Materials and Methods

1. Synthetic Blood Penetration Testing

Synthetic blood penetration of respirators and other PPE was evaluated using the ASTM F1862 method (1). This test evaluates the resistance of masks to penetration by the impact of a synthetic blood. It is a pass/fail test based on visual detection of synthetic blood penetration.

Test Apparatus: A synthetic blood penetration test apparatus (Blood Spurt Tester, model, SDL Atlas LLC, SC) was used to evaluate blood penetration following the ASTM F1862 method. The test apparatus consists of a specimen-holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with an interchangeable canula and a valve controller. The specimen holder and the supporting frame of the fixture are rigid to resist the impact of the blood spraying process. The height of the specimen holder is 420 mm corresponding to the height of the synthetic blood reservoir. A targeting plate with a 0.5 cm hole is placed 1 cm in front of the mask to make sure that the synthetic blood hit the target area of the mask. The actuated valve is attached to a stable metal stand to withstand any flex during activation by the pneumatic control. The valve is positioned correctly so that the exit of the canula is 30.5 cm from the point of impact on the specimen mask.

Preparation of Test Apparatus & Calibration: The fluid reservoir was filled with approximately 1 liter of fresh synthetic blood (Johnson, Moen & Co. Inc., Rochester, MN) and a canula was installed on the front of the pneumatically controlled valve. The canula used in the method was a 1.27 cm (0.5 inch) long 18 gauge stainless needle with an internal diameter of 0.084 cm (0.033 inch). The synthetic blood penetration test was performed only at velocities of 450 and 635 cm/sec, corresponding to blood pressures of 80 and 160 mm of Hg, respectively. The reservoir pressure was adjusted to approximately 8 psi or 12 psi to achieve a velocity of 450 cm/sec or 635 cm/sec, respectively. The test apparatus was calibrated for each target velocity by delivering the synthetic blood for a 1-sec difference in spurt duration. The weight of synthetic blood delivered for a 0.5 sec and a 1.5 sec spurts was collected in separate small beakers. The two weights of the samples were recorded and the difference between the two weights was calculated. According to ASTM F1862, the target difference in weight plus lower and upper limits for a velocity range should be within 2% of the target. The target difference in weights for the test at the target velocities of 450 and 635 cm/s will be 2.506 g and 3.537 g, respectively. In this study, the acceptable weight range was between 2.456 g and 2.556 g for the 450 cm/sec velocity and was between 3.466 g and 3.607 g for the 635 cm/s velocity, which are within the specified ranges.

During testing, 2.0 ml (2.0 g) of synthetic blood was delivered to the test sample at target velocities of 450 cm/sec and 635 cm/sec by setting the valve timer to 0.825 sec and 0.550 sec, respectively. After every 15 samples, a check was performed to ensure that the test apparatus is still delivering 2.0 g of synthetic blood by collecting and weighing the output passing through the targeting hole. A shift of <0.10 g is acceptable. If the shift is >0.10 g, all prior data since the last calibration were discarded. The canula was cleaned after testing 15 samples.

Prior to testing, samples were conditioned in an environmental chamber (Caron Environmental Chamber, Model 6001-1, Marietta, OH) for 4-6 hours at a temperature of 21 ± 5^{o}C and $85 \pm 5\%$ RH, to simulate the humidity conditions of the mask on a wearer. Each test sample was removed from the environmental chamber and mounted on the testing apparatus, centered, and a 2-ml volume of synthetic blood was dispersed at the target velocity within a minute. The synthetic blood penetration through the mask was assessed visually. For comparison, a control mask with a drop of synthetic blood placed on the inner side was used.

2. Flammability Testing

The flammability of respirators and other PPE was evaluated using the CPSC CS-191-53 flammability method (2) with a 45° Automatic Flammability Tester (Model M233G, SDL Atlas LLC, SC). The flammability of respirators and other PPE materials was tested inside the metallic draft-proof ventilated chamber (35.3 x 36.8 x 21.6 cm (height x width x depth)). The front of the chamber has a glass door to permit observation of the entire test. The test material was supported in a specimen rack.

Flammability Test Method: Five test specimens (5 x 15 cm) each test material were cut to size. Each specimen was mounted in a specimen holder. The specimen holder supports and holds the fabric specimen. The specimen holder consists of two 2 mm (0.06 in) thick 'U' shaped matched metal plates. The plates are slotted and loosely pinned for alignment. The specimen was firmly sandwiched in between the metal plates with clamps mounted along the sides. The two plates of the holder cover all but 3.8 cm (1.5 in) of the width of the specimen for its full length. Next, the samples were preconditioned in an oven at 105 ±3°C for 30 minutes, and then removed from the oven and placed in a desiccator. After cooling, the specimen holder was supported on the specimen rack of the flammability tester at 45° angle.

The samples were tested using chemically pure butane flame. The flame length was adjusted to 16 millimeters (5/8") as specified in the standard. The ignition timer of the test chamber was preset to one second. The stop thread and weight were set in place. Upon starting the test, the flame automatically impinged on the specimen and the results were recorded. If the specimen burned and the timing thread was broken, the falling weight would trigger a switch to stop the burn timer. The burn time was recorded and averaged for the five test specimens. The burn time is defined as the time elapsed from the time of ignition until the stop thread is severed. Based on the average burn time, the flammability class was assigned.

To confirm the flammability results obtained in our laboratory this study, five of the 11 N95 FFR models (3M V-Flex 9105, Dräger1350, 3M 9210, Willson Saf-T-Fit, and Kimberly-Clark 62126) were also tested using the 16 CFR 1610 flammability test by a third party independent (TPI) laboratory.

3. Respirator Rigidity Testing

The rigidity testing was to address the penetration of synthetic blood through respirators and other head/facial PPE in a surgical environment. There are scenarios in which sprays and splashes occur outside of surgical operations. For example, significant volumes of respiratory secretions from infected individuals are released in the form of a sneeze or cough at high velocity, which can spray or splash on a nearby individual wearing a SM or FFR. The possibility that some devices may allow the penetration of biological fluids exists because of the wide variation in their construction. The design of many surgical N95 FFRs and N95 FFRs prevents the inner surface of the respirators touching the user's face. On the other hand, some models including the flat-fold type respirators may touch the facial skin during breathing indicating that nasal secretions can diffuse through the mask under high humidity conditions of the mask.

The rigidity of respirators was evaluated using a breathing advanced head form setup**.** The rigidity of the respirator when distorted may touch the head form surface at heavy breathing conditions. This was tested using a fluorescent tracer coated on the inside of the respirator. The distorted respirator, when touches the surface of the head form is expected to show fluorescence on the head form. The advanced testing head form was connected to a breathing system, which includes a breathing simulator, an

artificial lung, and a humidity system to produce humidified air that is exhaled by the head form. The breathing head form mimicked human breathing, which produced high humidity and temperature inside the breathing area of the respirator. A fluorescent tracer (Glo Germ) dissolved in water was used to coat the inside of the respirator, using a brush. The respirator was dried at 80^0C in an air oven for 1 hr. The dried respirator was mounted on the advanced head form. As the humidified air was exhaled, the Glo Germ on the inside lining of the respirator was transferred to the head from upon contact of the respirator, when distorted/collapsed. The experiments were done at different breathing flow rates. At the end of the test, the respirator was carefully removed and an ultraviolet lamp was used to examine Glo Germ transfer to the head form.

References:

1. ASTM (2000) F1862: Standard test method for resistance of medical face masks to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity). In: Annual Book of ASTM Standards, Philadelphia, PA 19111-5098, pp 1340-1448
2. United States Consumer Product Safety Commission (2008) Laboratory Test Manual for 16 CFR Part 1610: Standard for the flammability of clothing textiles