Report of the Auditor-General



Report 2 of 2022

SA Health's management of personal protective equipment





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Delivered to the President of the Legislative Council and the Speaker of the House of Assembly on 24 January 2022 and published on 27 January 2022 pursuant to section 38(2)of the *Public Finance and Audit Act 1987*

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24 January 2022

President
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Parliament House
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Speaker House of Assembly Parliament House ADELAIDE SA 5000

Dear President and Speaker

Report of the Auditor-General: Report 2 of 2022 SA Health's management of personal protective equipment

Under section 31(2) of the *Public Finance and Audit Act 1987* (PFAA), I have conducted a performance audit of the effectiveness of SA Health's management of personal protective equipment (PPE).

I present to each of you my independent assurance report on the findings of the audit.

Copies of this report have also been provided to the Treasurer and the Minister for Health and Wellbeing.

Content of the report

Our audit assessed the effectiveness of SA Health's planning, governance and distribution arrangements for PPE in ensuring appropriate PPE supplies are readily available where and when needed.

We concluded that SA Health has established some sound planning, governance and distribution practices for PPE. We also concluded that some elements of the PPE arrangements are not operating effectively. These matters require action to ensure preparedness for significant peaks in PPE demand that could arise as COVID-19 restrictions are progressively lifted, new COVID-19 variants emerge and in any future health emergencies.

Procedural fairness for this report was completed over the Christmas period for 2021. During this time SA Health were responding to the Omicron variant which emerged in late November 2021. Our report focussed on PPE arrangements for the period January 2021 to October 2021.

My responsibilities

Performance audits conducted under section 31(2) of the PFAA are assurance engagements that assess whether public sector programs or activities are achieving economy, efficiency and effectiveness in using available resources. These engagements conclude on the performance of the programs or activities evaluated against identified criteria.

The Auditor-General's roles and responsibilities in undertaking performance audits are set out in the PFAA. Section 31 of the PFAA empowers me to conduct these audits while sections 37 and 38 deal with the reporting arrangements.

The audit of SA Health's management of personal protective equipment was conducted in line with the Standard on Assurance Engagements *ASAE 3500 Performance Engagements*. We complied with the independence and other relevant ethical requirements for assurance engagements.

Acknowledgements

The audit team for this Report was Salv Bianco, Philip Rossi, Kenneth Anderson, Jodie Fitzgerald, Stephen Gladigau and Grace Lum.

The audit was undertaken while SA Health was responding to the COVID-19 pandemic. We appreciate the cooperation and assistance given by staff of the Department for Health and Wellbeing and local health networks during this challenging time.

Yours sincerely

Andrew Richardson **Auditor-General**

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1 Executive summary

1.1 Introduction

We have audited the effectiveness of SA Health's planning, governance and distribution arrangements for personal protective equipment (PPE) in ensuring appropriate PPE supplies are readily available where and when needed.

PPE is used to manage the risks of transmitting infectious diseases such as COVID-19 and contributes to safe working conditions in hospitals and other settings. It includes surgical masks, respirators, gloves, gowns and face shields. Infectious diseases may spread and there is an increased risk that South Australians could potentially endure serious illness or die if SA Health does not effectively manage PPE.

SA Health¹ has faced a complex, challenging and continuously evolving environment in procuring and distributing PPE for local health networks (LHNs), medi-hotels and the SA Ambulance Service Inc (SAAS) during the COVID-19 pandemic. It has also supplied PPE to other SA Government agencies and external organisations in responding to the pandemic.

Our audit focused on PPE arrangements for the period January 2021 to October 2021 and SA Health's preparedness to respond to current and future threats and challenges to maintaining appropriate PPE supplies.

1.2 Conclusion

We concluded that SA Health has established some sound planning, governance and distribution practices for PPE. We also concluded that some elements of the PPE arrangements are not operating effectively. These require action to ensure preparedness for significant peaks in PPE demand that could arise as COVID-19 restrictions are progressively lifted, new COVID-19 variants emerge and for any future health emergencies.

We found that the sound planning, governance and distribution practices SA Health established for PPE include:

- working with a South Australian based business to establish local manufacturing capacity for PPE masks to mitigate overseas supply chain risks
- developing reports and dashboards to monitor PPE stock on hand across SA Health and making inventory management system data easier to interpret for non-system users
- engaging a consultant to perform an initial supply chain risk review and a 'refresh' review to identify risk treatment strategies and improvement opportunities
- updating policies and procedures on the selection and use of PPE to reflect emerging evidence on COVID-19 transmission

¹ SA Health comprises the Department for Health and Wellbeing (DHW), LHNs and SAAS.

engaging a consultant to perform a COVID-19 Workplace Readiness Review on behalf
of the Office of the Commissioner for Public Sector Employment, which included work
health and safety risks relating to PPE.

South Australia successfully suppressed COVID-19 before borders were opened on 23 November 2021 and the State did not experience the infection levels and demand for PPE occurring in many other jurisdictions. SA Health responded appropriately in the early stages of the pandemic and focused on increasing PPE stock holdings and exploring a range of options to secure critical PPE supplies. This included partnering with a South Australian business to manufacture key items of PPE that were experiencing high demand and were difficult to source.

Based on data provided by SA Health, as at the end of November 2021 it was generally meeting its targeted stock levels of a minimum of 6 to 12 months' worth of supply for key pandemic PPE items. For surgical masks, SA Health relied on just in time supply arrangements. It was revising target stock levels.

However, we found that elements of SA Health's planning, governance and distribution arrangements for PPE are not operating effectively, including:

- SA Health's role in supplying PPE to the State as a whole and its PPE stockpiling strategy are unclear
- there are gaps in SA Health's PPE demand forecasting methodology and its emergency
 PPE stock holding model is not supported by documented analysis and sound evidence
- SA Health does not have an up-to-date PPE strategic procurement plan
- the key PPE strategy governance group did not meet regularly in 2021 and there are gaps in PPE reporting to governance committees
- there are no system records of PPE held in imprests² and there are gaps in PPE reporting to LHN imprest owners.

This increases the risk that appropriate PPE supplies may not be readily available where and when needed as COVID-19 pandemic restrictions are progressively lifted, new COVID-19 variants such as the Omicron variant emerge and in any future health emergencies.

Sections 1.3 and 1.4 provide further details on our findings and recommendations.

1.3 What we found

SA Health, like all health authorities around the world, has faced a complex, challenging and continuously evolving environment in procuring and distributing PPE during the COVID-19 pandemic. It also managed the transition to a new distribution centre for hospital supplies in 2021, which required a significant resource commitment. As a result, SA Health has had to balance the need to update PPE plans, strategies and policies to reflect lessons from the COVID-19 pandemic experience with other competing priorities.

An imprest is the name given to the store of inventory held in each hospital ward. Imprests hold the inventory needed, including PPE, for patient care and staff safety for that ward.

Our interviews with Nurse Unit Managers at LHNs highlighted they were concerned about potential future shortages of PPE at hospital sites as the State 'opens up' and patients with COVID-19 enter public hospitals.

We considered these challenges in formulating our findings and recommendations.

PPE planning

We found that SA Health's roles and responsibilities for meeting the PPE supply needs of other SA Government agencies and South Australia as a whole in a health emergency are unclear, including PPE stockpiling arrangements.

We also found:

- SA Health's PPE demand forecasting methodology does not capture all elements necessary to effectively forecast PPE demand, including epidemiological data and scenario modelling
- SA Health's emergency PPE stock holding model is not supported by documented analysis and sound evidence
- SA Health does not have an up-to-date strategic procurement plan that sets out how it will meet ongoing PPE requirements.

Section 4 provides further details on our findings for PPE planning.

PPE governance

We found that the key governance group enabling LHN input into SA Health's PPE strategy did not meet regularly in 2021 and there are gaps in reporting provided to governance committees on PPE stock availability and fit testing results.

We also found:

- consultant recommendations to improve the management of PPE supply chain risks have not been systematically monitored to confirm their implementation
- the roles and responsibilities of SA Health's Procurement and Supply Chain Management Unit (PSCM) and the LHNs for key PPE management activities are unclear as the service level agreement (SLA) for procurement and supply chain services remains in draft
- there is scope to improve checking processes for providing assurance that all PPE in the SA Health purchasing catalogue meets Therapeutic Goods Administration (TGA) quality standards.

Section 5 provides further details on our findings for PPE governance.

PPE distribution

We found that there are no system records of PPE held in imprests and secondary local

stores,³ which results in a lack of visibility of stock levels at these locations. LHNs are also not receiving sufficient information about PPE items that are in low supply or unavailable.

Several LHNs maintain secondary local stores of PPE and in some cases source their own PPE, as they are concerned that they may not be able to readily access all the PPE supplies they need from the SA Health distribution centre if demand surges.

We also found that the PPE distribution management processes for Health Service Support (HSS) at hospital sites are not documented and are unclear.

Section 6 provides further details on our findings for PPE distribution.

1.4 What we recommended

We communicated our recommendations in a letter to SA Health dated 19 November 2021, before the SA Government lifted COVID-19 community and business restrictions on 23 November 2021. We considered that actions to help SA Health effectively meet PPE needs after the lifting of restrictions needed to be prioritised at the time we issued our letter. We also made recommendations to help SA Health prepare for any future health emergencies and to improve its ongoing business-as-usual management of PPE.

SA Health is still responding to the COVID-19 pandemic and we acknowledge that competing priorities may make it difficult to address all of our audit findings in the short term. We understand that SA Health will adopt a risk-based approach to implementing our recommendations.

1.4.1 Priorities for responding to reduced COVID-19 restrictions

We recommended SA Health prioritise the following recommendations to help it effectively meet PPE needs as COVID-19 community and business restrictions progressively reduce:

- update SA Health's demand forecasting methodology for PPE to consider expected infection transmission rates, hospitalisation rates and models of care, and PPE usage policies
- provide regular reporting to those responsible for governance on PPE stock held against targeted stock levels and forecast demand
- closely monitor the need for key governance groups responsible for managing PPE across SA Health to meet regularly for the remainder of the COVID-19 pandemic
- perform periodic monitoring and checking to confirm that staff across all LHNs requiring PPE fit testing have been tested promptly
- provide LHN imprest owners with timely and reliable information on the availability of PPE stock items, including any supply delays

Secondary local stores are an additional store of PPE that can be accessed by hospital staff if they do not have the required items of PPE in their imprest.

 develop a common approach and procedures across SA Health for managing secondary local stores of PPE.

We also recommended that SA Health continually engage with staff responsible for managing PPE stock across hospital sites on any concerns they have about stock levels for the remainder of the COVID-19 pandemic.

1.4.2 Preparedness for future health emergencies

To help ensure effective preparedness for any future health emergencies, we recommended SA Health focus on the following:

- clarify, document and communicate SA Health's roles and responsibilities for supplying
 PPE to external organisations in a health emergency
- liaise with the Commonwealth Government to formally agree on SA Government and Commonwealth roles and responsibilities for PPE supplies in a health emergency
- update the strategic procurement plan for PPE and the viral respiratory disease pandemic response plan to reflect the planned stockpiling approach for PPE in a health emergency
- review the PPE emergency stock holding model and targeted PPE stock levels to ensure they reflect lessons from the COVID-19 experience locally, interstate and internationally
- consider assessing the feasibility of upgrading its inventory systems to track PPE items used and quantities of PPE stock held in imprests.

We acknowledge that in deciding how to prepare for future health emergencies, SA Health must balance cost, value-for-money and efficiency considerations with the need to ensure worker safety and the resilience and capability of PPE systems and processes.

1.4.3 Other recommendations to improve business-as-usual operations

We recommended SA Health implement the following other recommendations to improve its ongoing management of PPE:

- finalise all pending sections in the SLA between PSCM and the LHNs, including performance measures, and ensure it is agreed and approved by all the parties
- document whether PPE supply chain risk treatment and improvement opportunity recommendations made by consultants are accepted and monitor the implementation of accepted recommendations against targeted completion dates
- document checks to verify that all PPE purchased is on the Australian Register of Therapeutic Goods
- document roles and responsibilities for all staff across the PPE distribution process.

SA Health should consider implementing these recommendations as soon as practical when it transitions to business-as-usual operations.

1.5 New direct to imprest distribution model

SA Health finished constructing a new distribution centre for hospital supplies in September 2021 and has started work to implement a new direct to imprest distribution model. We have not reviewed the new distribution centre and model as they were not fully operational at the time of our audit.

The new direct to imprest model will involve more PPE supplies being held centrally in the new distribution centre and lower stocks being held at metropolitan hospital sites.

Ensuring appropriate PPE supplies are available could be challenging for SA Health as it transitions to a new distribution model at the same time as COVID-19 restrictions are progressively lifted by the SA Government. It may need to manage a significant spike in PPE demand while implementing this major change.

SA Health will need to ensure that ordered PPE supplies are delivered promptly to hospital imprests to maintain frontline hospital staff confidence in PPE availability. As more PPE supplies will be held centrally in the distribution centre under the new model, there will also be a greater risk to maintaining appropriate PPE supplies across SA Health if the distribution centre is damaged or destroyed. It is therefore important that business continuity plans for the new distribution centre are established promptly, tested and updated regularly.

SA Health should consider our findings and recommendations as it progresses the implementation of the new distribution centre and direct to imprest model. Section 2.6.5 provides further details on these changes and the associated risk and challenges.

1.6 Response to our recommendations

SA Health responded positively to our detailed findings and advised us how it would action our recommendations with target completion dates.

SA Health's response to each of our recommendations is outlined in sections 4 to 6 of our report. SA Health plans to implement actions identified in its response by June 2022.

The Chief Executive of DHW also provided a response to our proposed report to Parliament, which is included as Appendix 5.

2 Background

2.1 PPE overview

2.1.1 What is PPE and why is it important?

PPE refers to devices or clothing worn to control health and safety risks.

The effective use of PPE in healthcare settings mitigates the risk of workers and patients acquiring and transmitting infectious diseases and contributes to safe working conditions in both pandemic and business-as-usual conditions.

To maximise the level of protection that PPE offers, PPE users must know how to select the right PPE for the task at hand and use it appropriately. Lack of access to the right PPE, insufficient fit testing and the incorrect use of PPE has led to healthcare workers worldwide contracting COVID-19.4,5,6

2.1.2 Main types of PPE for infection control purposes

Our audit focused on the key types of PPE that SA Health identifies as essential to preventing the transmission of infection.⁷ Figure 2.1 summarises these PPE types and their purpose.

Figure 2.1 Key types of PPE for infection control

PPE type

Description



Aprons and gowns provide protection against contamination of the skin, uniforms or clothing with infectious microorganisms.

A classification system for healthcare protective apparel has been developed based on the liquid barrier performance. Barrier protection is rated from level 1 to level 4, with level 4 providing the highest level of protection.

Burki, T 2020, 'Global shortage of personal protective equipment', The Lancet. Infectious diseases, July, volume 20, pages 785-786.

Quigley, A, Stone, H, Nguyen, P Y, Ahmad Chughtai, A, MacIntyre, C R 2021, 'Estimating the burden of COVID-19 on the Australian healthcare workers and health system during the first six months of the pandemic', International Journal of Nursing Studies, volume 114, 103811.

Ananda-Rajah, M, Veness, B, Berkovic, D, et al 2021, 'Hearing the voices of Australian healthcare workers during the COVID-19 pandemic', BMJ Leader, volume 5, pages 31-35.

SA Health's Personal Protective Equipment (PPE) Selection Policy Guideline, version 3.0, approved in December 2020.

PPE type

Description



Face and eye protection includes face shields, safety glasses and goggles.

Safety glasses and goggles protect the eyes from potentially infectious blood or body fluids. A face shield provides protection to other parts of the face, as well as the eyes.



Gloves can protect patients and health workers from exposure to potentially infectious microorganisms. The following types of gloves are used in infection prevention:

- non-sterile single use gloves
- sterile single use gloves.



Respirators are used to prevent inhalation and contact with infectious pathogens which can be airborne.

Particulate Filter Respiratory Protective Devices (P2/N95 respirators) are designed to be tight-fitting. Air leaks around respirator edges will not achieve the level of protection needed to protect the wearer's health. Section 2.1.3 discusses fit testing and fit checking of respirators.



Single use surgical masks⁸ provide a barrier to splashes and droplets impacting the wearer's nose, mouth and respiratory tract.

There are three levels, based on factors including bacterial filtration efficiency and fluid resistance. Level 1 provides the lowest level of protection and level 3 the highest for surgical masks. The level of surgical mask selected is based on the risk of the wearer being exposed to blood or body fluids.

Source: Developed from SA Health's Personal Protective Equipment (PPE) Selection Policy Guideline, approved on 9 December 2020.

Appendix 1 provides additional information on surgical masks and respirators.

2.1.3 Fit testing and fit checking

To provide maximum protection to wearers, P2/N95 respirators need to be properly fitted and wearers trained in how to use them safely.

SA Health policy requires wearers of P2/N95 respirators to have a fit test before they first start wearing them to determine which brand and size of respirator fits optimally to provide them with the highest level of protection.

Surgical masks discussed in figure 2.1 relate to the type of masks used in a healthcare setting. At the time of this Report, face masks are mandated for use in South Australia in community settings. The SA Health website states that suitable face masks for the general public include reusable cloth masks and single-use surgical masks. There is no specified grade of surgical mask for use in the community, unless required in certain healthcare settings.

Fit testing measures the effectiveness of the seal between the respirator and the wearer's face. An effective seal is essential for preventing hazardous airborne substances from leaking in.

Workers should only use the type and size of respirator that they have been fitted to. Hospital sites keep records of the specific respirators that each worker has been fitted to. Fit testing should be repeated whenever a different size or make of respirator is used, or if an individual's facial structure changes (for example, after facial surgery or weight fluctuations).

In addition to fit testing, wearers must also self-perform a fit check each time they put on a P2/N95 respirator to check whether a good facial seal has been achieved.⁹ If leaks are detected, the respirator must be readjusted.

2.1.4 SA Health's role and responsibility for supplying PPE

SA Health has work, health and safety responsibilities to provide its workers with safe working conditions, including appropriate PPE.

There is also a reasonable expectation that SA Health, as the lead agency for public health, has a role in ensuring that the State has sufficient PPE supplies.

Figure 2.2 shows that SA Health has provided PPE supplies to several organisations in responding to the COVID-19 pandemic. This has included other SA Government agencies, local government, aged care providers and private businesses.

Figure 2.2: PPE provided by SA Health to other organisations from January 2020 to November 2021

	Number of _ units (millions)	Cost (\$millions)		
Organisation type		Provided free of charge ¹	Provided on cost recovery basis	Total cost
Aged care	14.0	3.1	1.2	4.3
Businesses	1.1	0.6	0.1	0.7
SA Government agencies	18.2	3.6	2.8	6.4
Local government	1.1	0.9	0.2	1.1
Non-government organisations	0.5	0.3	0.1	0.4
Other health services	1.3	0.1	0.3	0.4
Other	0.8	0.1	0.8	0.9
Total	37.0	8.7	5.5	14.2

Source: SA Health (unaudited).

1 Weighted average unit cost. SA Health advised that some goods were supplied by the Commonwealth Government.

⁹ SA Health 2020, Respiratory Protection Against Airborne Infectious Diseases Clinical Guideline, version 1.4, Infection Control Service, Communicable Disease Control Branch, approved 22 June 2020.

PPE supplies have generally been provided in response to specific requests from individual organisations and changes in SA Government requirements for the use of PPE (for example, the mandated use of masks in SA Government high schools).

2.2 PPE procurement planning

2.2.1 Background

SA Health requires uninterrupted supply of PPE to safely deliver health services to South Australians.

DHW's PSCM plays an integral role in central procurement planning, purchasing and distribution to support PPE requirements across the whole of SA Health. While SA Health entities are encouraged to procure PPE through PSCM, they can obtain it directly from suppliers provided the amounts procured are within delegated thresholds. Our audit focused on central PPE procurement planning performed by PSCM on behalf of all SA Health entities.¹⁰

From January 2020 to November 2021, PSCM purchased 235.5 million units of PPE at a total cost of \$128.4 million. Figure 2.3 breaks down purchases by type of PPE.

Face and eve Respirators Gloves Surgical mask Units purchased 12.9 million 1.1 million 154.9 million 12.4 million 54.2 million \$27.7 million \$4.9 million \$31.6 million \$17.8 million \$46.4 million Cost

Figure 2.3: PPE purchased by PSCM from January 2020 to November 2021

Source: SA Health (unaudited).

SA Health and other healthcare providers worldwide have had difficulties procuring the PPE supplies needed to meet unprecedented demand during the COVID-19 pandemic. This was particularly so in the early stages of the pandemic due to a surge in global demand for PPE and unforeseen supply chain disruptions.

The COVID-19 pandemic exposed vulnerabilities in SA Health's PPE supply chain, including:

- suppliers being unable to manufacture sufficient quantities of required goods due to shortages in manufacturing capacity and raw materials
- reliance on limited suppliers for some PPE products
- limited supply and/or delays in receiving goods from overseas suppliers due to export restrictions.

¹⁰ Section 2.5.1 provides further details on SA Health entities and relevant governance structures.

The supply shortages, compounded by the surge in worldwide demand, led to significant increases in the price of PPE. In March 2020, the World Health Organisation reported that the price of surgical masks had increased by six times, N95 respirator prices had trebled and gowns doubled.¹¹

Demand for PPE critical to infection control is expected to remain high as borders open up both locally and internationally and we continue to live with COVID-19.

While SA Health advised us that supply is stabilising for some PPE items as supply chains begin to normalise, securing supply for particular types of PPE, such as certain gloves, continues to be challenging. SA Health also advised us that manufacturing capacities are likely to remain constrained throughout 2022 and 2023, and subject to the impacts of COVID-19 resurgences and emerging variants.

2.2.2 Procurement planning

The procurement planning process develops procurement objectives based on business needs and determines the best value-for-money strategy to achieve those objectives. The rigour of planning should be proportional to the scale and risk profile of the procurement activity.

The procurement strategy should be based on a sound understanding of organisational needs, the supply market for the procurement being undertaken and risks. Selecting the most appropriate strategy should consider the costs and benefits of different procurement strategies and the organisation's appetite for risk.

Supply disruptions during the COVID-19 pandemic have highlighted the importance of having:

- a comprehensive understanding of supply chain risks
- procurement plans with mitigating strategies to reduce the impact of supply continuity disruptions.

2.2.3 SA Health's procurement strategy

SA Health's procurement strategy has evolved over the past two years to respond to supply chain disruption risks from the COVID-19 pandemic. Figure 2.4 summarises key elements of SA Health's current procurement strategy for PPE.

World Health Organisation 2020, Shortage of personal protective equipment endangering health workers worldwide, viewed 8 November 2021, https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide.

Figure 2.4 Key elements of SA Health's PPE procurement strategy



Supplier panels exist to provide SA Health with PPE on an ongoing basis. Staff are strongly encouraged to purchase PPE from suppliers on these panels. SA Health found long-standing relationships with panel suppliers to be highly valuable during COVID-19, particularly in peak periods where suppliers prioritised limited available stock for their established customers.



In response to COVID-19, SA Health expanded its supplier panels, with an aim to have a minimum of two suppliers for each key type of PPE, to help reduce supply continuity risk posed by sole-supplier awards.



To reduce reliance on overseas suppliers and mitigate offshore manufacturing supply risks, SA Health partnered with Central Packaging (S.A.) Pty Ltd (trading as Detmold) to locally develop and manufacture surgical masks and P2/N95 respirators. Section 2.2.4 has further information about these arrangements.

2.2.4 Detmold manufacturing arrangements

Difficulties securing a sufficient supply of surgical masks and P2/N95 respirators led SA Health to explore local manufacturers with capacity and capability to rapidly set up production to meet its requirements. Detmold, a South Australian based company with experience in manufacturing paper and board-based packaging products, was identified as a suitable manufacturer.

In March 2020, SA Health appointed Detmold to its panel of suppliers and an agreement was reached for SA Health to purchase a minimum quantity of 45 million masks initially, and on an as-needs basis thereafter. The agreement is for two years, with two extension options (two years plus two years).

Detmold worked with SA Health to rapidly develop suitable surgical and respirator masks, and began supplying masks to SA Health within 18 weeks. ¹² SA Health advised that up to 30 November 2021, Detmold had supplied it with a combined total of 54.5 million surgical masks and respirators. This has enabled SA Health to meet its internal demand and support the demand from other SA Government agencies, community groups and external organisations.

As part of the arrangement, SA Health contributed 80% of the cost of purchasing 10 mask manufacturing machines to enable Detmold to set up operations. Under the agreement, Detmold owns the equipment, but there is a call option that allows SA Health to purchase the equipment in certain circumstances if Detmold stops manufacturing masks within the first three years.

Detmold 2021, *Detmold Medical One Year Anniversary*, viewed 3 November 2021, https://www.detmoldgroup.com/our-story/latest-news/one-year-anniversary-of-detmold-medical/.

Detmold has now expanded its manufacturing facility to 20 machines and has the capacity to produce one million masks a day. 13

2.2.5 SA Health is updating its strategic procurement plan

At the time of our audit, PSCM advised us that it is updating SA Health's strategic procurement plan. It is assessing the medium to long-term impact of COVID-19 on anticipated usage and spend, with consideration to long-term changes in clinical PPE usage practices and a better knowledge of cost drivers.

As part of updating the strategic procurement plan, SA Health has engaged a consultant to further review supply chain risks and provide strategic advice on emergency stock holding models and value-for-money outcomes.

2.3 Emergency stock holding model

2.3.1 Overview

Stockpiling involves accumulating stock above and beyond business-as-usual needs for use when there are interruptions to supply. Stockpiles are best suited to addressing shorter-term interruptions while other sources of supply are found or existing supply chains are restored. As such, a stockpile may be one of multiple strategies in a broader emergency stock holding model used to mitigate the risk of supply disruptions.

Maintaining a stockpile of PPE enables SA Health to readily access PPE so that it can continue to safely provide health services if there are supply disruptions. For the stockpile to be useful in emergency situations, it needs to hold the right types of PPE to meet user needs, have enough stock to meet expected demand and be readily accessible by those who need it.

Stockpiling may also have financial benefits if stock is bought when prices are low to mitigate the risk of future price rises.

There are, however, costs involved in keeping a stockpile, such as storage costs and the potential for stock obsolescence if stock is not used before it expires. The costs and benefits of maintaining a PPE stockpile therefore need to be weighed up when considering the PPE stock holding model to be adopted.

2.3.2 SA Health's stockpile

In 2016, SA Health began planning to set up a stockpile of PPE supplies in preparation for a pandemic. The aim of the stockpile was to mitigate the risk of core clinical services being impacted by short-term supply disruptions. The stockpile was not established at that time.

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¹³ ibid.

¹⁴ Productivity Commission 2021, *Vulnerable Supply Chains*, Study Report, July, page 125.

Once the COVID-19 pandemic started, SA Health sought to accumulate stock of critical PPE items and establish a stockpile. High levels of demand and supply chain disruptions made this task challenging in the early stages of the pandemic.

Figure 2.5 shows monthly stock levels from January 2020 to November 2021.

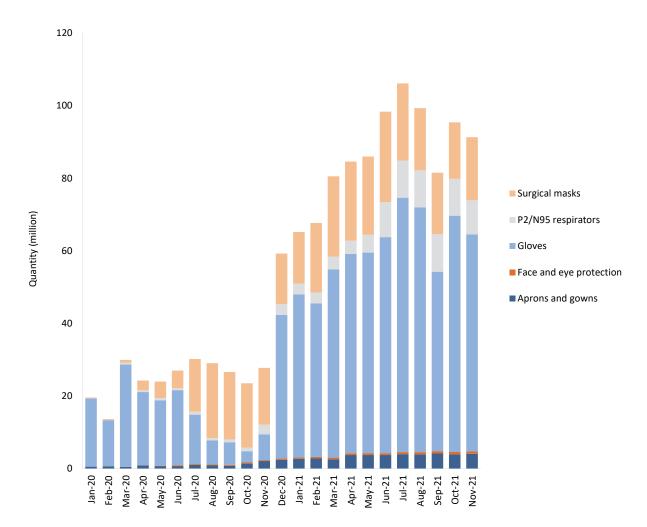


Figure 2.5: Month-end PPE stock levels from January 2020 to November 2021

Source: SA Health (unaudited).

Growth in stock levels is mainly due to increased stock holdings of gloves, followed by surgical masks and respirators. As at the end of January 2020, SA Health had only 55,000 P2/N95 respirators on hand. Stock levels increased to 520,000 units by the end of March 2020 and climbed to 10.4 million units by the end of September 2021.

Figure 2.6 contains stock levels for key types of PPE as at 30 November 2021 as advised by SA Health. It shows that as at 30 November 2021, based on usage patterns experienced during COVID-19 cluster periods that occurred before borders re-opened, SA Health has:

- 45 months' worth of supply of respirators
- 5 to 23 months' worth of supply for other types of PPE.

Figure 2.6: Stock on hand as at 30 November 2021

	Stock on hand ⁻ Units (millions)	Months of supply ¹		
Type of PPE		Based on standard usage	Based on cluster usage ²	Targeted months' worth of stock
Aprons	0.7	8	9	6
Face shields	0.4	35	18	12
Gloves	59.8	8	9	6
Gowns	3.4	9	7	6
P2/N95 respirators	9.4	141	45	12
Safety glasses and goggles	0.2	47	23	12
Surgical masks	17.4	23	5	12
Total	91.3			

Source: SA Health (unaudited).

The targeted stock levels in figure 2.6 are based on recommendations provided by SA Health's Emergency Management Unit, reflecting demand for PPE experienced during the 2009 – 2010 swine flu pandemic. As at 30 November 2021, SA Health was meeting its targeted stock levels, except for surgical masks. SA Health advised that it has just in time supply arrangements with Detmold which negate the need for SA Health to hold significant amounts of surgical masks and respirators.

At the time of our report, SA Health advised us that it was revising its targeted stock levels to reflect outcomes from demand modelling recently performed by the University of Adelaide and SA Health's current supply arrangements.

2.3.3 National Medical Stockpile

SA Health's PPE stock is supplemented by the National Medical Stockpile (NMS).

The NMS is a strategic reserve of supplies managed by the Commonwealth Government to help meet high demand during a national health emergency. It includes drugs, vaccines, antidotes and PPE.

The NMS is not a general supplier of product and will only release stock where commercial supply is unavailable and there is a demonstrated need or clinical advice for its use. As the NMS is a supplier of last resort, SA Health must have robust planning to ensure it has sufficient PPE stock holdings for emergency situations. During the 2009 – 2010 swine flu pandemic the NMS was depleted of medical gowns, masks and eyewear. This reinforces that reliance cannot be placed on the NMS and the importance of SA Health's responsibilities to ensure it has its own adequate supply of PPE.

¹ Calculated based on usage rates experienced from September 2020 to September 2021.

² There is generally more PPE used during COVID-19 cluster periods compared to standard periods in order to control the spread of COVID-19. SA Health advised that this usage is offset by a reduction in PPE usage due to elective surgeries being put on hold. This has resulted in higher months' worth of supply of gloves and gowns during COVID-19 cluster periods compared to standard periods.

¹⁵ SA Health 2016, Acquisition Plan Healthcare Apparel (Disposable, Non-Sterile), version 7.7.

SA Health advised that the NMS supplied 4.7 million surgical masks and P2/N95 respirators to SA Health to help with the State's COVID-19 response.

There is no formal agreement between the Commonwealth and SA Governments specifying their respective roles and responsibilities for PPE in a health emergency or the objectives of the national and South Australian PPE stockpiles. Section 4.2.6 provides further details.

2.4 Demand for PPE

2.4.1 Historical demand for PPE

Figure 2.7 shows demand for PPE based on internal and external customer orders from 1 January 2020 to 30 November 2021.

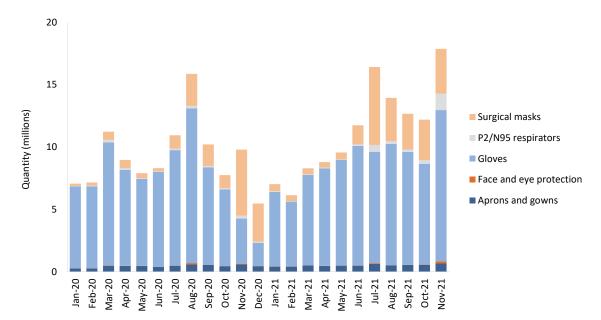


Figure 2.7: PPE demand from 1 January 2020 to 30 November 2021

Source: SA Health (unaudited).

There has been significant variability in demand for PPE over this period reflecting the continuously evolving nature of the COVID-19 pandemic. Demand ranged from 5.5 million units per month in December 2020 to 17.9 million units in November 2021 (227% increase) which demonstrates the volatility of demand. This reinforces the importance of sound planning and governance practices to ensure preparedness for significant peaks in demand which may occur as COVID-19 pandemic restrictions are progressively lifted, new COVID-19 variants emerge and for future health emergencies.

Figure 2.7 shows:

- between January 2020 and March 2020 demand for PPE increased by 59% as a public health emergency was declared in South Australia.
- demand surged in August 2020 reflecting demand for PPE from aged care facilities following the introduction of an emergency management direction mandating PPE requirements for aged care workers.

- demand increased in November 2020 in response to a new cluster of COVID-19 cases which occurred in mid-November 2020.
- demand decreased in December 2020 due to a decline in the number of COVID-19 cases and lower health system activity associated with seasonal trends.
- demand rose sharply in July 2021, particularly for surgical masks, due to a cluster of COVID-19 cases and the introduction of mask wearing mandates in certain settings.
 From 28 July 2021, masks became mandatory in high school settings. SA Health provided the Department for Education with 2.9 million surgical masks to assist public high schools to comply with this requirement.
- demand for PPE peaked in November 2021 reflecting increased demand for PPE from customers in preparedness for borders re-opening on 23 November 2021.

Section 2.4.2 contains more information about the different factors influencing PPE demand.

2.4.2 Demand forecasting

SA Health needs to have a sound understanding of how much PPE it needs for future requirements so that it can:

- develop well informed strategic and operational plans to meet those requirements
- optimise the amount and type of inventory held
- effectively address supply and distribution risks.

The process of predicting future demand for inventory items such as PPE is known as demand forecasting. It involves using past data, trends and other known variables that impact demand to predict future customer demand over a period of time.

Figure 2.8 summarises the key steps in the demand forecasting process.

Decide on future forecast period

Review historical base demand

Review historical base demand

Review models to forecast demand

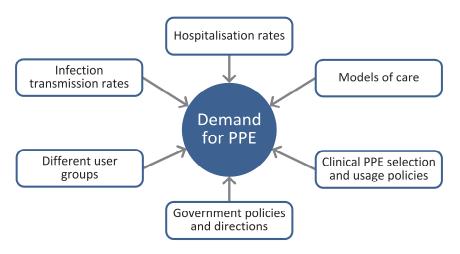
Figure 2.8: Demand forecasting process¹⁶

Demand forecasting is a valuable activity in business-as-usual periods, and even more so during a pandemic to adequately prepare for future surges in demand.

Figure 2.9 summarises some of the different variables that influence demand for PPE.

Adapted from Oracle NetSuite 2020, Inventory Forecasting: Types, Best Practices, and Benefits, viewed 4 November 2021, https://www.netsuite.com/portal/resource/articles/inventory-management/inventory-forecasting.shtml.

Figure 2.9: Examples of variables influencing demand for PPE



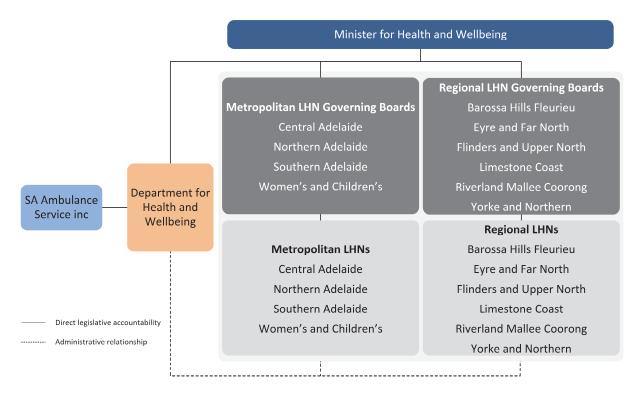
Section 4.2.2 discusses SA Health's demand forecasting further.

2.5 PPE governance arrangements

2.5.1 Overview of SA Health entities

Figure 2.10 summarises the relationship between SA Health entities and the Minister for Health and Wellbeing.

Figure 2.10: Relationship between SA Health entities and the Minister for Health and Wellbeing



The Minister for Health and Wellbeing is responsible for ensuring that:

- the public health system meets the requirements of the South Australian community
- the LHN Governing Boards are operating effectively and in line with their legislative requirements.

DHW is responsible for overall leadership and strategic direction for the delivery of public health services in South Australia and supports the LHNs through high-level direction and performance management.

The LHN Governing Boards are responsible for local health service delivery by the LHNs, including performance and budget achievement, clinical governance, safety and quality management and risk management. LHN Chief Executive Officers are responsible for the day-to-day operations of the LHNs.

SLAs between DHW and the LHNs set out their responsibilities, performance expectations and funding arrangements. Additionally, PSCM has established a draft SLA with the LHNs and SAAS specifically for providing procurement and supply chain services. At the time of our audit, it was not finalised. Section 5.2.5 has further details.

2.5.2 PPE governance groups and committees

Our audit focused on the operations of governance groups and committees that played a key role in managing PPE across SA Health during 2021. Figure 2.11 summarises these groups and committees.

COVID-19 response

PPE Clinical Advisory Group

Ongoing

PPE and Pharmacy Governance Group

Team

Committee

Metropolitan LHNs

Rural Support Service

Figure 2.11: Key PPE governance groups and committees

PPE Clinical Advisory Group

The PPE Clinical Advisory Group was established in April 2020 in response to the COVID-19 pandemic. Its role is to provide advice and recommendations to DHW on clinical and technical requirements for PPE developed and manufactured in South Australia to respond to the COVID-19 pandemic. It reports to the PPE and Pharmacy Governance Group.

The group consists of representatives from DHW and the LHNs from a wide range of areas including PSCM, infection control, nursing and midwifery, allied health, work health and safety, and emergency management. Regional LHNs are represented through the Rural Support Service.¹⁷

¹⁷ The Rural Support Service supports the six regional LHNs with business services, governance and risk assurance, workforce development and clinical services development and support.

PPE and Pharmacy Governance Group

The PPE and Pharmacy Governance Group was established in April 2020 in response to the COVID-19 pandemic and reports through the Acute Health Care Readiness Workstream¹⁸ to the State Control Centre – Health.

It is chaired by DHW's Chief Medical Officer and consists of DHW representatives from health services programs, infection control, nursing and midwifery, and work health and safety. Metropolitan LHNs are represented through their Chief Operating Officers and Regional LHNs are represented through a Rural Support Service representative.

The PPE and Pharmacy Governance Group has a key role in enabling clinical and LHN input into SA Health's PPE strategy and ensuring appropriate PPE supplies are available where and when needed. This includes:

- providing clinical governance for the appropriateness, technical specification and use of PPE supplies
- achieving staff confidence in a stable PPE supply
- supporting the monitoring and oversight of the PPE supply chain
- coordinating information related to PPE use across metropolitan and regional LHNs
- providing recommendations to inform PPE stock management and distribution processes across SA Health, other relevant SA Government departments and other relevant external agencies
- identifying gaps and risks related to the management of PPE during the COVID-19 pandemic.

DHW Leadership Team

The DHW Leadership Team is a high-level decision-making and leadership group within DHW. It acts as a mechanism to address priority reforms and other high priority issues requiring a collaborative cross-departmental response, such as the procurement, use and distribution of PPE.

The DHW Leadership Team consists of the DHW Chief Executive and leads from key workstreams.

SA Health Procurement Governance Committee

The SA Health Procurement Governance Committee provides direction and oversight of procurement, contracting and supply chain management across SA Health. It reports directly to the DHW Chief Executive and has representatives from DHW and the LHNs. Regional LHNs are represented through the Rural Support Service.

SA Health was declared the lead agency for the response to the COVID-19 pandemic. To effectively plan for and manage the response, SA Health established a number of workstreams that reflect its core business and system enablers. The Acute Health Care Readiness Workstream is one of seven workstreams.

2.5.3 Selection and use guidance

Providing guidance on the selection and use of PPE forms part of SA Health's infection control processes. The COVID-19 pandemic brought additional focus to PPE and its effective use and resulted in additional guidance being prepared and provided to staff.

Selection and use guidance is provided through documented policies and guidelines issued by DHW. These are supported by training, local operating procedures at LHNs and the extensive use of printed signage in hospitals to outline PPE requirements.

While there are numerous SA Health policies and procedures that include guidance on PPE, two key documents govern the selection and use of PPE across SA Health:

- Personal Protective Equipment (PPE) Selection Policy Guideline
- COVID-19 Personal Protective Equipment Decision Matrix Protocol.

The guideline is the overarching policy on the use of PPE. The matrix was first established in 2020 and sets out the appropriate use of PPE for any suspected or confirmed case of COVID-19 that presents to a hospital or is cared for in a supervised quarantine environment.

The guideline and matrix outline the PPE required to manage the risk of exposure to hazards including the transmission of infectious diseases, and directly impact the types and quantities of PPE that must be available to SA Health staff. Both documents have been updated to reflect emerging information about infection transmission and the most effective use of PPE to increase worker safety. The PPE and Pharmacy Governance Group reviewed both documents before the updates were approved.

More information on PPE selection and use guidance is provided in Appendix 2.

2.5.4 Compliance with quality standards

PPE is subject to regulation by the TGA under the *Therapeutic Goods Act 1989* (Cth). PPE that meets the definition of a medical device must be recorded in the Australian Register of Therapeutic Goods to legally be imported or supplied in Australia.

More information on TGA regulation is included in Appendix 3.

2.6 PPE distribution arrangements

2.6.1 Overview of the distribution model in place during our audit

The distribution of PPE to hospitals, medi-hotels and other sites is managed centrally for SA Health by PSCM.

A central distribution centre receives, stores and distributes items of PPE and other consumables to hospitals across all LHNs, medi-hotels and SAAS. The SA Health distribution network includes 73 public hospitals and six medi-hotels.

Nine metropolitan hospitals and 14 regional hospitals have a bulk store or warehouse facility operated by PSCM staff. A bulk store receives supply of PPE from the distribution centre or direct from suppliers. Items are then distributed to where they are required across the hospital site.

An inventory imprest is located in each hospital ward or department to hold the items required for treating patients and staff safety. There may be many imprests within each hospital site. For example, Port Pirie Hospital has 14 imprests while the Lyell McEwin Hospital has over 60. Each imprest is replenished frequently through a reordering process that is described in section 2.6.3.

Figure 2.12 shows how PPE is distributed to SA Health hospitals and medi-hotels.

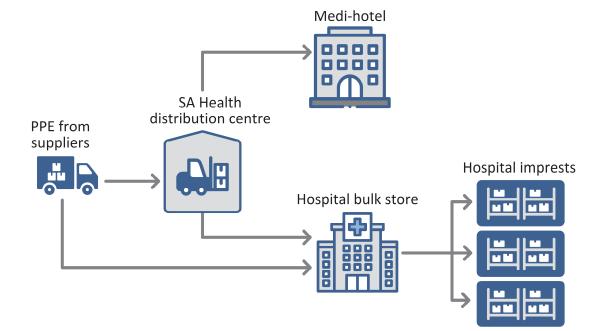


Figure 2.12: Overview of the PPE distribution process

2.6.2 Additional warehousing required to hold PPE stock

Due to the large quantities of PPE required by SA Health during the COVID-19 pandemic, an arrangement was made with a third party provider for additional warehousing space for bulk pallet storage of PPE.

PPE has been held at this facility since March 2020 and SA Health advised us that the arrangement will continue throughout 2022.

PPE can be moved from this warehouse to the distribution centre when it is required for distribution to hospitals, medi-hotels and other sites.

2.6.3 Key systems used for PPE distribution

There are two key systems used to record and manage PPE across SA Health locations:

- Oracle Inventory Management System (Oracle)
- Imprest Management System (IMS).

Oracle is used for the following key inventory management functions:

- receiving items at the distribution centre and bulk stores
- recording minimum and maximum quantities of inventory for each location (imprest, bulk stores and distribution centre)
- recording product information
- ordering replenishment inventory
- producing picking slips, which staff use to obtain products from the warehouse and prepare to transport to the required location
- recording the shipping and movement of inventory from the distribution centre to the bulk stores and imprests.

The IMS interfaces with Oracle and allows reordering of items to be completed with a barcode scanner.¹⁹ HSS staff visit each imprest room over a weekly cycle and scan the barcodes from each imprest item. As the system records the maximum quantity to be held for each item, it will determine the amount that needs to be ordered when the quantity remaining on the shelf is entered.

The items that need to be replenished will be requisitioned from either the onsite or regional bulk store, the distribution centre or direct from the supplier based on the sourcing information recorded for that item in Oracle.

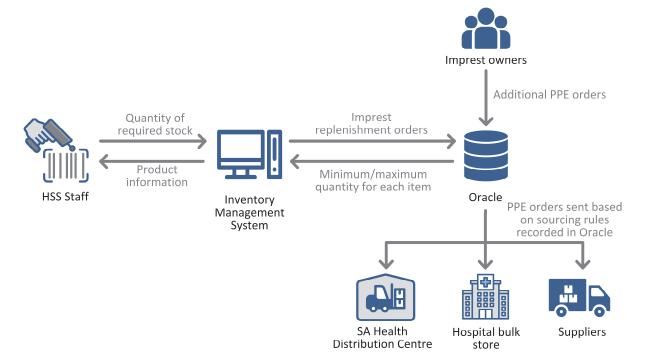


Figure 2.13: Overview of key systems used for PPE distribution

¹⁹ The Royal Adelaide Hospital does not use the IMS. It has an automated imprest system that is operated by a contracted facility operator. Medi-hotels do not have direct access to Oracle or the IMS. They use a manual ordering system.

2.6.4 SA Health staff involved in the distribution of PPE

The distribution of PPE across the SA Health network relies on key groups of staff. Figure 2.14 outlines the key staff involved in making sure that PPE is available where and when it is needed.

Figure 2.14 Outline of key SA Health staff groups involved in PPE distribution

Procurement Goods and Logistics Team

- Team within PSCM.
- Responsible for the distribution centre, managing supply chain and providing inventory management support to the LHNs.
- Central managers of the supply and distribution of PPE.

Health Service
Support

- Part of the Procurement Goods and Logistics Team in PSCM.
- Manage the bulk stores and warehouses in hospitals.
- Pick orders and deliver to hospital imprests.
- Work closely with LHN staff to ensure that PPE and other inventory items are available where needed.
- Usually the first point of contact for LHN staff for PPE.

Imprest owners

- The Nurse Unit Manager for each hospital ward or medi-hotel is the imprest owner.
- The Nurse Unit Manager is responsibile for managing the overall function of the ward which includes clinical care and business management (staffing, worker health and safety and managing budgets).
- Manage the imprest to ensure that all inventory required is on hand.

2.6.5 New distribution centre and direct to imprest distribution model

Construction of SA Health's new distribution centre was completed in September 2021 and it became fully operational from January 2022.

PSCM advised us that the new distribution centre provides:

- a larger facility which can store higher volumes of consumables including PPE
- improved technology and processes to increase efficiency and reduce picking errors, including the automated retrieval of items.

PSCM has also started to implement a direct to imprest distribution model. Under this model, imprest orders will be picked directly from the new distribution centre, resulting in a reduction of bulk stores at metropolitan hospitals which will only hold critical stock items. PSCM advised us that it expects this distribution model will:

- reduce the amount of inventory held across SA Health
- reduce the amount of handling
- improve turnaround times for replenishing inventory to imprests.

The increased reliance on PPE and other inventory being supplied direct to imprest from the new distribution centre will require SA Health to effectively manage:

- the performance of transport contractors given the increased reliance on the timely transfer of PPE and other inventory between the distribution centre and hospital sites
- any increased risks from having PPE and other inventory stored primarily at a single location
- communication with imprest owners so that they understand the implications of changes to bulk stores and reduction in HSS staff at metropolitan hospital sites.

3 Audit mandate, objective and scope

3.1 Our mandate

The Auditor-General has authority to conduct this audit under section 31(2) of the *Public Finance and Audit Act 1987*.

3.2 Our objective

We assessed the effectiveness of SA Health's planning, governance and distribution arrangements for PPE in ensuring appropriate PPE supplies are readily available where and when needed.

3.3 What we reviewed and how

Our audit focused on PPE arrangements for the period January 2021 to October 2021 and SA Health's preparedness to respond to current and future threats and challenges to maintaining appropriate PPE supplies.

To assess the effectiveness of its PPE planning, governance and distribution arrangements, we considered whether SA Health had established or developed:

- an effective procurement plan to meet its PPE requirements
- appropriate processes to determine the quantity and type of PPE required
- sound governance arrangements for managing PPE supplies
- effective monitoring of PPE supplies to ensure planned stock levels are maintained
- an appropriate process to ensure PPE supplies meet relevant quality standards
- effective monitoring of PPE stock levels in LHNs and medi-hotels to:
 - identify when additional supplies are required
 - ensure orders made are received promptly
 - ensure supplies are distributed where they are needed
- effective processes for communicating PPE selection and use requirements and ensuring that that fit testing is conducted in line with relevant policies, procedures and guidelines.

Our audit focused on DHW and the following metropolitan and regional LHNs:

- Central Adelaide Local Health Network Incorporated
- Northern Adelaide Local Health Network Incorporated
- Southern Adelaide Local Health Network Incorporated
- Barossa Hills Fleurieu Local Health Network Incorporated
- Yorke and Northern Local Health Network Incorporated.

We conducted interviews with staff and examined documentation from one hospital in each of the selected LHNs and from two medi-hotels to obtain staff views and gather evidence on PPE distribution processes, selection and use guidance and fit-testing arrangements.

3.4 What we did not review

We did not review:

- the State's COVID-19 response
- the management of medi-hotels
- procurement processes used for PPE purchases
- the clinical appropriateness of PPE items held or guidance released to staff for the selection and use of PPE.

SA Health finished constructing a new distribution centre in September 2021 and is implementing a new direct to imprest distribution model. We did not review the new distribution centre or the direct to imprest distribution model as they were not fully operational at the time of our audit.

4 Planning

What we found

We found that the following elements of PPE planning were not operating effectively:

- SA Health's role in meeting the PPE supply needs of other SA Government agencies and the State as a whole is not clear
- SA Health's PPE demand forecasting methodology does not include elements necessary to effectively forecast PPE demand
- the current emergency PPE stock holding model is not supported by documented analysis and sound evidence
- SA Health's stockpiling arrangements for PPE in a viral respiratory disease pandemic are unclear
- SA Health does not have an up-to-date strategic procurement plan for PPE.

We also found the following area which needs to be improved to ensure PPE planning is effective:

• SA Health does not have a formal agreement with the Commonwealth Government specifying respective roles and responsibilities for PPE in a health emergency.

What we recommended

To help ensure SA Health could effectively meet PPE needs as COVID-19 restrictions were progressively lifted, we recommended it prioritise the update of its PPE demand forecasting methodology to consider expected infection transmission rates, hospitalisation rates and models of care, and PPE usage policies.

To help it effectively prepare for future health emergencies, we recommend SA Health:

- clarify, document and communicate its roles and responsibilities for supplying PPE to external organisations in the event of a viral respiratory disease pandemic
- periodically review its emergency PPE stock holding model to ensure it is appropriate and supported by robust analysis, sound evidence and lessons from recent relevant experience
- update the viral respiratory disease pandemic response plan to reflect its planned approach for PPE during a health emergency and the respective roles and responsibilities of DHW business units and the LHNs
- update its procurement strategic procurement plan for PPE to meet ongoing business needs and prepare for future health emergencies
- liaise with the Commonwealth Government to formally agree on the objectives of national and South Australian PPE stockpiles and the sharing of information on PPE items and quantities held in these stockpiles.

4.1 Introduction

Effective planning is required to ensure appropriate PPE is available where and when needed across SA Health and is particularly important in preparing for future health emergencies. Figure 4.1 outlines the key steps for effective PPE planning.

Figure 4.1: Key steps for effective PPE planning



Identify the organisations that SA Health is responsible for supplying PPE.



Forecast PPE demand based on the needs of these organisations and potential different scenarios.



Identify PPE stock requirements to meet forecast demand.



Develop a procurement strategy to meet identified PPE stock requirements.

Sections 2.2 to 2.4 provide further details on SA Health's PPE planning approach.

4.2 Findings

4.2.1 SA Health does not have a clear role in meeting the PPE supply needs of other SA Government agencies and the State as a whole

Recommendation

We recommend SA Health clarify and document its roles and responsibilities for supplying PPE to external organisations in the event of a health emergency and during business-as-usual periods. This includes clarifying SA Health's roles and responsibilities for sourcing, storing and supplying PPE for:

- other SA Government agencies
- local government
- aged care facilities
- other health care providers (such as private hospitals and general practice)
- disability organisations
- private businesses.

We recommend SA Health clearly communicate its PPE roles and responsibilities directly and on its website to:

- ensure external stakeholders have a common understanding and awareness of SA Health's role
- clarify what organisations in each sector need to do in maintaining their own PPE supplies.

Finding

SA Health established a COVID-19 Response PPE Distribution Decision Matrix for the provision of PPE to specified groups, including general practice, whole of government, non-government organisations, the National Disability Insurance Scheme and aged care providers.

The matrix does not specify SA Health's roles and responsibilities for meeting the PPE supply needs of other SA Government agencies or external organisations, including:

- the circumstances in which agencies and external organisations can approach SA Health for PPE supplies
- when they must secure their own supplies.

This lack of formalised roles and responsibilities means SA Health's role in ensuring South Australia has appropriate PPE supplies where and when they are required is unclear. This increases the likelihood of PPE shortages in South Australia as the demand for PPE that SA Health is planning to meet and procure for may not be consistent with the expectations of other SA Government agencies and external organisations. This risk is increased where organisations external to SA Health have difficulties procuring their own PPE supplies.

SA Health response

SA Health has updated the PPE Distribution Decision Matrix and documented the PPE Distribution and Prioritisation Process to assist with the distribution of PPE throughout South Australia and ensure that PPE stock is available in sufficient supply to meet the requirements of all industries.

These documents were distributed to members of the PPE and Pharmacy Governance Group and approved on 29 November 2021.

The documents will be published on the SA Health intranet.

4.2.2 SA Health's demand forecasting methodology does not include elements necessary to effectively forecast PPE demand

Recommendation

We recommend SA Health update its demand forecasting methodology for PPE across the SA Health system to consider:

- infection transmission rates
- hospitalisation rates and models of care
- clinical guidance on PPE selection and use
- the range of different users that SA Health is responsible for supplying with PPE.

We also recommend SA Health:

- perform demand forecasting for different potential scenarios to plan and prepare for best and worst case outcomes
- engage with LHNs to confirm that site-specific factors have been considered in the forecasting methodology
- regularly review its forecasting methodology and assumptions used to ensure that they remain up to date and appropriate, including changes to clinical guidance on PPE usage that have an effect on demand and lessons from recent experiences
- compare forecast and actual outcomes regularly to test the reliability of its demand forecasting model.

Finding

Effective demand forecasting is necessary to identify the types and quantities of PPE required to meet SA Health's needs and safely deliver health services.

SA Health currently forecasts ongoing demand for PPE based solely on historical PPE usage patterns. Given the constantly evolving nature of the COVID-19 pandemic, historical usage patterns on their own are not always a reliable indicator of future PPE demand.

Experience during the COVID-19 pandemic has shown that PPE demand can rise very quickly and diverge from historical usage patterns if there are increased infections in the community or changes are made to guidance on the use of PPE, such as the introduction of requirements to wear masks in all indoor public spaces. Section 2.4.2 provides more details on the factors influencing PPE demand.

Consistent with experience in other jurisdictions, additional elements need to be considered to effectively forecast PPE demand including epidemiological data and scenario modelling.

At the time of our audit, SA Health was developing a project roadmap to improve its demand planning and forecasting approach.

SA Health response

SA Health engaged a university to assist with its PPE demand modelling in preparation for the opening of South Australia's borders.

SA Health will continue to regularly review its PPE demand modelling and assumptions to ensure they are appropriate and relevant. This includes capturing the effects on PPE demand of any changes in clinical guidance and comparing forecast to actual outcomes to confirm the reliability of its demand forecasting model.

4.2.3 SA Health's emergency PPE stock holding model is not supported by documented analysis and sound evidence

Recommendation

We recommend SA Health:

- periodically review its emergency stock holding model, including underlying
 assumptions, to ensure that it is appropriate. The chosen model should be supported
 by documented analysis, sound evidence and lessons from relevant recent experience
- clearly define roles and responsibilities for determining the appropriate emergency stock holding model.

Finding

SA Health's target stockpile levels at the time of our audit were six months for gloves, gowns and aprons and 12 months for surgical masks, respirators, safety glasses/goggles and face shields. SA Health advised us that these target levels were based on recommendations provided by the Emergency Management Unit, reflecting demand for PPE experienced during the 2009 – 2010 swine flu pandemic. We found the targeted levels used by SA Health did not align with the recommendations from the Emergency Management Unit, which proposed that nine months' stock of key PPE items should be maintained to ensure SA Health can continue to manage presentations during a pandemic outbreak.

We found SA Health was unable to provide documented analysis substantiated by appropriate evidence to support the basis for:

- the target PPE quantity of 6 to 12 months' worth of supply
- the range of PPE products held as emergency stock.

It is important that the emergency stock holding model is backed by robust analysis supported by appropriate evidence to provide a well-informed basis for identifying PPE requirements. This includes consideration of relevant recent local, interstate and international COVID-19 experience to better prepare for future health emergencies.

SA Health response

SA Health engaged a university to assist with its PPE demand modelling in preparation for the opening of South Australia's borders.

SA Health has used the PPE modelling report to define ongoing minimum/maximum requirements for PPE stock levels and product range. SA Health will also use the data in the report to create a calculator and methodology factsheet to update PPE requirements.

Additionally, SA Health will develop a new PPE emergency stock holding model procedure to document the process and clarify responsibilities.

One LHN indicated that the emergency PPE stock holding model needs to reflect LHNs' activity profile and ideally be proactively managed by the Procurement Goods and Logistics Team of PSCM.

4.2.4 SA Health's stockpiling arrangements for PPE in a viral respiratory disease pandemic are unclear

Recommendation

We recommend SA Health update the VRD pandemic response plan to reflect the planned approach for PPE in a health emergency, including:

- whether it plans to maintain a stockpile for each type of PPE to ensure supplies do not run low during periods of extremely high demand
- the key steps to be followed for PPE supplies in the preparedness, response and recovery phases
- the roles and responsibilities of relevant SA Health units including LHNs.

The potential costs and benefits of maintaining stockpiles for PPE items should be considered, as holding additional stock in PPE categories may provide SA Health with a buffer enabling it to purchase stock when prices are favourable.

The updated VRD pandemic response plan should be communicated to all responsible parties, including LHNs, to ensure they are aware of PPE stockpiling arrangements and respective roles and responsibilities.

Finding

SA Health's planned approach to securing appropriate PPE supplies in the preparedness, response and recovery phases of a viral respiratory disease pandemic is outlined in the SA Health Viral Respiratory Disease Pandemic Response Plan (including influenza, COVID-19, SARS and MERS) (VRD pandemic response plan), which was last updated in March 2020.

We found the PPE stockpile arrangements in the VRD pandemic response plan did not reflect actual practice during the COVID-19 pandemic, as a central PPE stockpile was not being maintained in line with the plan.

SA Health also advised us that the level of PPE stock it holds has evolved during the COVID-19 pandemic. For example, it entered into an agreement with Detmold to manufacture PPE masks locally in 2020 and it considers there is a reduced need for it to hold large stocks of masks given this new local manufacturing capacity.

Without an up-to-date VRD pandemic response plan, SA Health's PPE stockpile arrangements for a viral respiratory disease health emergency are unclear. For example, it is not clear whether it plans to maintain stockpiles for PPE supplies that are not manufactured in South Australia by Detmold, such as gloves, gowns and aprons.

Our interviews with Health Service Support staff also indicated that LHN roles and responsibilities for pandemic stockpiles of PPE under the plan were unclear and generally not followed. For example, the plan states that monitoring PPE stock levels and distributing PPE within the LHNs is the responsibility of LHNs, but this role has instead been performed by PSCM during the COVID-19 pandemic. This lack of clarity increases the likelihood of inconsistent or ineffective PPE stockpiling practices being adopted by LHNs.

SA Health response

The VRD pandemic response plan provides a strategic outline of the SA Government's and SA Health's response to a viral respiratory disease pandemic in Australia and describes the high-level decisions and broad approach the SA Government and health sector will take to respond to a pandemic.

The PPE distribution plan which is a subplan of the VRD pandemic response plan describes how the control, supply and distribution of PPE should be managed. The PPE subplan is significantly out of date, in light of COVID-19, and a university has been engaged to update the subplan.

The subplan will be updated in consultation with relevant areas such as the Communicable Disease Control branch, infection control advisory group, enabler workstream and State Control Centre Health. Once completed the subplan will be communicated to all key stakeholders.

One LHN indicated that HSS staff are the only logistics/supply chain personnel attached to the LHN and they, by default, manage local deficits in supply chain skills. Confirmation of their roles and responsibilities and integration with the LHN warrants consideration.

4.2.5 SA Health does not have an up-to-date strategic procurement plan for PPE

Recommendation

We recommend SA Health update its strategic procurement plan for PPE to meet ongoing business needs and prepare for future health emergencies. The plan should identify procurement objectives, strategic actions with implementation time frames and performance measures.

The plan should also consider:

- the costs and benefits of different strategies to mitigate the impact of supply disruptions
- expected levels of PPE demand based on the current selection and use guidance
- outcomes and recommended actions from recently completed independent consultant reviews of supply chain risks
- PPE demand from other SA Government agencies and external organisations
- the storage capacity of the new distribution centre and how this impacts the level of PPE stock that can be held
- PPE stockpiling arrangements in the VRD pandemic response plan.

Finding

We found that SA Health does not have an up-to-date strategic procurement plan that sets out how it is going to meet its PPE requirements, now and into the future. We found that existing strategic procurement plans for key types of PPE critical for infection control were

developed up to eight years ago and are out of date. Supply chain risks and demand requirements have significantly changed since these plans were developed.

We also found that the existing plans do not reflect:

- the current scope of users that SA Health supplies with PPE
- the mechanisms that SA Health has implemented in response to COVID-19 to secure supply continuity, such as establishing local mask manufacturing facilities and expanding supplier panels
- improvements recommended by an independent consultant in their supply chain risk review and outcomes from lessons learnt exercises performed by SA Health.

Without an up-to-date strategic procurement plan:

- SA Health lacks a clear, integrated plan of action to procure PPE in the current operating environment and respond to risks being faced
- procurement objectives, priorities, time frames and responsibilities for actions are unclear.

This increases the risk of insufficient or inappropriate PPE being procured to meet user needs and not achieving value-for-money outcomes.

SA Health advised us that it is working on updating its strategic procurement plan and is assessing the medium to long-term impact of COVID-19 on expected PPE usage and spend. This includes taking into account long-term changes to clinical practice increasing PPE usage beyond the current emergency conditions and better knowledge of cost drivers. As part of updating the strategic procurement plan, an independent consultant has been engaged to provide strategic advice on:

- emergency stock holding models
- how best value-for-money outcomes can be achieved in the current COVID-19 impacted marketplace.

SA Health response

SA Health will establish a strategic procurement and category management plan specifically for PPE categories.

4.2.6 SA Health does not have a formal agreement with the Commonwealth Government specifying respective roles and responsibilities for PPE in a health emergency

Recommendation

We recommend SA Health liaise with the Commonwealth Government and formally agree on Commonwealth and SA Government roles and responsibilities for PPE supplies in a health emergency, including:

• the respective objectives of national and South Australian PPE stockpiles

- the types of PPE to be held in national and South Australian PPE stockpiles
- regular and systematic information sharing on PPE items and quantities in national and South Australian PPE stockpiles
- the circumstances in which the SA Government can access the NMS
- deployment arrangements for the NMS.

The formal agreement should reflect lessons from the COVID-19 pandemic that can be applied to future health emergencies.

Finding

The Commonwealth Government established the NMS as a strategic reserve of drugs, vaccines, antidotes and PPE for use in national health emergencies.

There is no formal agreement between the Commonwealth and SA Governments specifying respective roles and responsibilities for PPE in a health emergency or the objectives of the NMS and SA Government PPE stockpiles. This includes a lack of formal agreement on the roles of the Commonwealth and SA Governments for supplying PPE to general practitioners and aged care providers during a health emergency.

We concluded that SA Health needs a clear understanding of the role of the NMS, what is held in it and the circumstances in which it can supply PPE, to ensure SA Health can effectively plan for meeting South Australia's PPE needs.

A formal agreement with the Commonwealth Government will help to ensure:

- there is a common understanding of State and Commonwealth roles and responsibilities for PPE in a health emergency, including the supply of PPE to general practitioners and aged care providers
- transparency on national and state PPE stock holdings and the allocation and distribution of national and state PPE supplies
- the adoption of a coordinated approach to limit the duplication of PPE management activities between the Commonwealth and SA Governments.

Section 2.3.3 provides further details on the Commonwealth Government's NMS.

SA Health response

SA Health is responsible for ensuring adequate supplies of PPE for SA Health. The Commonwealth Government has a national stockpile of PPE supplies which can be accessed by State Governments but only when there is no alternative.

The Commonwealth Government has implemented a formal request process for the NMS should the state require assistance. This process will continue to be utilised by SA Health if needed.

Any agreement with the Commonwealth Government would have to capture other states and the Commonwealth Government would be responsible for coordinating this.

Audit comment

We acknowledge the Commonwealth Government's lead role in formalising arrangements for national PPE stockpiles. In our view, the value in the SA Government pursuing a formal agreement with the Commonwealth Government is to help ensure all PPE users, including GPs and aged cared providers, understand who will assist them in the event of widespread and severe PPE shortages.

4.2.7 Expired PPE may not be identified and actioned promptly

Recommendation

We recommend SA Health:

- record expiry dates in Oracle for PPE, with priority given to PPE supplies that are critical for emergency situations and have a higher risk of stock obsolescence
- analyse PPE stock to determine whether it is likely to be used before it expires. Where excess stock is detected, strategies should be implemented to minimise stock loss.

Finding

SA Health is holding a significant amount of PPE stock in preparation for surges in demand for PPE during the COVID-19 pandemic.

We found that most COVID-19 pandemic PPE stock with a limited useful life did not have expiry dates recorded in the Oracle inventory management system.

As certain types of PPE may no longer be effective for infection control purposes once it has expired, product expiry dates should be actively managed to ensure that PPE on hand can be readily used when it is needed.

Without expiry date data, SA Health cannot effectively identify stock nearing or past its expiry date to ensure expired stock is replaced promptly and minimise stock loss. This increases the risk that expired stock will not be detected until it is picked or replenished²⁰ and that PPE cannot be readily used when needed.

SA Health response

While transitioning to the new distribution centre, SA Health will manually capture expiry dates in a register and will review this information quarterly to ensure all stock on hand is within expiry dates.

Following completion of the transition to the new distribution centre, SA Health will review system options to effectively capture appropriate expiry date data in the Oracle inventory system.

²⁰ SA Health staff check expiry dates on product packaging when picking and replenishing stock to ensure expired stock is not issued.

5 Governance

What we found

We found that the following elements of PPE governance were not operating effectively:

- the key governance group enabling LHN input into SA Health's PPE strategy did not meet regularly in 2021 and there are gaps in the reporting provided to PPE governance committees on stock availability
- there is scope to improve the monitoring and checking performed to ensure fit testing for respirators is completed promptly across all LHNs.

We also found the following areas which need to be improved to ensure effective governance over PPE:

- there are gaps in guidelines and processes for prioritising the allocation of PPE to other SA Government agencies and external organisations
- the roles and responsibilities for key PPE management activities are unclear as the SLA between PSCM and the LHNs for procurement and supply chain services remains in draft
- consultant recommendations to improve the management of PPE supply chain risks were not systematically monitored to confirm their implementation
- reporting and checking processes could be improved to provide assurance that all PPE in the SA Health purchasing catalogue is recorded in the Australian Register of Therapeutic Goods.

What we recommended

To help ensure SA Health could effectively meet PPE needs as COVID-19 restrictions were progressively lifted, we recommended it:

- closely monitor the need for key PPE governance groups to meet regularly for the remainder of the COVID-19 pandemic
- provide regular reporting to PPE governance committees on PPE stock on hand against targeted stock levels and fit testing coverage of staff across all LHNs.

To help ensure effective preparedness for future health emergencies and improve the ongoing management of PPE, we recommend SA Health:

- finalise the SLA between PSCM and the LHNs and obtain approval from all party delegates
- document whether consultant recommendations made on managing supply chain risks are accepted and monitor the implementation of accepted recommendations against targeted completion dates

- establish guidance on the release of PPE supplies to other SA Government agencies and external organisations during periods of high demand for PPE, including PPE request assessment criteria and approval processes
- document procedures for checking that PPE purchased is on the Australian Register of Therapeutic Goods and retain evidence of the checks performed.

5.1 Introduction

Effective governance arrangements are required to ensure appropriate PPE is available where and when needed across SA Health, including:

- establishing clear lines of accountability to ensure a rapid and coordinated PPE response during a health emergency
- communicating information on PPE stock levels to key stakeholders to ensure confidence is maintained in the availability of PPE supplies
- monitoring PPE fit testing to ensure it is performed when required and that PPE purchased meets TGA quality standards.

Section 2.5 provides further details on PPE governance arrangements.

5.2 Findings

5.2.1 The key governance group enabling LHN input into SA Health's PPE strategy did not meet regularly in 2021 and does not have direct regional LHN representation

Recommendation

We recommend the PPE and Pharmacy Governance Group continue to meet regularly for the remainder of the COVID-19 pandemic. In the event a decision is made to suspend regular meetings, we recommend the decision be approved by a quorum of the group under its terms of reference and recorded in its minutes.

We also recommend SA Health consider updating membership requirements for the PPE and Pharmacy Governance Group to reflect direct representation from regional LHNs.

Finding

The PPE and Pharmacy Governance Group has a key role in enabling clinical and LHN input into SA Health's PPE strategy and ensuring appropriate PPE supplies are available where and when needed. Section 2.5.2 provides further details on the roles and responsibilities of the group.

We found the PPE and Pharmacy Governance Group did not meet for a period of seven months between December 2020 and June 2021. It reconvened in July 2021 and met regularly for the remaining period of our audit.

SA Health advised us that in December 2020 there was no longer work for the PPE and Pharmacy Governance Group to do and there was collective agreement that it would not continue to meet regularly. This was on the understanding that it would reconvene if any members of the group required it to do so. We found that the decision not to meet regularly was not formally approved and recorded in the group's minutes.

Our interviews with LHNs indicated that the PPE and Pharmacy Governance Group is a valuable forum for providing LHN input on the management of PPE, including:

- PPE technical specifications
- update of PPE selection and use guidance
- monitoring of PPE stock availability at LHNs
- monitoring of PPE fit testing performed at LHNs
- management of PPE risks during the COVID-19 pandemic.

LHNs highlighted concerns about potential shortages of PPE as the State 'opens up' and more patients with COVID-19 enter public hospitals.

Regional LHNs also indicated that they do not have direct representation on the group and therefore PPE issues and challenges specific to regional LHNs, such as timely supply to remote locations, may not be raised and addressed.

Consistent with the feedback from our LHN interviews, we concluded that the PPE and Pharmacy Governance Group should meet regularly throughout the COVID-19 pandemic and that direct regional LHN representation on the group should be considered. This will ensure the group can respond promptly to emerging risks and issues, such as those related to the easing of restrictions and any new outbreaks or strains of the virus. It will also enable ongoing LHN input into PPE management across SA Health and help ensure LHN staff have confidence in stable PPE supply by providing ongoing visibility over PPE stock levels and how PPE risks are being managed.

SA Health response

SA Health is undertaking a review of the committee structure which underpins the health system response to managing COVID-19. The role and functioning of the PPE and Pharmacy Governance Group is being considered as part of this broader governance review.

The frequency of future meetings and arrangements for a pause in meetings will be considered as part of this review and be included within the PPE and Pharmacy Governance Group's terms of reference.

The membership of the PPE and Pharmacy Governance Group will be reviewed after the governance review to reflect its function and included within revised terms of reference.

5.2.2 Gaps in reporting on PPE stock availability to governance groups

Recommendation

We recommend SA Health provide PPE governance groups and others who have a role in overseeing and managing PPE stock availability with regular reporting on:

- targeted PPE stock levels and how actual stock on hand compares to these targets
- explanations for any unfavourable variances between targeted and actual stock levels
- forecast demand against supply
- key performance indicators for critical types of PPE products.

Finding

An emergency stock items dashboard is the main form of regular reporting on stock levels provided to PPE governance groups. It is based on data from SA Health's Oracle inventory management system. It shows various metrics for stock at the distribution centre and in bulk stores, including stock on hand in single units and the number of days' worth of stock on hand.

We found that reporting provided to PPE governance groups does not clearly state the targeted stock levels that SA Health is aiming to maintain at a category level and how stock on hand compares to these targets. As a result, PPE governance group members are unable to determine whether there is sufficient PPE stock on hand to meet targeted levels and future demand requirements.

We also found that PPE governance groups are not provided with reporting on key performance indicators on stock availability for critical types of PPE products, non-standard product purchases and LHN replenishment times. Reporting on these indicators will provide PPE governance group members with information on PPE supply and demand across the health system to help them identify stock management issues and develop strategies to ensure the ongoing availability of PPE.

Section 2.5.2 provides further details on the PPE governance groups.

SA Health response

SA Health will review the Emergency Stock Items Dashboard to include additional data and commentary including targeted stock levels.

5.2.3 SA Health monitoring to ensure fit testing for respirators is completed promptly across all LHNs could be improved

Recommendation

We recommend SA Health implement periodic monitoring and checking to identify medical and nursing staff across all LHNs who require fit testing for particulate filter respirators (PFRs). This monitoring should focus on ensuring all staff assigned to higher risk areas where infectious aerosols are generated have a record of a successful fit test.

We also recommend regular ongoing reporting be provided to an SA Health governance committee on the number of outstanding fit tests required at each LHN. This reporting should detail the action taken to ensure all outstanding fit tests identified are completed promptly.

Finding

SA Health protocols state that PFRs (P2/N95 respirators or equivalent) are required to be worn in a variety of circumstances, including when providing routine care for individuals with suspected or confirmed COVID-19. A PFR is a medical device designed to protect the wearer from infectious aerosols generated directly from the patient or created during aerosol-generating procedures.

Where SA Health staff are required to wear PFRs, they must undergo fit testing to determine which PFR best fits their face and achieves an adequate seal. Fit testing is necessary to ensure PFRs work effectively in preventing the spread of infectious diseases.

We found that there is no regular reporting on whether PFR fit testing is being promptly performed for LHN staff who require it.

Our interviews at LHNs identified Nurse Unit Managers at some regional sites who were not satisfied that fit testing had been completed for all relevant staff. They stated that regional hospitals did not always have access to adequate resources (fit testing machinery and appropriately qualified personnel) to conduct timely fit testing. Information provided to us by metropolitan and regional LHNs also identified several employees requiring a fit test who were yet to have a successful fit test.

SA Health needs to perform regular monitoring and checking to obtain assurance that fit testing for PFRs is being performed promptly where required across all LHNs. Without this monitoring and checking, SA Health may not effectively identify outstanding required fit tests and implement appropriate follow-up action. This increases the risk that PFRs used by some staff will not fit properly and will be ineffective in preventing the spread of infectious diseases.

SA Health response

SA Health advised that monitoring to ensure fit testing is completed promptly in line with policies and procedures is the responsibility of LHNs.

LHNs responded that they have, or plan to implement, a range of processes to monitor PPE fit testing including:

- prioritising high risk areas for fit testing (eg emergency departments and intensive care units)
- updating the CHRIS human resources system to record data on fit testing completed
- providing regular reporting to LHN governance committees on numbers of staff fitted and escalating instances of non-compliance where appropriate.

Audit comment

We acknowledge the actions individual LHNs are implementing to monitor fit testing at their sites. However, in our view, there is also value in having central governance committee oversight on the status of fit testing across LHNs to ensure outstanding fit tests are identified and actioned appropriately on an ongoing basis.

5.2.4 Gaps in guidance on prioritising the allocation of PPE when it is in high demand

Recommendation

We recommend SA Health:

- establish guidance on the prioritisation and allocation of PPE to other SA Government agencies and external organisations for circumstances where PPE is in high demand and limited supplies are available (for example, a tiered priority system that allocates PPE according to relative need)
- develop a framework that defines assessment and approval requirements for releasing PPE supplies to external organisations, particularly in high risk situations such as when stock needs to be conserved and large and/or unusual quantities are requested.

Finding

PPE shortages were experienced across the world, including in South Australia, at the beginning of the COVID-19 pandemic as supply chains came under pressure.

To ensure preparedness for emergency situations where PPE is in high demand and limited supplies are available for distribution, it is important that SA Health has clear guidance and processes in place for directing PPE supplies where they are needed most.

We found:

- the prioritisation basis for allocating PPE to external organisations is not defined
- key processes to assess and approve external requests for PPE and associated responsibilities are not documented.

Without a clear prioritisation system, supplies of critical PPE may not be provided to those most in need in a fair and consistent manner, especially when the health system is under pressure and quick decisions need to be made.

SA Health response

SA Health updated the COVID-19 Personal Protective Equipment Distribution Decision Matrix in November 2021. This tool will be used to assist the rationalisation and distribution of PPE throughout South Australia to ensure that the current stock is available in sufficient supply to meet the requirement of all industries.

One LHN indicated that the inability to monitor/project the impact of activity surges at an LHN level is a risk to the supply chain. The approval process to release PPE in high demand should be based on activity modelling.

5.2.5 The roles and responsibilities of the PSCM and LHNs for key PPE management activities are unclear as the draft SLA is not finalised

Recommendation

We recommend SA Health:

- finalise all pending sections in the SLA for procurement and supply chain services, including materials management and demand planning performance measures
- obtain signed approval for the SLA from all party delegates
- monitor SLA performance measures through regular reporting to a governance committee.

When the new distribution centre and direct to imprest model commence operation, the responsibility matrix and performance measures should be reviewed to ensure they are consistent with the new model.

Finding

PSCM, the LHNs, SAAS and Statewide Clinical Support Services have established a draft SLA for the provision of procurement and supply chain services.

The draft SLA has several pending sections yet to be finalised, including key performance indicators, and has not been agreed by all relevant parties. This increases the risk that PSCM and LHN roles and responsibilities for PPE procurement, inventory management and distribution activities outlined in the draft SLA may be unclear or disputed.

The key performance indicators in the draft SLA also may not be agreed to and regularly reported against, including:

- stock availability
- external supplier delivery performance
- internal delivery performance
- the accuracy of demand forecasting.

Regular reporting on stock availability, delivery performance and the accuracy of demand forecasting performance indicators could provide LHNs with additional comfort that appropriate PPE supplies will be available where and when needed at their sites.

SA Health plans to transition to a new distribution centre and direct to imprest model in 2022, which will involve significant changes in PSCM and LHN roles and responsibilities. It is important that the responsibility matrix and performance measures in the SLA are consistent with the new model to ensure the effective management of PPE.

SA Health response

PSCM will continue to liaise with LHNs to establish an SLA which captures the points recommended by Audit.

One LHN indicated that the responsibilities for planning, sourcing, procuring, contracting and receipting must be clearly defined.

5.2.6 Consultant recommendations to improve the management of PPE supply chain risks were not systematically monitored for implementation

Recommendation

We recommend SA Health assess all PPE risk treatment and improvement opportunity recommendations made in the October 2020 supply chain risk review and the follow-up review commenced in August 2021. The assessments should be documented and should indicate whether the recommendations and improvement opportunities have been accepted and the supporting rationale. Responsible officers should also be assigned to each accepted recommendation and improvement opportunity and targeted completion dates for implementation set.

Further, we recommend SA Health monitor the implementation of accepted supply chain risk review recommendations and improvement opportunities through regular reporting to a governance committee.

Finding

An independent consultant completed a supply chain risk review for SA Health in October 2020. The review identified the risk exposure for several PPE items as extreme (headwear, gloves, gowns and aprons) and high (eye protection, coveralls, masks and face protection).

The review suggested several treatments to mitigate these PPE risk exposures and system, data and process improvement opportunities to manage supply chain risks, including:

- increasing stock levels and investigating long-term demand planning activities with suppliers who do not foresee shortages in their supply chain
- monitoring countries that prohibit the exportation of critical medical consumables and equipment required by SA Health and preferencing suppliers that do not operate in high risk locations
- closely monitoring all price increases and undertaking a review in 12 months to ensure a return to pre-COVID-19 prices
- commencing stock audits on selected suppliers to ensure they hold contractually obligated stock.

SA Health did not develop action plans for the risk treatment recommendations and improvement opportunities to mitigate supply chain risks in the October 2020 report or monitor their implementation. As a result, it does not have assurance that they have all been appropriately implemented. This increases the likelihood that risks to the PPE supply chain may not be effectively managed.

SA Health re-engaged the independent consultant in August 2021 to follow up the October 2020 supply chain risk review.

SA Health response

SA Health will begin implementation of agreed actions when the follow up supply chain risk review that commenced in August 2021 is finalised.

5.2.7 Checks to ensure all PPE purchased is in the Australian Register of Therapeutic Goods should be documented

Recommendation

We recommend SA Health document procedures on the process for checking that PPE is in the Australian Register of Therapeutic Goods. We also recommend SA Health document the checks performed and retain evidence of this check.

Finding

PPE in the Australian Register of Therapeutic Goods (ARTG) has been assessed by the TGA for compliance with a set of essential principles that address quality, safety and performance.

We found there is no documented procedures outlining the process for checking that PPE is in the ARTG, including who performs the check, when it occurs and how it is evidenced.

We also found that checks performed to ensure PPE in the SA Health purchasing catalogue is recorded in the ARTG were not documented. Consequently, there is no audit trail to evidence performance of the check and provide management with assurance that all PPE in the SA Health catalogue is in the ARTG and complies with TGA quality, safety and performance principles.

Section 2.5.4 provides further details on PPE quality standards.

SA Health response

At the time of the audit, SA Health did not provide evidence of performing a check against the ARTG for a specific sample of PPE.

SA Health advised that when a PPE product is required to be checked against the ARTG, evidence of this check having been completed is recorded in the procurement evaluation documentation for the product.

Audit comment

In our view, the check that PPE is in the ARTG should be documented in a procedure and evidence of the check should be retained.

6 Distribution

What we found

We found that the following elements of PPE distribution are not operating effectively:

- LHN imprest owners are not receiving sufficient information about PPE items that are in low supply or are unavailable
- SA Health does not have system records of PPE on hand for imprests and secondary stores, which results in a lack of visibility of stock levels at these locations.

We also found the following areas that need to be improved to ensure effective distribution of PPE:

- several hospital sites are maintaining their own secondary local stores of PPE,
 which does not align with SA Health inventory management procedures
- HSS roles and responsibilities for key distribution processes are not documented and are unclear
- PPE is not always stored securely in imprests and one regional warehouse did not have suitable conditions for storing PPE.

What we recommended

To help ensure SA Health could effectively meet PPE needs as COVID-19 restrictions were progressively lifted, we recommended it:

- provide LHN imprest owners with timely and reliable information on the availability of PPE stock items, including items experiencing delays in supply
- consider developing a common approach and procedures across SA Health for the maintenance of secondary local stores of PPE by hospital sites.

To help ensure effective preparedness for future health emergencies, we recommend SA Health consider assessing the feasibility of upgrading inventory systems for tracking PPE items used and quantities of PPE stock held in imprests.

To improve the ongoing management of PPE, we recommend SA Health:

- document roles and responsibilities for all staff across the distribution process, along with key operating and management processes
- review the physical storage of PPE at hospital sites to confirm they provide an appropriate level of security and a suitable environment to protect the quality of PPE.

6.1 Introduction

Effective distribution arrangements between the central distribution centre and LHN bulk stores and imprests ensure that appropriate PPE is available where and when needed across SA Health.

As part of our audit of the distribution of PPE, we selected a sample of metropolitan and regional hospitals and spoke to HSS staff and Nurse Unit Managers from each of them. We also selected two medi-hotels and spoke to Advanced Nurse Unit Managers assigned to them. We spoke to nurse unit managers as they are the imprest owners for their units/departments.

Our findings reflect the responses we received in our interviews. We considered these responses collectively and have summarised the issues that were common across most of the staff we interviewed.

Section 2.6 provides further details on SA Health's PPE distribution arrangements, including the management of bulk stores and imprests during the period of our audit and the new direct to imprest model planned for implementation in 2022.

6.2 Findings

6.2.1 Imprest owners do not receive sufficient information about PPE items that are in low supply or are unavailable

Recommendation

We recommend SA Health review PPE inventory processes, system functionality and reporting to provide imprest owners with timely and reliable information on the availability of PPE stock items, including items experiencing delays in supply. Existing PPE dashboards showing stock on hand across SA Health may provide useful information to imprest owners if supported by guidance on how to access and interpret the information.

We also recommend that SA Health provide clear direction on steps that imprest owners should take to ensure their imprest is carrying all necessary items of PPE, particularly where there are supply delays.

Finding

Most hospital and medi-hotel imprest owners we interviewed indicated that they do not receive sufficient information when PPE items are unavailable or are low in stock at the distribution centre.

Imprest owners provided examples of actions they had to take because they were only made aware of supply delays when particular stock, including PPE, was unavailable in their imprest room. These actions included:

 Nurse Unit Managers and HSS staff having to contact distribution centre staff or suppliers to determine the nature of the PPE supply issue

- sourcing PPE items needed urgently from other imprest rooms
- sourcing alternative PPE items from a different supplier.

We found the process for the alternative sourcing of PPE when supplies were not immediately available from the distribution centre was not consistent between or within sites. Rather than relying on the distribution centre for information about supply issues or for assistance with sourcing additional products, some Nurse Unit Managers have developed direct relationships with PPE suppliers.

Imprest owners also advised us that they have been frustrated and confused about the supply system due to a lack of communication on items with supply issues and uncertainty about the process for sourcing alternatives. They told us that the current approach is reactionary, time consuming and inefficient.

Given the issues highlighted by imprest managers, there is a risk that PPE items may not be immediately available from imprest stores when required and nurses may spend time on PPE procurement and inventory management activities rather than patient care.

We found that the information gaps on PPE stock levels were being addressed by HSS staff in one regional area by circulating information on PPE stock levels from the supply chain analysis dashboards to imprest owners.

SA Health response

SA Health will develop a template to share with imprest owners with information extracted from the Emergency Stock Items Dashboard. This report will be summarised in a manner that can be understood by imprest owners.

6.2.2 Maintenance of secondary local stores of PPE by hospital sites does not align with SA Health inventory management procedures

Recommendation

We recommend SA Health develop a common approach and procedures to ensure the processes for operating secondary local stores of PPE across hospital sites are transparent and consistent. This approach should ensure appropriate access to PPE is maintained and staff safety is prioritised at hospital sites, while also aligning with management expectations for efficient PPE inventory management across the SA Health system.

Finding

Hospital sites established secondary local stores of PPE in March/April 2020 to help address PPE supply shortages due to increased demand across the world. Secondary local stores are an additional store of PPE that can be accessed by hospital staff if they do not have the required items of PPE in their imprest.

We found that several hospitals continue to maintain their secondary local stores of PPE. This practice does not align with SA Health inventory management policies and procedures.

Creating and maintaining secondary local stores of PPE at hospitals increases the risk that:

- accurate quantities of PPE held across SA Health are not known, which makes it difficult to determine demand and supply requirements and may impact the integrity of the supply chain
- additional resources are required to store, monitor and manage them
- the storage and rotation of PPE is not in line with best inventory management practices
- PPE management processes and access to PPE are inconsistent across different hospitals.

Our enquiries with LHN staff found there was a common view that it is essential to maintain local stores to ensure the undisrupted supply of PPE and prioritise staff safety, as they are concerned that they will not be able to readily access what they need from the distribution centre if a PPE demand surge occurs in the future. One LHN advised us that the need to maintain local stores was also based on experienced delays and lack of information about stock availability and delivery quantities and timing.

SA Health response

SA Health has centralised the management of PPE through the DHW PSCM division.

In collaboration with LHNs, PSCM has implemented a process by which a new secondary store of PPE can be added to the Oracle inventory system as a LHN stock location.

LHNs may order additional PPE stock on the Oracle inventory system from the distribution centre for secondary stores.

6.2.3 LHNs do not have system records of PPE in imprests and secondary stores

Recommendation

We recommend SA Health conduct a cost-benefit analysis on enhancing the functionality of current systems to maintain records of stock levels and movements of key PPE held in imprests and secondary local stores.

Finding

We found that there are no inventory system records of the actual quantity of PPE stored in imprests or secondary stores held at LHNs.

The items ordered and delivered to the imprests are recorded in Oracle but there is no system to record items as they are used from imprests and secondary stores. As there is no record of when PPE is used there is no record of the quantity of PPE on hand in imprests at any given time. SA Health therefore does not have visibility over PPE stock levels held at hospital sites.

The lack of accurate information on PPE held at each hospital site increases the risk that:

- SA Health will not be able to effectively respond to future PPE demand surges and may run out of PPE at certain locations
- excessive quantities of PPE may be held at some locations without being identified.

We were advised that LHNs had to implement daily stocktakes of PPE in March 2020 to find out how much PPE was on hand. Some LHNs have continued to conduct regular stocktakes so that they know how much PPE they have at their hospital sites.

The LHNs advised us that these stocktakes took significant time and impacted on the time Nurse Unit Managers and other staff have available for their core responsibilities.

SA Health response

LHN imprest rooms are managed via a replenishment process. PSCM staff regularly scan products in all imprests which triggers the automatic reorder of PPE supplies from the distribution centre based on reorder points.

The reorder points have been recalculated to ensure stock does not drop below a minimum level and does not exceed the maximum amount agreed to be held in each imprest. Although current systems do not show actual stock on hand in imprests, the revised reorder points and replenishment process should ensure that PPE products do not drop below minimum quantities agreed with LHNs.

SA Health further advised that the PSCM is working with LHNs to review minimum and maximum stock levels and it is not considering upgrading the Oracle inventory system to reflect PPE stock levels and movements in imprests at the present time.

6.2.4 Roles and responsibilities for key distribution processes are not documented and are unclear

Recommendation

We recommend SA Health document and communicate roles and responsibilities for all staff across the distribution process, along with key operating and management processes for the distribution of PPE and other consumables.

Finding

We found that HSS staff are not clear about some of their roles and responsibilities. For example, they advised us that there was no clarity on the responsibilities they and central PSCM staff had for:

- following up back order items
- communicating with imprest owners about supply delays
- assisting with identifying and sourcing replacements for out-of-stock items.

We also found that many processes carried out by HSS staff at various locations are not documented.

Where there is a lack of clarity over roles and responsibilities and key operational and management processes are not documented, there is a risk that:

- processes will be inconsistent across different locations
- processes will not be in line with management expectations for the distribution of PPE
- sound management and operational processes may not continue when staff leave the organisation
- tasks might be duplicated between HSS staff and central inventory management and customer service teams.

SA Health response

SA Health will consolidate and update the responsibility matrix for PPE and communicate it to all relevant staff. Whilst most of these areas have existing procedures and protocols it is recognised that an overarching responsibility matrix that clearly defines roles and responsibility across the supply chain would be beneficial.

6.2.5 Imprest owners are not provided with training or information about their roles and responsibilities for managing imprests

Recommendation

We recommend SA Health provide imprest owners with training and information about their roles and responsibilities for managing imprests. The training should be offered at regular intervals to capture staff who become imprest owners when they move into Nurse Unit Manager roles.

Finding

Discussions with Nurse Unit Managers across our sample of hospitals and departments revealed that they do not receive specific information or training on:

- processes required to manage the imprest
- how the distribution system operates
- an imprest owner's scope of responsibilities.

We were also advised that they had not been provided with any policies or procedures on the processes they should follow or the responsibilities of key officers involved in the distribution process.

The Nurse Unit Managers expressed the view that they would benefit from obtaining a broader understanding of how the supply chain works, from distribution centre processes through to their imprest.

Where imprest owners do not have adequate information or understanding about the processes involved in operating their imprests they are more likely to require ongoing assistance from HSS staff, make errors in ordering/receiving stock and not respond efficiently or effectively to PPE supply issues.

SA Health response

SA Health will document the roles and responsibilities of imprest owners for managing imprests and communicate these to imprest owners, HSS staff and relevant staff in PSCM.

6.2.6 PPE is not always stored securely and one regional warehouse did not provide suitable conditions for storing PPE

Recommendation

We recommend SA Health review PPE physical storage arrangements at each site to confirm that they provide an appropriate level of security and a suitable environment to protect PPE. In doing so, we recommend a risk-based approach that focuses on key items of PPE in terms of desirability, safety and any expected spikes in demand.

Finding

The interviews we conducted with Nurse Unit Managers and Health Service Support staff at a sample of hospital sites identified that:

- many imprest rooms are not secure or restricted, meaning that anyone in the hospital can access the items in the imprest
- imprest rooms with swipe card access were generally able to be accessed by all hospital staff, not just those working in that particular area or department
- PPE is often stored in areas outside of the imprest due to the limited space available. The alternate storage areas are not always secure and do not restrict access
- one regional hospital warehouse has ongoing issues with a leaking roof. This requires
 PPE and other consumables to be stored in a smaller area or wrapped in plastic to
 avoid water damage.

Where PPE is not stored in a secured and restricted area, there is an increased risk that it may be misappropriated and therefore not available for use. We were advised that this risk was realised in 2020 when the State, in responding to the COVID-19 pandemic, entered into restrictions and lockdowns. Many hospitals had to take additional measures to keep items of PPE secure during these times.

Where the physical conditions are not appropriate for storing items of PPE, there is an increased risk that they will not be in a suitable condition for use when required and there may be additional costs to replace spoiled items.

SA Health response

Several LHNs responded that reviews of PPE physical storage arrangements have commenced at their sites to confirm their suitability. These reviews generally focus on bulk stores as they contain a much larger number of items than imprests.

LHNs also advised the actions taken to ensure the security of PPE including:

- reviews of key and swipe card access to PPE storage areas
- review of access logs to PPE storage areas
- ensuring security escorts are required when staff access PPE stores out of hours
- recent upgrades made to storage areas.

LHNs also indicated that any required repairs to storage facilities identified will be actioned promptly.

Appendix 1 – Additional information on surgical masks and respirators

Figure A1.1: Comparison between surgical masks and respirators

level 3, based on barrier performance. • Level One – low barrier protection, used when the wearer is not at risk of blood or body fluid exposure. • Level Two – moderate barrier protection, used when there is minimal exposure to blood or body fluids. • Level Three – maximum barrier protection, used when there is a risk of blood or body fluid splash or droplet exposure to microorganisms. Face seal fit Loose-fitting Level One – low barrier protection, used when the wearer is not at risk of blood or body fluid splash or droplet exposure to microorganisms. appropriate for non-oil based particles. The 95 in N95 indicates that the respirator is 95% efficient at filtering out contaminants like dusts, mists and fumes. P2 is a respiratory filter rating under Australian and New Zealand Standards that requires protection against airborne particles with 94% efficiency. Tight-fitting No Yes		Surgical mask	Respirator
Filtration Surgical masks are rated from level 1 to level 3, based on barrier performance. Level One – low barrier protection, used when the wearer is not at risk of blood or body fluid exposure. Level Two – moderate barrier protection, used when there is minimal exposure to blood or body fluids. Level Three – maximum barrier protection, used when there is a risk of blood or body fluid splash or droplet exposure to microorganisms. Face seal fit Fit testing requirement Purpose and use Surgical masks are rated from level 1 to level 3, based on barrier performance. Level One – low barrier performance. Level One – low barrier protection, used when the wearer is not at risk of blood or body fluid exposure to blood or body fluids. Page is a respiratory filter rating under Australian and New Zealand Standards that requires protection against airborne particles with 94% efficiency. Tight-fitting Yes Reduces the wearer's exposure to nonoil particles, including small particle aerosols and large droplets.			
level 3, based on barrier performance. • Level One – low barrier protection, used when the wearer is not at risk of blood or body fluid exposure. • Level Two – moderate barrier protection, used when there is minimal exposure to blood or body fluids. • Level Three – maximum barrier protection, used when there is a risk of blood or body fluid splash or droplet exposure to microorganisms. Face seal fit Fit testing requirement Purpose and use level 3, based on barrier protection, used when the wearer with protection against large droplets, splashes or sprays of bodily or other The 95 in N95 indicates that the respirator is 95% efficient at filtering out contaminants like dusts, mists and fumes. P2 is a respiratory filter rating under Australian and New Zealand Standards that requires protection against airborne particles with 94% efficiency. Tight-fitting Yes Reduces the wearer's exposure to nonoil particles, including small particle aerosols and large droplets.	Protection	Droplet protection	Airborne transmission protection
used when the wearer is not at risk of blood or body fluid exposure. • Level Two – moderate barrier protection, used when there is minimal exposure to blood or body fluids. • Level Three – maximum barrier protection, used when there is a risk of blood or body fluid splash or droplet exposure to microorganisms. Face seal fit Purpose and use Used When the wearer is not at risk of blood or body fluid splash or droplet exposure to microorganisms In e 95 in N95 indicates that the respirator is 95% efficient at filtering out contaminants like dusts, mists and fumes. P2 is a respiratory filter rating under Australian and New Zealand Standards that requires protection against airborne particles with 94% efficiency. Tight-fitting Yes Reduces the wearer's exposure to nonoil particles, including small particle aerosols and large droplets.	Filtration	_	The N in N95 indicates that the mask is appropriate for non-oil based particles.
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protection, used when there is a risk of blood or body fluid splash or droplet exposure to microorganisms. Face seal fit Loose-fitting Fit testing requirement Purpose and use Fluid resistant and provides the wearer with protection against large droplets, splashes or sprays of bodily or other Purpose and large droplets.		protection, used when there is minimal exposure to blood or	Australian and New Zealand Standards
Fit testing requirement Purpose and use Fluid resistant and provides the wearer with protection against large droplets, splashes or sprays of bodily or other Yes Reduces the wearer's exposure to non-oil particles, including small particle aerosols and large droplets.		protection, used when there is a risk of blood or body fluid splash or droplet exposure to micro-	airborne particles with 94% efficiency.
Purpose and use Fluid resistant and provides the wearer with protection against large droplets, splashes or sprays of bodily or other Reduces the wearer's exposure to non-oil particles, including small particle aerosols and large droplets.	Face seal fit	Loose-fitting	Tight-fitting
use with protection against large droplets, oil particles, including small particle splashes or sprays of bodily or other aerosols and large droplets.	~	No	Yes
	•	with protection against large droplets, splashes or sprays of bodily or other	

Appendix 2 – Guidance on PPE use and selection

Guidance on PPE selection

The selection of specific PPE items is based on the risk of transmission of potentially infectious micro-organisms.

SA Health's Personal Protective Equipment (PPE) Selection Policy Guideline outlines each type of PPE and provides a risk assessment table to help the user determine when that item of PPE is required.

Additionally, the SA Health COVID-19 Personal Protective Equipment Matrix sets out the items of PPE that should be used when treating patients:

- with suspected or confirmed COVID-19
- with COVID-19 risk factors
- without COVID-19 risk factors
- undergoing aerosol generating procedures.²¹

Guidance on PPE use

PPE must be used correctly to effectively protect against the risk of infection transmission.

The key aspects of correct PPE usage are ensuring that donning (putting on PPE) and doffing (taking off PPE) are undertaken in a methodical sequence, which includes thorough hand hygiene and respirators being properly fit tested and fit checked (see section 2.1.3).

Donning PPE Doffing PPE 1. Perform hand hygiene 1. Remove gloves 2. Put on gown 2. Perform hand hygiene 3. Put on mask or respirator 3. Remove gown 4. Perform hand hygiene 4. Put on protective eyewear 5. Remove eye protection 5. Put on gloves 6. Perform hand hygiene 6. Check everything is in place 7. Remove mask 8. Perform hand hygiene

Figure A2.1: Sequence for donning and doffing PPE

An aerosol generating procedure describes an activity that can result in the release of small airborne particles (aerosols) or droplets. Under certain conditions, the release might contain potentially transmissible amounts of viral material. The Aerosol Society, COVID-19: SARS-CoV-2 Aerosol Mechanisms, Aerosol Generating Procedures, viewed 22 November 2021, <www.aerosol-soc.com/covid-19/aerosol-generating-procedures/>.

To ensure that staff are aware of the important practices that should be followed for the effective use of PPE, SA Health has:

- provided training to staff
- placed posters showing the correct donning and doffing process in hospital wards and medi-hotels
- conducted spot audits to ensure that staff are following the required practices.

Appendix 3 – Therapeutic Goods Administration regulation

Medical devices are regulated by the TGA under the *Therapeutic Goods Act 1989* (Cth). Non-sterile PPE that is presented or claims to be for preventing the transmission of disease between people is considered a medical device.²² These products therefore need to be included in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied.

The TGA assesses medical devices for compliance with essential principles covering quality, safety and performance. The level of assessment is based on how much risk the product poses to the user.

Figure A3.1 summarises the TGA's regulatory framework for medical devices.

Figure A3.1: TGA regulatory framework for medical devices

Pre-market assessment

Conformity assessment

- The manufacturer applies conformity assessment procedures to demonstrate that the medical device meets all applicable essential principles and is safe and performs as intended.
- The sponsor (person or company responsible for supplying the medical device in Australia) ensures that appropriate conformity assessment procedures have been applied to the medical device.

Market authorisation

Inclusion in the ARTG

- Evidence of conformity assessment submitted to and accepted by the TGA.¹
- The sponsor applies for the medical device to be included on the ARTG.
- The TGA assesses the application and approves for the medical device being included on the ARTG.

Post-market monitoring

Ongoing compliance

- The manufacturer monitors the medical device's performance and safety and ensures continued compliance with the essential principles.
- The TGA carries out post-market monitoring to ensure ongoing regulatory compliance and safety of medical devices supplied to the Australian market.
- To support the TGA's post-monitoring activities, the sponsor has ongoing reporting responsibilities to the TGA including adverse incidents, overseas regulatory actions and results of investigations undertaken by the manufacturer.

¹ The sponsors of a class 1 medical device that does not have a measuring function and is not intended to be supplied sterile (low risk medical device) can submit a declaration of conformity for the device with their application to include the device in the ARTG.

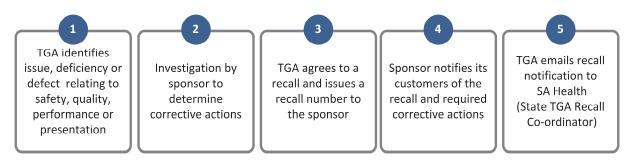
Australian Government, Department of Health, Therapeutic Goods Administration 2021, Regulation of Personal Protective Equipment and COVID-19, viewed 1 December 2021, https://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19.

SA Health relies on the TGA's regulatory processes for PPE to provide it with assurance over the quality, safety and performance of the PPE it purchases. SA Health advised us that it checks to ensure the PPE in the SA Health purchasing catalogue is in the ARTG when:

- a new product is added to the catalogue
- there is significant change to a PPE product's manufacturing arrangements.

The TGA may approve a recall action to resolve issues or deficiencies with the safety, quality, performance or presentation of the PPE that it regulates. Figure A4.1 outlines the process established by the TGA to initiate a recall action.

Figure A4.1: TGA process to initiate a recall action



There is a list of SA Health contacts who are to receive a copy of any TGA notifications. It includes contacts for the LHNs, Biomedical Engineering, procurement and medi-hotels. The State TGA Recall Co-ordinator forwards TGA notifications received to those on the contact list for actioning.

Individual SA Health sites are responsible for reviewing and actioning TGA notifications where required. Safety and Quality Units in the hospitals keep a register of TGA notifications and a list of actions taken in response.

Appendix 4 – Glossary of abbreviations and terms

Abbreviation/Term	Description
ARTG	Australian Register of Therapeutic Goods
DHW	Department for Health and Wellbeing
HSS	Health Service Support
LHN	Local health network
NMS	National medical stockpile
PFR	Particulate filter respirator
PPE	Personal protective equipment
PSCM	Procurement and Supply Chain Management Unit
SAAS	SA Ambulance Service Inc
SLA	Service level agreement
TGA	Therapeutic Goods Administration
VRD pandemic plan	SA Health Viral Respiratory Disease Pandemic Response Plan

Appendix 5 – Response from the Chief Executive, DHW under section 37(2) of the *Public Finance and Audit Act 1987*

OFFICIAL: Confidential

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Dear Mr Richardson

RE: REPORT OF THE AUDITOR-GENERAL: REPORT 2 OF 2022 – SA HEALTH'S MANAGEMENT OF PERSONAL PROTECTIVE EQUIPMENT

Thank you for your letter dated 17 January 2022, enclosing a copy of the Auditor-General's proposed Report 2 of 2022: SA Health's management of personal protective equipment.

The recommendations for improvement made by the Auditor-General have generally been accepted.

The COVID-19 pandemic presented a number of challenges for health systems across the world, with Personal Protective Equipment a key part of both the initial and ongoing response plan.

The Procurement and Supply Chain Management branch within the Department, on balance, responded well to the increasing demands associated with the pandemic and continues to improve its systems and processes to support not only the public health system, but also the broader State of South Australia.

Yours sincerely

DR CHRISTOPHER MCGOWAN

Chief Executive

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CC: Ms A Andrews, Executive Director, Procurement and Supply Chain Management Mr C Robberts, Chief Risk & Integrity Officer

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