was robust when recalculating with different metrics (e.g., median).

Equation 2: Correction Factor (CF) = 
$$\frac{Mean C_{ReferenceSP}}{Mean C_{SP}}$$

Summary statistics of TIL% for each mask were generated and compared using a Kruskal-Wallis test. A multiple regression model of TIL was developed with the following categorical variables: mask, face size, task, and time. Data from one task for one volunteer (both repeats) were excluded from the regression analysis (n = 62), as every TIL value was greater than 100% (Volunteer P8, Mask: Surgical (M) w/bandage). We checked for serial correlation in the time series data using the Durbin-Watson (DW) statistic. The use of a Cochrane-Orcutt first-order autoregressive regression improved the DW statistic in the final model from 0.16 to 2.59 (Montgomery et al., 2015). A time covariate was included to account for any differences in TIL between the two five minute time periods of each test. Data analysis was performed using Stata 13.1 (StataCorp, College Station, TX, USA).

#### RESULTS

Three volunteers were classified as having 'short-wide' faces, two were 'small', four were 'medium', and one was 'large' (Zhuang et al., 2007) as reproduced here in Figure 3. Additional information such as gender can be found in supplementary table A1.



**Figure 3:** Five-size face-sizing system based on principal component analysis (Zhuang et al, 2007). P1-P11 are the individual volunteers. P5 dropped out of the study before taking any tests

Table 1 gives the overall summary statistics of the TIL of each mask, aggregated over the 10 volunteers and two tasks. The N95-equiv. mask was unique in demonstrating a mean and median TIL of <10%. The mean TIL values ranged from 22-35% for the other masks. After removing data from one of the volunteers wearing the Surgical (M) mask with bandage, where all data points were above 100% TIL, the mean value decreased from 32% to 24% for that intervention, also achieving a more similar value to the median TIL. The Surgical (M) and Basic flat-fold (I) masks were very similar, both with mean and median values of 35% and 31%, respectively.

 Table 1: Total Inward Leakage (TIL) % for each mask after correction and removal of challenge concentrations < 5th percentile.</th>

		% TIL						
Mask	N	AM	SD	Min	5 <sup>th</sup> percentile	50 <sup>th</sup> percentile	95 <sup>th</sup> percentile	Max
N95-equiv.	1951	8.6	11.9	0.0	0.3	5.1	35.0	84.4
PM <sub>2.5</sub> Surgical (J)	1939	22.2	14.3	1.5	6.0	19.3	47.8	115.2

Surgical (M) w/bandage (dropping volunteer with >100% TIL)	1825	24.1	19.7	1.3	4.9	18.3	66.2	193.5
Surgical (M) w/bandage	1887	32.0	53.4	1.3	5.0	18.8	82.5	758.2
Basic flat-fold (I)	1963	34.9	16.2	6.8	18.4	31.1	63.4	146.8
Surgical (M)	1947	34.9	20.1	3.5	9.4	31.3	68.8	201.5

M = Mexico; J = Japan; I = Indonesia

N = number; AM: Arithmetic Mean; SD = standard deviation; Min = minimum; Max = maximum

Nine volunteers completed the brushing task, whilst eight volunteers completed the sweeping task; seven individuals completed both tasks. Overall, mean TIL% appeared very similar for brushing (24.9%, SD = 19.6) and sweeping (25.0%, SD = 19.1) activities (Figure 4). One of the volunteers wore the Basic flat-fold (I) in a different orientation during the brushing task. For this volunteer, whilst the mean TIL for sweeping was similar between the composite of the other masks (33%; SD = 20.5) and the Basic flat-fold (I) mask (30%; SD = 19.1), there was a significant difference (p < 0.001) foundbetween the other masks and the Basic flat-fold (I) for the brushing task (19%; SD = 13.7 vs. 42%; SD = 9.1, respectively).



Figure 4: Boxplot of TIL for each mask, separated by task.

TIL varied according to face shape with volunteers with 'short-wide' faces having a mean TIL of 24% (SD = 16.4), 'small' faces having 20% TIL (SD = 19.5), 'medium' faces having 28% TIL (SD = 20.2), and the volunteer with a 'large' face having a mean TIL of 28% (SD = 20.6). One volunteer of a 'medium' face size possessed facial hair and had a higher overall mean TIL of 29% (SD = 18.5), compared to an average of 24% (SD = 19.4) for the rest of the volunteers (p < 0.001).

A log-linear model was determined to be a better fit using the Bayesian Information Criterion (Table 2). TIL varied significantly among different masks and face sizes, but not for the tasks or between the two 5-minute periods in each test (on each side of the chamber). Relative to the N95-equiv. mask, the Surgical (M) mask with the bandage and the  $PM_{2.5}$  Surgical (J) resulted in respectively 4.6 and 5.0 times more TIL (p < 0.001) (once the data for volunteer 8 were removed for Surgical (M) w/bandage; Table 1). The Surgical (M) and Basic flat-fold (I) masks permitted 7.6 and 7.8 times more TIL, respectively, than the N95-equiv. mask (p < 0.001). Using a bandage with the Surgical (M) mask lowered the TIL of that mask by 40%.

The largest increase in TIL attributed to face size was 'medium' compared to 'small', increasing TIL by a factor of 1.8 (p < 0.001). Whilst face size demonstrated a significant effect on TIL, there was no evidence of a consistent trend with increasing face size, i.e. there was a factor of 1.8 increase in TIL from 'small' to 'medium' and only a 1.4 times increase from 'small' to 'large' face size (p = 0.012).

There was no evidence of a TIL difference resulting from sweeping or brushing (p = 0.603), nor was there an effect on TIL over time (p = 0.669).

	Coefficient	95% Confide	p-value	
Mask				
N95-equiv.	-	-	-	-
Surgical (M) w/strap	4.6	3.5	5.9	<0.001
PM <sub>2.5</sub> Surgical (J)	5.0	3.9	6.4	<0.001
Surgical (M)	7.6	5.9	9.7	<0.001
3D Basic (I)	7.8	6.1	10.0	<0.001

 Table 2: Log-linear multiple regression results for predictors of Total Inward Leakage (TIL).

Face size				
Small	-	-	-	-
Large	1.4	1.1	1.9	0.012
Short-wide	1.6	1.3	1.9	<0.001
Medium	1.8	1.5	2.3	<0.001
Task				
Sweeping	-	-	-	-
Brushing	1.0	1.1	1.2	0.603
Time				
0-4 minutes	-	-	-	-
5-10 minutes	1.0	0.9	1.0	0.669
Constant	2.3	1.8	2.9	<0.001

From the wearer questionnaire data (supplementary tables A2-A4), the Basic flat-fold (I) mask was identified as being the most comfortable for both tasks, with reasons for this largely focusing on the mask being light, thin and feeling like a mask was not being worn. Also, for both of the simulations, the Surgical (M) mask with the bandage was reported as being the hardest to breathe with, as it was closer to the face and due to the thickness of the material.

The best and worst mask protection rating was very similar across the two simulations of brushing and sweeping (Supplementary table A3). For both tasks, the N95 equiv. mask was ranked as the best mask in terms of perceived protection. The main reasons given for this were the security and sturdiness of the fit. The Basic flat-fold (I) and Surgical (M) masks were both perceived to be the worst in terms of protection as they were thought to have a lot of gaps and poor fit.

### DISCUSSION

We present the first evidence on the effectiveness of various types of RP worn by communities to reduce exposure to volcanic ash. Until now, agencies have not offered specific advice on the types of protection to be used, often preferring to state simply that a 'mask' or 'cloth' can be worn (see database of advice sources at: www.ivhhn.org/resources/global-ash-advice.html; IVHHN, 2017).

In Part I of this study (Mueller et al., Submitted), we showed, categorically, that the FE of different materials used for protection in volcanic eruptions, around the world, can vary substantially, with cloth materials performing particularly poorly. However, a range of masks performed very well, with six types achieving median FEs of  $\geq$  96% for Aloxite and  $\geq$  89% for volcanic ash. As Rengasamy and Eimer (2012) discuss in their study, which tested N95 masks for nanoparticle penetration, TIL is a combination of filter penetration and faceseal leakage. Their results indicate that faceseal leakage allows particles inside the mask, regardless of size, whilst filter penetration is dependent on particle size. Masks with higher FE have been found to have lower TIL (Rengasamy et al., 2014b), which our results confirm, despite using a completely different study design, e.g., N95-equiv. median FE > 99% for Aloxite; TIL < 10% (Mueller et al. Submitted). However, Mueller et al. found that the Basic flat-fold (I) mask had a high median FE (98% for Aloxite), but a relatively low TIL (31%), likely due to poor fit and, therefore, a large faceseal leakage component. This effect was also shown by Grinshpun et al. (2009), who found that particles passing through by faceseal leakage outnumbered those passing through the filter.

The best-performing mask of those tested was the N95-equiv. mask, with < 10% mean TIL (median FE > 99% for Aloxite) (Mueller et al., Submitted). The volunteers were not trained on how to wear and fit the masks for respiratory protection so the results show that, with no training, good protection can still be achieved with this, and possibly other, N95-style masks, regardless of face shape. Facial hair might negatively affect the seal of the mask: the one volunteer with facial hair in our study had a slightly higher overall mean TIL (29% versus 24%) when compared to the other volunteers across all masks. More individuals would need to be studied to confirm any such effect for volcanic ash, although it is well-documented in the use of industrial respirators (Bolsover, 1992). Indeed, the higher overall mean for 'medium' face size was due, in part, to the facial hair of this individual affecting the mask seal.

The volunteers perceived that the N95-equiv. mask was the most protective due to sturdiness and fit. It was also the only mask that volunteers did not adjust during the tests, indicating that it fitted well once donned. However, most of the volunteers ranked it as being uncomfortable to wear. This mask is designed to meet industry standards and has several design features, in particular, two head straps, foam around the rim, a nose clip, and an exhalation valve to let humid air out. The presence of a nose clip does not necessarily mean a good fit, as Jung et al. (2014b) found in their study, where the worst performing mask had a sturdy nose clip that did not adjust well to the wearers' faces, which created considerable leakage in the nose area.

Given the results of this study, agencies should consider whether the added protection afforded by industry-certified, N95-style masks, even in community settings, outweighs the cost and logistical considerations of stockpiling such interventions (they can be much thicker than surgical masks). They also ought to consider the fact that such masks have a shelf life (in Europe, this is stipulated through PPE regulations). It is not clear by how much the FE would decrease if masks were out of date; it is expected that other components, e.g., the foam seal around the nose area and the elasticated head straps, are likely to degrade first (3M, Alan McArthur, personal communication), and this was recently observed (by CJ Horwell) for N95 masks stockpiled in Indonesia, where the head straps had completely disintegrated.

The standard surgical mask from Mexico (Surgical (M)) had 35% mean TIL, which means that, on average, over a third of PM<sub>2.5</sub> particles were entering the inside of the mask. This mask material showed significantly different results for the FE tests with two volcanic ashes compared to Aloxite, with the FE for Aloxite being significantly higher (Mueller et al., submitted). As we used Aloxite in the current study, it is possible that higher TIL results may have been obtained if the masks were challenged with volcanic ash. This mask, as with all standard surgical masks, was fitted with a nose clip and pleats to aid with facial covering, but volunteers reported that the ear loops stretched, sometimes requiring knots to be tied to improve fit. Surgical masks are not designed specifically to filter particles

but, rather, to prevent droplets passing from the wearer to a patient (Lipp, 2003) and vice versa, so it is not easy to seal them to the face. It should be noted that not all surgical masks provide the same FE (Mueller et al., Submitted), nor do they offer the same fit or facial seal.

Wearing the Surgical (M) mask with an additional bandage intervention significantly reduced the mean TIL in that mask from 35% to 24%, although the volunteers found this intervention reduced the comfort and breathability of the mask. This is because the bandage held the mask so close to the face that the mask touched the nose and mouth so volunteers found it tight and warm/humid. In addition, the presence of the bandage was observed to increase the size of gaps in the chin area and sometimes opened gaps in the nose area. The volunteers were also observed to adjust the bandage on several occasions during the tasks, due to slippage. Clearly, in real-life scenarios, the effectiveness of wearing the additional intervention needs to be weighed against the likelihood that people would actually use this intervention for any length of time, particularly in hot or humid climates.

The PM<sub>2.5</sub> Surgical (J) mask, which comes with additional 'flaps' on the cheeks and chin, performed less well than the N95-equiv. mask (22% versurs <10% mean TIL), despite having a similarly high median FE (98% for Aloxite) (Mueller et al., Submitted). However, it was more effective than the standard surgical mask from Mexico (Surgical (M) 35% mean TIL). This difference could be due to both the higher FE of the material and the additional adaptations to improve fit. In fact, only one volunteer fitted the mask correctly (pulling out the chin strap in 3 out of 4 tests). The gauze cheek flaps automatically pop out as the mask opens most of the time, suggesting that the volunteers may not have noticed the additional adaptation during donning. Information supplied to help individuals fit this mask correctly could lead to less TIL. A gap was visible under the chin for most of the volunteers when wearing this mask, but it was not as pronounced as for the Surgical (M) mask. These PM<sub>2.5</sub> Surgical (J) masks are readily available in Japan, but procurement elsewhere is unknown. They offer a good alternative to the standard surgical mask, being just as easily stockpiled, but they are more expensive.

Given that surgical masks are thought to be the most distributed intervention (Horwell et al., 2017), an important question is whether to continue to recommend and supply standard surgical masks to reduce exposure to volcanic ash. Van der Sande et al. (2008) conclude that, regardless of fit, any type of mask is likely to decrease exposure to viruses and, therefore, infection risk at a population level indicating that any mask is better than wearing no mask. This and other ethical questions are considered in detail by McDonald et al. (2017). Agencies that do choose to distribute such masks have an ethical responsibility to provide factual, accompanying information on likely efficacy and strategies for achieving the best facial seal. Standard surgical masks are, by far, the cheapest mask-style intervention, especially when purchased, in bulk, by agencies (e.g., for stockpiling against viral pandemics). It is encouraging to know that a simple measure such as using a bandage, to secure the mask in place, can increase the fit of the mask to the face, and significantly improve its effectiveness.

The performance of the Basic flat-fold (I) mask was, overall, very similar to the Surgical (M) mask. In the FE study (Mueller et al., Submitted), this mask had performed almost as well as the industrycertified masks (median FE 99 for Aloxite), indicating that facial seal played a major role in its increased TIL. Similar results were also observed for industry-certified versus other facemasks by Cherrie et al. (Accepted) for their study of masks used against urban air pollution in China. Therefore, agencies and the public should not be misled by the high FE of the material of such masks, and any assertions of protection from PM<sub>2.5</sub> on the packaging, particularly as they have no way to be secured to the face. The wide, unadjustable ear loops are part of the mask material and the flimsy material does not stay against the face easily. In fact, it is not even totally clear to the wearer which way up it should be worn (as seen for one of our volunteers) and this was observed to have a substantial, detrimental impact on TIL in the brushing task. Volunteers were observed to have large gaps between the chin and the mask, except for the largest face size, with this volunteer perceiving this mask to be highly protective. The volunteers perceived that it was the most comfortable mask, allowing easy breathing (presumably because air was infiltrating around the edges of the mask), but they also

generally perceived that it did not offer much protection. This could perhaps be improved by adding an external adaptation, such as a bandage, as we did for the Surgical (M) mask in our experiments.

The questionnaire survey identified that some volunteers found that the probe caused some distortion of the surgical masks tested. It is possible that such distortion affected the TIL by pulling the masks away from the face. Referring to the photographs taken before each test (Figure 2A), it was noticed that the Surgical (M) mask fitted poorly with obvious gaps around cheeks and chin for most volunteers prior to the probe being attached, although this was worsened by the attachment of the probe. For the Surgical (M) w/bandage, the bandage pulling the mask downwards caused most problems, although the probe pulling the mask out of position was commented on twice (by two separate volunteers). For the PM<sub>2.5</sub> Surgical (J) mask, photos indicated that the probe may have created gaps around the nose and cheeks or may have pulled the mask out of place (five volunteers). Therefore, we can assume that real-life use of these masks, especially if the fit-adaptations are used, might offer improved protection on that observed in this study. Reassuringly, the Grinshpun et al. study (2009) measured similar TILs for surgical masks as compared with our study.

The volunteers had a range of facial shapes, and we expected that smaller faces might result in worse TIL but, in fact, the best TIL across all masks was for the small faces. Nevertheless, with a small number of volunteers, it is difficult to draw firm conclusions on the role of face size. The study was limited in that all of the masks used were designed for adult use and it is not clear how effective any of these masks would be for children. Van der Sande et al. (2008) showed that children had significantly poorer protection than adults when wearing the same type of mask. These results might be related to the masks not being designed for children's very small faces and thus not providing a good fit. Children's masks used by Jung et al. (2014a) were simply adult masks reduced in size. The authors question if reducing the size only, without giving any further consideration of breathing volume, pattern and rate, is a suitable strategy for protecting children from dust exposure.

We tested two cleaning-related activities (sweeping and brushing) to determine whether different movements associated with the tasks induced different TILs among the masks. We found that the task did not substantially impact the TILs. We could not discern a difference related to potential movement of the mask with different activities. This indicates that an effective mask should remain effective during clean-up and likely other activities.

We did not observe any significant change in TIL with time through the tests; however, the overall test periods were only a short duration, so it is not clear how TIL may change over longer periods of use. This suggests a limitation of study results since, in real exposure environments, people may need to repeatedly wear RP for days or weeks. Van der Sande et al. (2008) found that protection for each mask type appeared stable over time, independent of activity, although a tendency towards reduced protection over time was observed for an N95 mask.

There has been some research into reuse and decontamination of N95 respirators in healthcare settings (e.g., NIOSH, 2014). Viscusi et al. (2009) attempted decontamination of masks using ultraviolet and microwave oven irradiation, bleach, ethylene oxide, and vaporized hydrogen peroxide on nine NIOSH-certified respirators, finding that microwave irradiation melted some samples but that overall filtration performance was not affected. No information in the literature on decontamination methods for masks used during volcanic ashfall was identified and so further research is required before specific decontamination methods for reuse of masks could be recommended.

Another possible limitation to our study is that we used a surrogate dust for the volunteer exposures. In the FE tests (Mueller et al., Submitted), the RP types were observed to generally perform better with Aloxite than they did with the two types of volcanic ash. However, given that the decreased performance of the masks in this TIL study has been mainly attributed to faceseal leakage, particle size distribution is unlikely to have had a substantial effect on the TIL.

22

#### CONCLUSIONS

In the first study of its kind, we assessed the effectiveness of various forms of respiratory protection used globally by communities to reduce exposure to volcanic ash. Using human volunteers simulating volcanic ash clean-up activities, we have shown that the industry-certified N95-equiv. mask offered the best protection (<10% TIL). Standard surgical masks had 35% TIL, which was substantially improved by tying a bandage over the top as an additional intervention (24% TIL), although comfort and perception of ease of breathing were considerably compromised. The use of a surgical mask designed to filter PM<sub>2.5</sub> particles was also an improvement on a standard surgical mask (22% TIL). A basic, flat-fold mask gave similar overall protection to a standard surgical mask (35%) despite the FE being better (Mueller et al., Submitted). This is likely due to the lack of possibilities to secure this mask to the face. Whilst these results offer the first objective evidence base for agencies to make informed decisions on procurement and distribution of masks during eruption crises, it should be noted that our study had some limitations, including the small sample size of adult volunteers and short time period of testing, which should be considered before generalising to community contexts.

#### ACKNOWLEDGEMENTS AND FUNDING

This project was funded by a grant from the Research for Health in Humanitarian Crises (R2HC) Programme. The R2HC programme aims to improve health outcomes by strengthening the evidence base for public health interventions in humanitarian crises. The R2HC programme is funded equally by the Wellcome Trust and the UK Department for International Development, with Enhancing Learning and Research for Humanitarian Assistance (ELRHA) overseeing the programme's execution and management. Development of the chamber was additionally co-funded by NERC/MRC grant NE/N007182/1.

We are grateful to Dr Mike Clayton (HSL), Mike Beveridge (IOM), Dr Miranda Loh (IOM) and Dr Richard Graveling (IOM) for their advice in planning and designing the TIL tests. Special thanks to the

23

volunteers who took part in this study. We also thank members of the HIVE project team in Japan, Indonesia and Mexico for sourcing and providing the different types of respiratory protection and the Durham Cartography Unit for photographing them. Thanks to Dr Judith Covey (Department of Psychology, Durham University) for advising on the questionnaire survey design and Dr Mark Booth for discussion on statistical analysis. Finally thanks to Dr Joanne Crawford and Hilary Cowie (both IOM) for reviewing earlier drafts of this manuscript. Finally thanks to the HIVE Advisory Group members for their helpful comments during the course of the project.

The use of any brand names in this article in no way endorses the use of the brand's products.

### REFERENCES

Bolsover, S.M., 1992. Leakage measurements on wearers of respiratory protective equipment with facial hair/beards/spectacles: summary of literature search. Journal of the International Society for Respiratory Protection 10, 15-22.

Brown, R.C., 1995. Protection against dust by respirators. International Journal of Occupational Safety and Ergonomics 1, 14-28.

Cherrie, J.W., Apsley, A., Cowie, H.A., Steinle, S., Lin, C., Horwell, C.J., Sleeuwenhoek, A., Mueller, W., Loh, M., Accepted. The effectiveness of facemasks used to protect Beijing residents against particulate air pollution. Occup Environ Med.

European Committee for Standardization, 1998. EN 140:1998; Respiratory Protective Devices: half-masks, quarter-masks; requirements, testing, marking.

European Committee for Standardization, 2001. EN 149:2001+A1:2009; Respiratory protective devices. Filtering half masks to protect against particles - Requirements, testing, marking

Grinshpun, S.A., Haruta, H., Eninger, R.M., Reponen, T., McKay, R.T., Lee, S.-A., 2009. Performance of an N95 Filtering Facepiece Particulate Respirator and a Surgical Mask During Human Breathing: Two Pathways for Particle Penetration. Journal of Occupational and Environmental Hygiene 6, 593-603.

Horwell, C.J., Baxter, P.J., Hillman, S.E., Calkins, J.A., Damby, D.E., Delmelle, P., Donaldson, K., Dunster, C., Fubini, B., Hoskuldsson, A., Kelly, F.J., Larsen, G., Le Blond, J.S., Livi, K.J.T., Mendis, B., Murphy, F., Nattrass, C., Sweeney, S., Tetley, T.D., Thordarson, T., Tomatis, M., 2013. Physicochemical and toxicological profiling of ash from the 2010 and 2011 eruptions of Eyjafjallajökull and Grímsvötn volcanoes, Iceland using a rapid respiratory hazard assessment protocol. Environmental Research 127, 63-73.

Horwell, C.J., Ferdiwijaya, D., Wahyudi, T., Dominelli, L., 2017. Use of respiratory protection in Yogyakarta during the 2014 eruption of Kelud, Indonesia: Community and agency perspectives. J Volcanol Geotherm Res. 10.1016/j.jvolgeores.2017.06.004

Horwell, C.J., Sparks, R.S.J., Brewer, T.S., Llewellin, E.W., Williamson, B.J., 2003. The characterisation of respirable volcanic ash from the Soufriere Hills Volcano, Montserrat, with implications for health hazard. Bulletin of Volcanology 65, 346-362.

HSE, 2013. Respiratory protective equipment and work: a practical guide, 4th ed. Health and Safety Executive, p. 59p.

Institute of Occupational Medicine, 2011. The IOM's position on occupational exposure limits for dust. <u>http://www.iom-world.org/media/93355/ioms\_position\_on\_oels.pdf</u>. Last accessed: 8 August 2017.

IVHHN, 2017. Global ash advice, International Volcanic Health Hazard Network <u>http://www.ivhhn.org/resources/global-ash-advice.html</u>. Last accessed: 20 November 2017.

Jung, H., Kim, J., Lee, S., Lee, J., Kim, J., Tsai, P., Yoon, C., 2014a. Comparison of Filtration Efficiency and Pressure Drop in Anti-Yellow Sand Masks, Quarantine Masks, Medical Masks, General Masks, and Handkerchiefs. Aerosol and Air Quality Research 14, 991–1002.

Jung, H., Lee, S., Lee, J., Kim, J., Tsai, P., Yoon, C., 2014b. Total inward leakage (TIL) testing of antiyellow sand and quarantine masks using NaCl aerosol. Journal of the International Society for Respiratory Protection 31, 104-115.

Lee, S.-A., Grinshpun, S.A., Reponen, T., 2008. Respiratory Performance Offered by N95 Respirators and Surgical Masks: Human Subject Evaluation with NaCl Aerosol Representing Bacterial and Viral Particle Size Range. The Annals of Occupational Hygiene 52, 177-185.

Lipp, A., 2003. The effectiveness of surgical face masks: what the literature shows. Nursing Times 99, 22-24.

McDonald, F., Horwell, C.J., 2017. Ethical considerations of recommending or distributing facemasks for community protection from ambient air pollution events, IHRR/Dealing with Disasters Conference, Durham, UK.

Montgomery, D.C., Jennings, C.L., Kulahci, M., 2015. Introduction to time series analysis and forecasting. John Wiley & Sons.

Mueller, W., Horwell, C.J., Apsley, A., Steinle, S., McPherson, S., Cherrie, J.W., Galea, K.S., Submitted. The effectiveness of respiratory protection worn by communities to protect from volcanic ash inhalation; Part I: Filtration efficiency tests. Int. J. Hyg. Environ. Health.

NIOSH, 1996. NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 42 CFR 84, DHHS National Institute for Occupational Safety and Health, Cincinnati, OH, pp. 96–101.

NIOSH, 2014. Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering FacepieceRespiratorsinHealthcareSettings.https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.htmlLast20 November 2017.

PanAmericanHealthOrganization,2017.VolcanicEruptions.<a href="http://www.paho.org/disasters/index.php?option=com\_content&view=article&id=704:volcanic-eruptions&Itemid=800&lang=en">http://www.paho.org/disasters/index.php?option=com\_content&view=article&id=704:volcanic-eruptions&Itemid=800&lang=enLast accessed: 23 August 2017.

Rengasamy, S., Eimer, B.C., 2012. Nanoparticle Penetration through Filter Media and Leakage through Face Seal Interface of N95 Filtering Facepiece Respirators. The Annals of Occupational Hygiene 56, 568-580.

Rengasamy, S., Eimer, B.C., Szalajda, J., 2014a. A Quantitative Assessment of the Total Inward Leakage of NaCl Aerosol Representing Submicron-Size Bioaerosol Through N95 Filtering Facepiece Respirators and Surgical Masks. Journal of Occupational and Environmental Hygiene 11, 388-396.

Rengasamy, S., Walbert, G.F., Newcomb, W.E., Faulkner, K., Rengasamy, M.M., Brannen, J.J., Szalajda, J.V., 2014b. Total Inward Leakage Measurement of Particulates for N95 Filtering Facepiece Respirators—A Comparison Study. The Annals of Occupational Hygiene 58, 206-216.

van der Sande, M., Teunis, P., Sabel, R., 2008. Professional and Home-Made Face Masks Reduce Exposure to Respiratory Infections among the General Population. PLoS ONE 3, e2618.

Viscusi, D.J., Bergman, M.S., Eimer, B.C., Shaffer, R.E., 2009. Evaluation of Five Decontamination Methods for Filtering Facepiece Respirators. The Annals of Occupational Hygiene 53, 815–827.

Zhuang, Z., Bradtmiller, B., Shaffer, R.E., 2007. New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. Journal of Occupational and Environmental Hygiene 4, 647-659.

### Supplementary material

Table A1: Description of volunteers, their facial shape, and in which parts of

Volunteer	Gender	Face Size	Part A	Part B
P1	Male	Short-wide	Y	Y
P2	Male	Medium	Y	Y
Р3	Female	Medium	Y	N
Р4	Female	Small (outwith the ellipse)	Y	Y
Р6	Male	Large	Y	Y
Р7	Female	Short-wide	Y	Y
Р8	Female	Short-wide	Y	N
P9*	Male	Medium	Y	Y
P10	Female	Small	Y	Y
P11	Female	Medium	N	Y

the study they took part

\* Participant had facial hair. P5 dropped out of the study before taking any tests.

**Table A2**: Results of volunteer questionnaire rankings indicating number of<br/>each response for perceptions of ease of breathing.

Rank	N ec	-95 Juiv.	Bas fol	ic flat d (I)	Su (	rgical (M)	Surgical (M) + Bandage		PM <sub>2.5</sub> Surg	ical (J)
	B*	<i>S</i> *	B*	<i>S</i> *	B*	<i>S</i> *	B*	<u>S*</u>	B*	<i>S</i> *
1 (Best)	3		6	8						
2	2	3	2			3			5	2
3	1	1			4	1	1		3	6
4		3	1		4	4	4	1		
5 (Worst)	3	1			1		4	7	1	
*Brushing (I	B), Sw	eeping	(S)							· ·

**Table A3:** Results of volunteer questionnaire rankings indicating number ofeach response for perceptions of protection provided.

Rank	N ec	N-95 equiv.		Basic flat fold (I)		gical M)	Surgical (M) + bandage		PM <sub>2.5</sub> Surgi	cal (J)
	B*	<i>S</i> *	B*	<i>S</i> *	B*	<i>S</i> *	B*	<u>S*</u>	B*	S*
1 (Best)	8	7	1					1		
2	1	1	1		1		5	3	1	4
3			2	1	2	2	2	3	3	2
4			1		2	6	1	1	5	1
5 (Worst)			4	7	4		1			1

\*Brushing (B), Sweeping (S)

**Table A4:** Results of volunteer questionnaire rankings indicating number of<br/>each response for perception of mask comfort.

Rank	N-95 equiv.	Basic flat fold (I)	Surgical (M)	Surgical (M) + bandage	PM <sub>2.5</sub> Surgical (J)
1 (Best)	1	2	1		3
2		5			2
3	3		2		2
4	2		3	2	
5 (Worst)	1		1	5	