

## **Evaluating the Safety and Effectiveness of Novel Personal Protective Equipment During the COVID-19 Pandemic**

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## Abstract

As health services worldwide respond to the coronavirus disease of 2019 (COVID-19) pandemic, rapid integration of innovative technology-based manufacturing solutions is a priority. In response to threatened supply chains, health services have been forced to exploring novel sources personal protective equipment (PPE). Given these challenges with PPE supply chains, companies and community members worldwide have progressed the design and manufacturing of face shields, often without any healthcare experience or conformity assessment, and with limited or no understanding of the regulation of medical devices in their jurisdiction. For the purposes of this article, “novel” sources of PPE are defined as non-traditional sources of PPE, including three-dimensional (3D) printing and obtaining PPE from non-traditional suppliers e.g. hardware stores and industrial suppliers. This paper provides an evaluation framework to make evidence-based decisions on how to evaluate the safety of novel PPE before distribution to clinicians, using the May 2020 case study of a locally manufactured 3D printed face shield.

## DIY PPE in the Australian regulatory framework

PPE is critical in protecting hospital staff during the treatment of patients throughout the COVID-19 pandemic. The increased usage of PPE worldwide, together with threatened manufacturing capability and disrupted supply chains, has resulted in reduced supplies of PPE reaching frontline workers, forcing the risk-averse healthcare system to investigate alternative pathways for procuring PPE. Clinicians have 3D printed and sourced PPE from industrial suppliers and hardware stores <sup>1</sup>. Reports of community groups reaching out to clinicians and hospitals, offering design and 3D printing capabilities to supply PPE, particularly face shields, are also wide-spread <sup>2,3</sup>. In addition, health services are purchasing PPE from local or international suppliers, such as the South Australia stockpile of N95 masks <sup>4</sup>, with lack of certainty around the compliance with the Therapeutic Goods Administration (TGA) regulations.

Banning novel PPE is reasonable when supply chains are robust, however when they are strained, using these products becomes a real consideration for health services. In September 2020, the TGA released advice on three supply levels of PPE (standard, contingency and crisis), with flexibility around compliance in crisis situations <sup>5</sup>. Guidance is needed to approach this situation with evidence and regard for the current regulatory environment. Rigorous assessment of PPE is critical, particularly given the high rate of healthcare worker COVID-19 infection rate globally and locally, including the clusters in Melbourne, Victoria, and Ipswich, Queensland, possibly contracted in hospital tea rooms or when doffing PPE <sup>6</sup>. Health services have little expertise or experience to assess novel PPE. This article outlines the current issues and a suggested approach for managing novel PPE in a healthcare setting, illustrated by a case study. This emerging area needs significant thought and consistency to ensure safety of staff and consumers.

PPE products intended for use in an Australian clinical healthcare setting meet the definition of a medical device if their intended use is for the prevention of transmission of disease between people <sup>2</sup>. For example, a face shield used by a nurse performing COVID-19 testing is considered a medical device, but the same shield used by a cleaner in a hospital kitchen is not. Medical devices are classified according to the level of risk they may pose to healthcare workers or patients. PPE generally fall in the lowest risk category of Class I non-sterile, non-measuring medical devices. PPE items require online listing on the TGA's Australian Register of Therapeutic Goods (ARTG) by their legal manufacturer and compliance with the Essential Principles for medical devices, and must:

1. Not compromise health and safety,
2. Be designed and constructed to conform to safety principles,
3. Be suitable for intended purpose,
4. Provide long term safety,
5. Not be adversely affected by transport or storage, and
6. Benefits to outweigh any side effects.

The PPE currently used in Australian healthcare settings is listed in Table 1 with TGA requirements. Clinical evaluation of devices is necessary to demonstrate compliance with the fourth principle

(provide long term safety). We use a case study to illustrate the approach taken by a health service to evaluate face shields.

## Case Study: 3D printing and evaluating face shields during crisis supply levels

Face shields are a form of PPE that protect the facial area and associated mucous membranes (eyes, nose, mouth) from splashes and sprays of bodily fluids. They form part of recommended PPE for COVID-19<sup>8</sup>. The efficacy of face shields is poorly characterised, but literature indicates they can reduce exposure to larger particles and contamination of respirator masks<sup>9</sup>.

Two open-source, 3D printable designs were selected based on collated feedback from the Australian COVID-SOS interest group (<https://twitter.com/covidsosaus>), a collaboration of clinicians and engineers advocating for the needs of front-line clinicians and providing stop-gap solutions. At the time of the study in May 2020, no recommended standardised testing method for face shields in a clinical context existed (Table 1). To complete our assessment, we reviewed the international literature<sup>9,10</sup>, and conducted a droplet protection efficacy evaluation of these face shield frames.

The two face shield headband designs were fitted with different lengths of clear visors (200µ GBC® PVC clear binder cover) as outlined in Appendix 1 and compared as a fixed unit to a disposable, commercial shield (Halyard Guardall®. The Melbourne School of Design (MSD v1) face shield was selected for its light weight and its ease of manufacturing using either 3D printing or laser cutting. The PRUSA RC3 design, endorsed by the Ministry of Health of the Czech Republic, has been widely disseminated as one of the first fully open-source face shield designs<sup>11</sup>.

Methods to evaluate the safety and performance of face shields include cough simulators and spray bottles<sup>9,10</sup>. The evaluation was performed using a SimMan 3G simulator manikin (Laerdal Medical®) set up to excrete 10mL of fluid particles per spray, thereby mimicking a cough spray. Food colouring (Queen Green Food Colouring Liquid) simulated bodily fluids.

As shown in Figure 1, four static, reproducible, standing positions were marked on the floor. These reflected a range of healthcare procedures, such as the position assumed by an airway doctor standing behind and bending over the patient (position 1), an airway assistant (position 2), a theatre staff member standing on the side of the bed (position 3), and another staff member at the end of the bed (position 4). Five participants were fitted with scrubs, head and shoe covers, a surgical gown and one of five face shields (Appendix 1 online at [mja.com.au](http://mja.com.au)) and photographed after a simulated cough in each position. Participants washed their face with soap and water and donned a clean shield in between each position. The study obtained ethical clearance (Royal Brisbane and Women's Hospital Human Research Ethics Committee - Number: LNR/2020/QRBW/64373).

The high-resolution photographs (Appendix 2 online at [mja.com.au](http://mja.com.au)) were independently assessed by 10 reviewers (administrators who could not differentiate a commercial from a prototype shield). The pass criteria was no visible contamination (green droplets) on the face and forehead once the shield was removed.

Our results (Appendix 3 online at [mja.com.au](http://mja.com.au)) demonstrated that PRUSA RC3 and MSD headbands, when used with a long visor, provide a level of physical protection against droplets comparable to commercial products. As such, they were deemed an acceptable alternative during crisis supply levels of face shields. Short visors are not recommended.

Our evaluation method provides valuable qualitative simulation testing prior to clinician evaluation in a low-risk clinical environment; and may be considered a method of providing assurance to healthcare workers about the quality checks completed prior to local distribution of novel PPE. The week following the simulation testing, clinical acceptance was evaluated by a Clinical Advisory Group of 10 healthcare workers. 18,000 headbands of the two designs were then crowdsourced over 3 weeks from Queensland makerspaces, universities, schools, businesses and community members using social media. Each batch was quality checked against the master samples, devices were released to non-clinical areas to relieve commercial stocks, and technical documentation, a cleaning procedure and a conformity assessment were implemented before release to clinical areas.

Some participants expressed concerns that non-visible aerosolised particles could fall through the gap at the top of the headbands or stay trapped behind the visor. A subsequent review of the

literature found that whilst some studies exist on the effects of aerosolised particles in an operating theatre environment <sup>12</sup>, little is known about how a face shield impacts this exposure <sup>13</sup>. This feedback suggests the need for further evaluation to assess efficacy against aerosolised particles, particularly in light of recommendations that face shields, without associated face masks, could help reducing community transmission <sup>14</sup>.

### A suggested approach to selecting novel PPE in the Australian Healthcare Setting

Sourcing PPE from non-traditional sources has been a hallmark of the COVID-19 pandemic. Health services have been poorly prepared to evaluate the efficacy and safety of novel PPE. Health care workers understandably are using these non-traditional devices as local supply issues and anxieties increase.

We have outlined the current TGA requirements for PPE to increase awareness of the relevant regulations. If novel PPE is to be deployed, it must be compliant with the TGA requirements and a clinical evaluation protocol should be developed. The resources and expertise required to develop these protocols are unlikely to exist routinely in most health services. A suggested flow chart for evaluating novel PPE is outlined in Figure 2.

The COVID-19 pandemic has highlighted the lack of readily available evaluation processes to provide health services with the assurance that PPE sourced using novel methods, such as crowdsourcing or 3D printing, is fit for purpose and TGA compliant. In October 2020, Celik et al, who also 3D printed face shields, conducted a review of international standards for industrial PPE. They highlight there is no universal standard applicable to face shields used in medical contexts, although international standards exist (including ANSI/ISEA Z87.1-2020, “American National Standard for Occupational and Educational Personal Eye and Face Protection”) <sup>15</sup>. In October 2020, the TGA did not state a mandatory standard for face shields, unlike for gowns, masks and gloves <sup>2</sup>. Throughout 2020, health services have investigated internal capabilities for conducting occupationally relevant assessment, while qualitative and quantitative Australian Standards testing sites are being set up nationwide. Ultimately, collaboration to establish and utilise these new testing capabilities will be key to enabling swift responses to PPE manufacturing challenges.

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PPE item	TGA requirement for manufacturer	Other standards to be applied by manufacturer
Face shield	Class I non-sterile, non-measuring allows the device to be self-assessed against the following criteria: - apply an appropriate conformity assessment procedure to the device, - evidence demonstrating that the device complies with the Essential Principles; as well as any other standard where conformity is claimed, - a system for post-market monitoring and taking corrective action in place, and - ensure any packaging and labelling complies with Australian regulatory guidelines - listing on the Australian Register of Therapeutic Goods	None listed by TGA
Gown		ANSI/AAMI PB70:2003
N95 mask		AS/NZS 1716:2012
Surgical face mask		AS/NZS 4381:2015
Gloves		AS/NZS 4179:1997

Table 1 – Therapeutic Goods Administration (TGA)-recommended testing standards for personal protective equipment as of 22 September 2020 <sup>2</sup>. Material face masks are not included as they are currently not recommended for use in a healthcare setting.



### Face shield efficacy against droplets exposure

1. Simulated airway management (15cm from patient face)
2. Simulated patient care (50cm from patient face)
3. Simulated patient conversation at side of bed (100cm from patient face)
4. Simulated patient observation at end of bed (200cm from patient face)

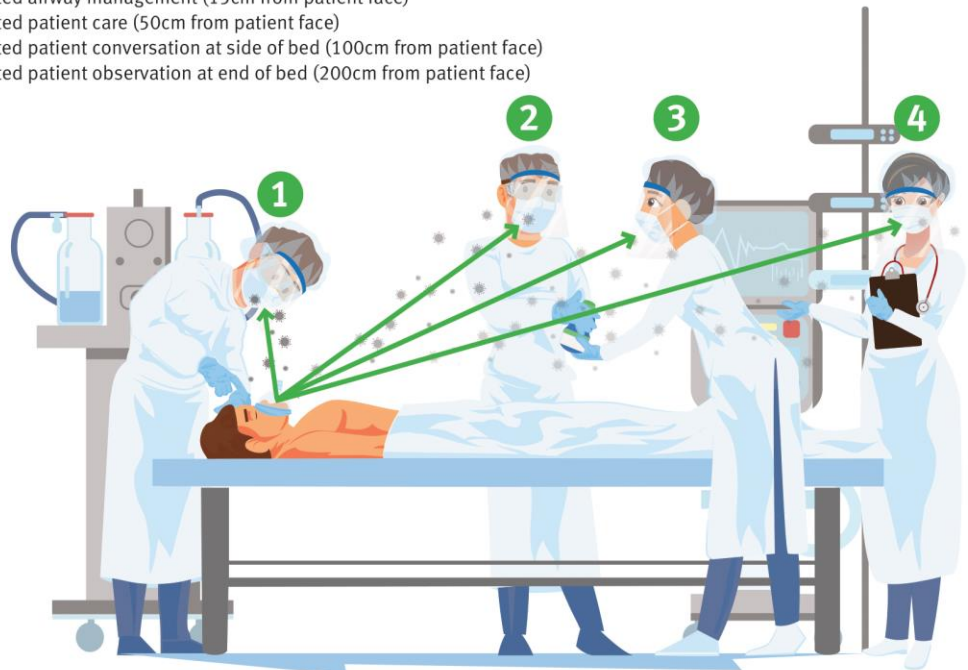


Figure 1. Droplet testing set up showing the four positions and distances used for the simulated cough.



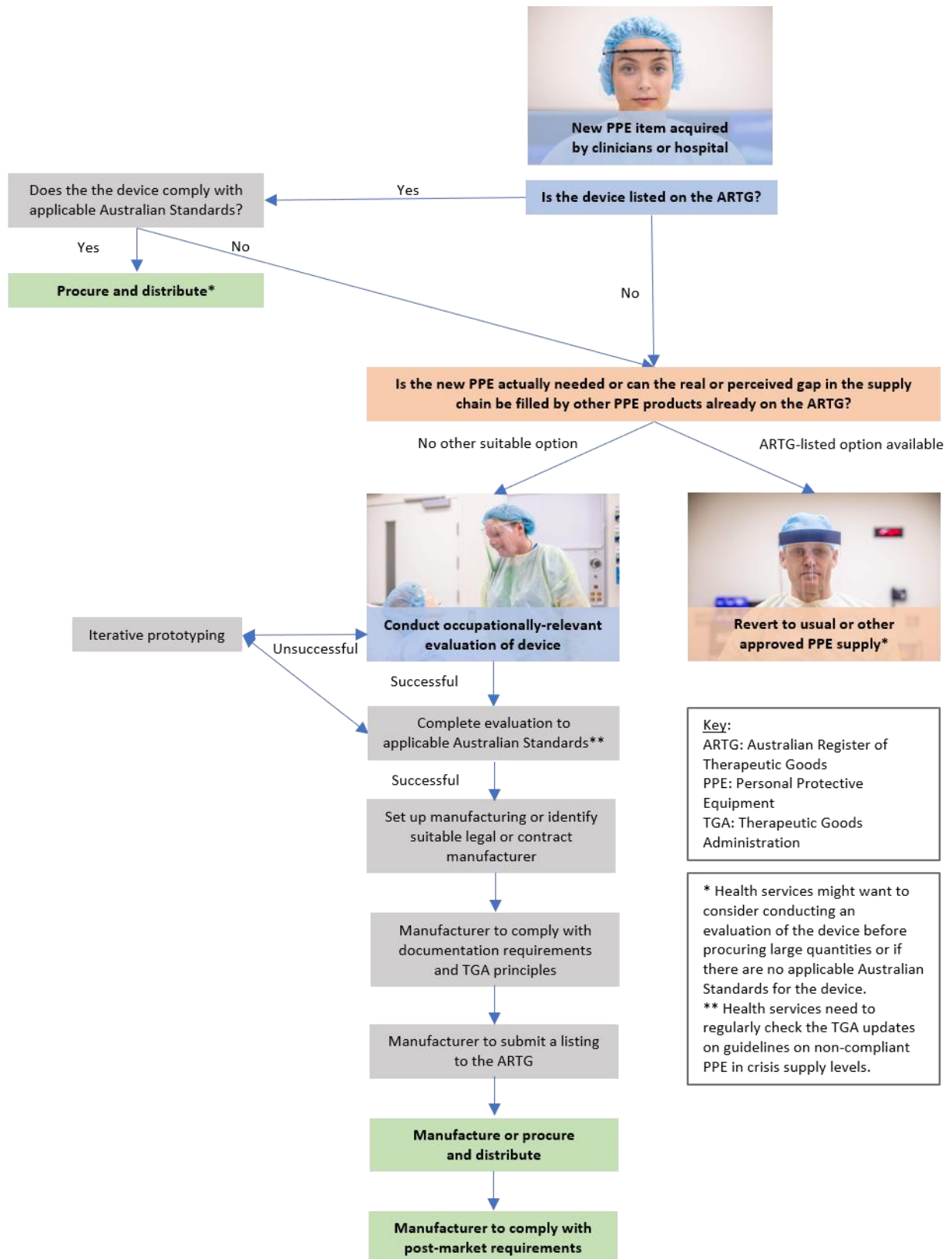







Figure 2. A suggested approach to selecting novel PPE in the Australian Healthcare Setting

Desselle MR, Kirrane M, Chao IT, Coles Black J, Woodruff MA, Chuen J, Sullivan C. Evaluating the Safety and Effectiveness of Novel Personal Protective Equipment During the COVID-19 Pandemic. *MJA* 2021.

Appendix 1 - Face shield designs and attributions

Shield	A	B	C	D	E
Headband	Foam	3D printed PLA	3D printed PLA	Laser cut PETG	3D printed PLA
Attribution	Commercial Control Halyard Guardall®	MSD v1 Melbourne School of Design, The University of Melbourne	MSD v1 Melbourne School of Design, The University of Melbourne (identical to B)	Modified version of C - courtesy ARC Hardware Incubator	PRUSA Printers - European RC3 version
Clear visor	33.5 cm wide x 22 cm long (comes already attached to headband)	200µ GBC® PVC Binder cover – Short cut - 26 cm wide x 6 cm length	200µ GBC® PVC Binder cover – Medium cut - 26 cm wide x 11.5 cm length	200µ GBC® PVC Binder cover - Long cut - 26 cm wide x 20 cm long	200µ GBC® PVC Binder cover - Uncut 29.7 cm x 21 cm length
Assembled shield (headband with attached clear visor)					
Citation: Desselle MR, Kirrane M, Chao IT, Coles Black J, Woodruff MA, Chuen J, Sullivan C. Evaluating the Safety and Effectiveness of Novel Personal Protective Equipment During the COVID-19 Pandemic. <i>MJA</i> 2021.					














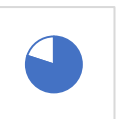




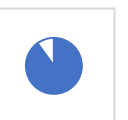

Appendix 2. Five different face shields were evaluated, including a commercially sourced control (A), three 3D printed models (B-MSD design, C-MSD design and E-PRUSA design) and a laser-cut model (D- modified MSD design) across a range of clear visors.

Face shield	A Control		B MSD short visor		C MSD medium visor		D Modified MSD long visor		E PRUSA long visor	
	With	Removed	With	Removed	With	Removed	With	Removed	With	Removed
With shield/after shield removal										
Position 1 15 cm										
Position 2 50 cm										
Position 3 100cm										
Position 4 200 cm										

Citation: Desselle MR, Kirrane M, Chao IT, Coles Black J, Woodruff MA, Chuen J, Sullivan C. Evaluating the Safety and Effectiveness of Novel Personal Protective Equipment During the COVID-19 Pandemic. *MJA* 2021

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Appendix 3 – Collated results from the independent qualitative review of photographic results. Passes are represented in blue and fails in white.

Shield	Shield A	Shield B	Shield C	Shield D	Shield E
15cm					
50cm					
100cm					
200cm					
Overall Pass Rate (n=40)	100%	0%	12.5%	75%	100%
Citation: Desselle MR, Kirrane M, Chao IT, Coles Black J, Woodruff MA, Chuen J, Sullivan C. Evaluating the Safety and Effectiveness of Novel Personal Protective Equipment During the COVID-19 Pandemic. <i>MJA</i> 2021.					