Review of the supply chain supporting the COVID-19 vaccine rollout

Australian Government Department of Health

FINAL V1.0

07 July 2022

Building a better working world

Table of contents

1. Executive summary

1.1 Background

In February 2021, vaccine immunisations to help prevent COVID-19 began in Australia, which signalled the start of the pathway out of the COVID-19 pandemic for the country. This COVID-19 vaccine rollout ('Program') was coordinated by the Australian Government Department of Health's (the 'Department') National COVID-19 Vaccine Taskforce (NCVTF) employing a phased approach, with at risk populations prioritised.

Given the scale and dynamic nature of the COVID-19 pandemic, the rollout of the COVID-19 vaccine required urgent and mass-scale global and local distribution of the vaccine. In Australia, warehouse and logistics service providers are well equipped to support cold-chain (i.e., 2°C to 8 °C) requirements for vaccines (e.g., AstraZeneca, Novavax). However, the ultra-cold and frozen supply chain requirements (-90 °C to -15 °C)[1] of the mRNA-based COVID-19 vaccines (e.g., Pfizer, Moderna) was unprecedented, presenting both local and global warehousing and transportation challenges. s47E, s47G, s47C

However, with over 95% of people aged 16 years and over now up-to-date with COVID-19 vaccinations[2], consideration is now being given to how the Program could continue to operate, with the s47E, s47C

Purpose of the report

This review documents **(1) the current supply chain arrangements** which are coordinated by the NCVTF, noting any capability and capacity constraints that might impact the transition to the Department; and **(2) potential models for use in the future**, considering supply chain constraints (e.g.: vaccine types, packaging), other existing government programs such as the National Immunisation Program (NIP), and examples from other countries.

s47G

1.2 Current Program supply chain

The current Program supply chain involves key activities of inbound logistics on vaccine arrival, warehousing and delivery of vaccines and consumables to vaccination administration sites ('Sites'). Figure I below illustrate a high-level overview of the current Program supply chain which includes

[1] Please visit https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster for more details on vaccines, including approvals for various cohorts and transport requirements

[2] ATAGI statement on defining 'up-to-date' status for COVID-19 vaccination | Australian Government Department of Health Australian Government Department of Health

five key process groups: A. Inbound logistics[3]; B. Demand planning, allocation, and distribution of vaccines; C. Wastage management; D. Reverse logistics and reallocations; and E. COVAX (COVID-19 Vaccines Global Access) and bilateral donations.

s47E, s47C

s47C

[3] The inbound logistics process starts with identifying demand, sourcing and procurement activities and establishing contracts with manufacturers. For the scope of this report, the focus of inbound logistics will commence from the point vaccines arrive in Australia.

s47C

1.3 Supply chain models and options

The COVID-19 vaccine rollout in other countries

Overall, the Australian Program supply chain is broadly similar to the international programs which were reviewed as part of this work i e. Canada United States and the United Kingdom. The key difference between Australia and these other countries is the absence of onshore manufacturing in Australia which impacted the lead time for va cine being available for distribution here, with additional custom clearances needing to be performed. However, the centralised approach to coordinate and manage vaccine distribution appears to be a key success factor for both Australia and the other selected countries. In particular, the United States and the United Kingdom contracted centralised warehouse and logistics service providers with the capacity and capability to manage ultra-cold and frozen supply chain requirements given the use of mRNA-based vaccines. This highlights the importance of frozen and ultra-cold capacities and capabilities moving forward and warrants further consideration for future Program supply chain models.

s47C

s47G

2. Introduction and background

This Chapter outlines the overview and purpose of the project, with particular attention to the approach and scope for reviewing the supply chain; and the key assumptions and limitations made in undertaking the analysis.

2.1 Project overview

The COVID-19 vaccine was rolled out in Australia from February 2021 in response to the COVID-19 pandemic. The nature of responding to a previously unknown infectious disease pandemic meant that a large volume of vaccines needed to be secured and distributed across a geographically dispersed population using a non-traditional cold-chain condition (-90 °C to -15 °C)[5] network and over a short period of time.

The National COVID-19 Vaccine Taskforce (NCVTF), known as Operation COVID Shield, was established on 8 June 2021 to coordinate and optimise the rollout; build public confidence through clear and consistent messaging; and deliver a safe and efficient rollout. The NCVTF coordinated the response with the states and territories through the Primary Care Response (PCR) and Vaccine Administrators Partners Program (VAPP) networks, employing a phased approach, with at risk populations prioritised.

Operation COVID Shield was conducted under the Office of the Coordinator General within the NCVTF, separate from the Department's immunisation arm. However, with over 95% of people aged 16 years and over now being up-to-date with COVID-19 vaccinations[6], consideration is being given to how this vaccination program could transition to the Department in the future, to manage COVID-19 vaccinations in line with the public health management of other infectious diseases.

2.1.1 Scope

The supply chain, for the purpose of this review, starts at the demand planning stage for vaccines and consumables, and concludes at the point of distribution to states and territories and other administration channels.

At the time of writing (June 2022), there are three types of COVID-19 vaccines (Table 1) currently in scope for the Program, each with different supply chain requirements[7]. As part of the Program, consumables (e.g., syringes, needles, sodium chloride, bandages, sharps containers) are provided to immunisation providers and are in-scope for this review.

Table 1: Summary of supply chain requirements for each vaccine type

Vaccine Manufacturer	Vaccine Type	Supply Chain Requirement
Pfizer	▸ mRNA vaccine	▸ Ultra-cold chain (-90 °C to -60 °C)
Moderna	▸ mRNA vaccine	▸ Frozen chain (-25 °C to -15 °C)
Novavax	▸ Protein-based vaccine	▸ Cold-chain (2°C to 8 °C)
AstraZeneca	▸ Viral vector vaccine	▸ Cold-chain (2°C to 8 °C)

[5] Australian Government Department of Health, 2022, COVID-19 Vaccines in Australia, https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster [accessed 30/06/2022]

[6] Australian Government Department of Health, 2022, ATAGI statement on defining 'up-to-date' status for COVID-19 vaccination, https://www.health.gov.au/news/atagi-statement-on-defining-up-to-date-status-for-covid-19-vaccination [accessed 30/06/2022]

[7] Australian Government Department of Health, 2022, COVID-19 Vaccines in Australia, https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster [accessed 30/06/2022]

Australian Government Department of Health

Distribution of vaccines is arranged via the following channels (shown below in Table 2):

Table 2: Vaccine distribution channels

Channel Type	NCVTF Role
Primary Health Network	▸ NCVTF has oversight of the distribution and administration activities via the Primacy Care Networks.
Other distribution network	▸ NCVTF manages the supply chain up to the point where vaccines and consumables are provided to the vaccination administration site ('Site'). Sites complete COVID-19 vaccine Stock Management reports that include current Stock on Hand (SOH), any doses administered by sites and any vaccine wastage fewer than 10 vials in a single incident. In addition, s47G is engaged to conduct data interrogation to provide further insights. *Note: for aged care, disability residential settings and detention centres, vaccination is administered through the In-Reach program[8], where a Primary Care Network provider such as a General Practice or a Vaccination Panel provider is engaged.*

s47E

2.2 Purpose of this review

This review aims to inform the future planning of the COVID-19 vaccine rollout ('Program') under the Department's management. Specifically, this review focuses on the components of the Program's supply chain that is coordinated by the NCVTF. This review examines two main areas:

- **Current state:** Depicting an overview of the current supply chain arrangements by mapping the current model, processes, technology, and supplier arrangements, noting any capability and capacity constraints that might impact transition to the Department.

s47C

[8] Australian Government Department of Health, 2021, Practice Incentive Payment, https://www.health.gov.au/sites/default/files/documents/2021/08/covid-19-vaccination-practice-incentive-payment-in-reach-residential-aged-care-and-disability-support-worker-covid-19-vaccination.pdf [accessed 30/06/2022]

[9] Australian Government Department of Health, 2021, Vaccine Administration Partners Program Panel, https://www.health.gov.au/initiatives-and-programs/vaccine-administration-partners-program-panel [accessed 30/06/2022]

Australian Government Department of Health

s47G

2.4 Scope, assumptions and limitations

2.4.1 Assumptions and limitations

The following assumptions and limitations have been made when developing this report:

Assumptions:

- **Vaccination approval:** Australia currently has approval for three types of COVID-19 vaccines for population aged 5 years and above (Table 1). Approval for below 5 years old is yet to be provided as at the development of this report (June 2022).[11]
- **Vaccination supply:** The supply of the vaccine is through a mix of offshore manufacturing locations. While the Australian Government is entering into a 10-year strategic partnership agreement with Moderna to build an onshore mRNA manufacturing facility, this report has been developed on the basis of this agreement being operational in 2024. In addition, contingency has been built in, considering the potential absence of a stable onshore supply caused by commissioning delays
- **Vaccine storage requirements:** The mRNA vaccines typically require a non-traditional cold-chain condition (-90 °C to -15 °C)[12]. It is assumed that vaccine technology and storage requirements will remain the same over the short term[6] resulting in the need to continue with most of the key elements of the current supply chain arrangements.
- **Changes over time horizons:** While COVID-19 vaccine demand is expected to largely stabilise, there are potential changes to the supply chain elements over the short (next 12 months), medium (2023-2025) and long[13] term (post-2025), which have been summarised below.
  - **Ongoing spikes to demand:** Demand is likely to see ongoing spikes in the short term due to updated public health directions based on new variants of concerns, additional boosters, or changes to cohorts (e.g., inclusion of under 5-year-old, inclusion of other cohorts for a second booster dose) but will potentially stabilise over the long term. In addition, natural disasters such as floods and bushfires could disrupt the domestic supply chain resulting in

[10] Please refer Appendix A for a full list of stakeholders consulted

[11] Australian Government Department of Health, 2022, COVID-19 Vaccines in Australia, https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster [accessed 30/06/2022]

[12] Australian Government Department of Health, 2022, COVID-19 Vaccines in Australia, https://www.health.gov.au/resources/publications/covid-19-vaccines-in-australia-a3-poster [accessed 30/06/2022]

[13] The short (next 12 months), medium (2023-2025) and long term (post-2025), has been proposed based on discussions, and information NCVTF provided to EY on the current state of play.

Australian Government Department of Health

mass wastage due to flooding, power outages and cold chain breaches. There is also potential for mass power outages to occur due to the upcoming / current energy crisis.

- **Industry partners:** There are limited partners with the required capability for manufacturing, onshore logistics and warehouse support over the short term. This puts a limit on the capacity of the supply chain to store and distribute COVID-19 vaccines at a given point in time.

- s47C

- **Geopolitical risk to Australia's supply chain:** Australia's isolated geographical location and the pandemic induced international supply chain crisis present key challenges and may disrupt Australia's COVID-19 vaccine supply chain and the required consumable supply chains. This report considers Australia's reliance on imports for the required input materials and the vaccines themselves.

s47E, s47C

Limitations

- **Information sources**: Documents reviewed in this report have been provided by the NCVTF or relevant stakeholders in June 2022. Additional analysis of the validity of the documents have not been undertaken. Where publicly available information has been used, the sources have been cited

These limitations should be considered when interpreting the findings in this report, while noting that the research and consultations undertaken are otherwise robust to enable the evaluation.

3. The supply chain supporting the COVID-19 vaccine rollout

This Chapter explores the current Program's supply chain arrangements, including the key players involved, the enabling technology, and key components that enabled the various processes. This Chapter also provides a highlight of key stakeholders' experience with the Program on what has worked well, and areas for improvement to inform the development of future supply chain options explored in Chapter 4.

3.1 Overview of the Program supply chain

A high-level overview of the current Program supply chain is outlined below (Figure 1). This has been developed based on detailed process maps provided by the NCVTF. The full list of process maps referenced is available in Appendix B. This high-level overview summarises the key activities carried out across the supply chain from the point of orders being placed with the vaccine manufacturer up to when vaccines and consumables are delivered to the Site (please refer to Figure 1 for the Program's distribution channels).

Data management and reporting activities are key supporting elements across the supply chain arrangements. However, they are not illustrated in below figures, for more information on these data management and reporting functions, please refer to the *National COVID-19 Vaccine Taskforce Workforce Review*.

As shown in the below high-level overview, there are five (A to E) key process groups which exist across the supply chain as follows:

A. **Inbound logistics**[14]**:** The regulatory testing, TGA approval and storage of vaccines arriving in Australia.

B. **Demand planning, allocation, and distribution of vaccines:** The modelling and forecasting, order and inventory management, allocation and transport of vaccines and consumables to various receiving hubs and Sites.

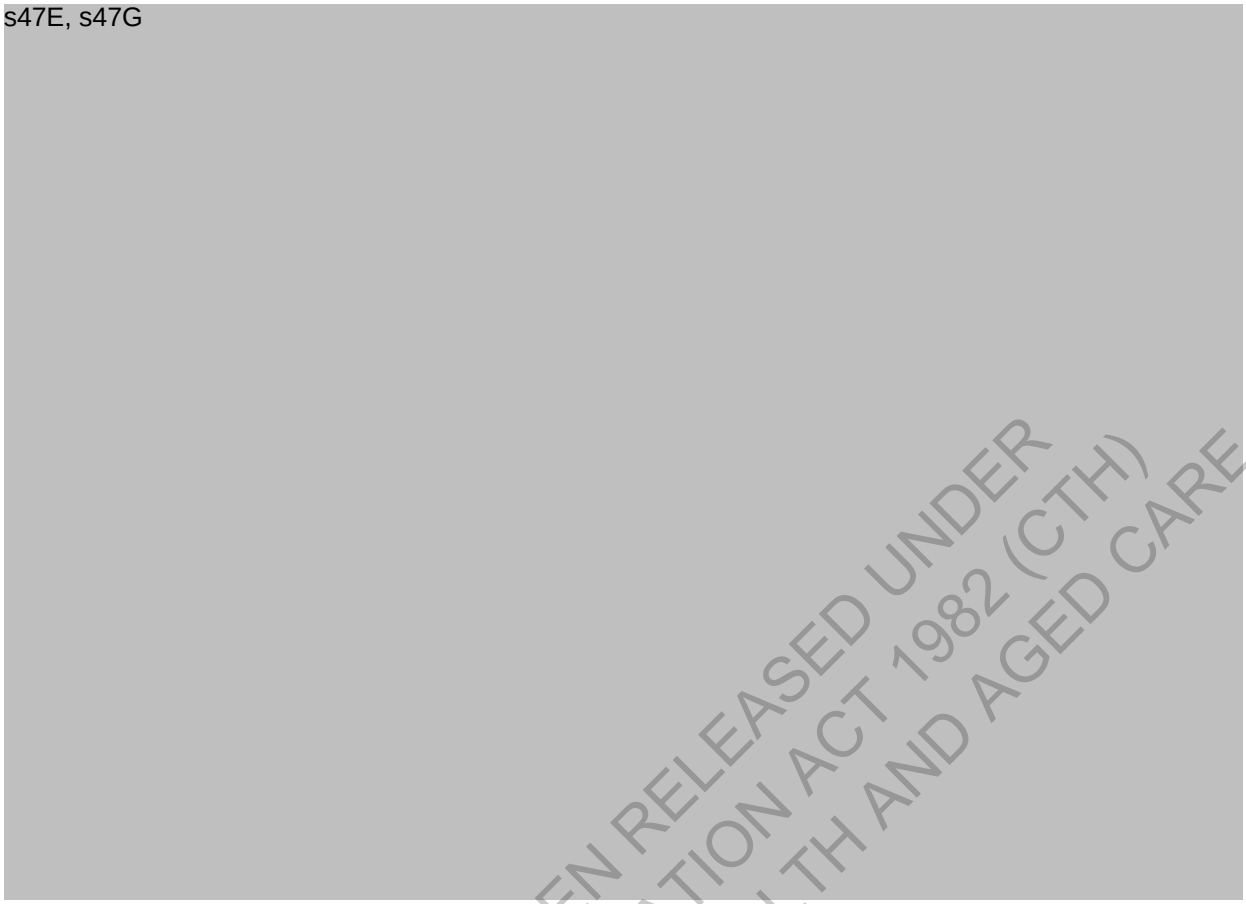
C. **Wastage management:** Reporting wastage and managing the destruction process.

D. **Reverse logistics and reallocations:** Redistribution or storage of excess vaccination doses and adjustments to existing orders.

E. **COVAX and bilateral donations:** Planning and coordination of vaccines to be distributed under COVAX and bilateral agreements.

[14] The inbound logistics process starts with identifying demand, sourcing and procurement activities and establishing contracts with manufacturers. For the scope of this report, the focus of inbound logistics will commence from the point vaccines arrive in Australia.

s47E, s47G



3.1.1 Key Players

The responsibilities of the two main groups involved in managing the Program's supply chain, the NCVTF and the warehouse and logistics service providers s47E, s47G are outlined in Table 3 below. These two groups have key roles across the supply chain and work in close collaboration.

s47E

s47E

3.1.3 Key components of the Program supply chain

This section explores the Program supply chain in more detail, across the five sub-processes outlined in Figure 1 within Section 3.1. These process groups have been developed by summarising detailed process maps provided by NCVTF. Refer to Appendix B for the list of process maps used to develop this summary.

3.1.3.1 Process Group A: Inbound logistics

Inbound logistics involves vaccine stocks being custom cleared and moved to the warehouse and logistics service providers' warehouse facilities before further distribution. s47E

are shown in Figure 2 below (which includes a thumbnail of Figure 1 highlighting the relevant area of the overall supply chain).

s47E, s47G

s47C, s47G

3.1.3.2 Process Group B: Demand planning, allocation, and distribution of vaccines

This group includes processes for both vaccines and associated consumables. The process starts at the point where the vaccine and consumables quantity requirements are established and covers the activities up to where deliveries are accepted by the Site.

For both vaccines (Figure 3) and consumables (Figure 4), the NCVTF conducts modelling and forecasting to identify demand. These inform the maximum allocation assumptions to be configured for each Site in CVAS. The Site places order through CVAS and can monitor the stock. Sites complete the COVID-19 vaccine Stock report by s47E. This captures details of SOH, number of doses administered to patients, any vaccine wastage fewer than 10 vials in a single incident and transfer of vaccine stock between Sites.

Key observations:

- s47C, s47E There may be transfers made from one warehouse and logistics service provider to another in order to meet order requirements. Modelling and forecasting of consumable allocation is done as part of the monitoring process.
- s47C, s47E
- Orders for consumables are typically placed automatically by CVAS when a Site places their vaccination order. Sites can choose to place orders for COVID-19 vaccine only. There is an option for ordering top up consumables. Consumables are distributed from different warehouses to vaccines and arrive as a separate delivery.
- s47C, s47E

3.1.3.3 Process Group C: Wastage Management

Wastage or scrap refers to stock that has been identified to be faulty and have been put aside and / or will be destroyed. This can include expired stock, damaged stock (e.g., water damage through flooding), rejected stock (i.e., not passed TGA testing) or stock that has gone missing in warehouse.

The WHO Global Wastage Rates currently reports a wastage rate of up to 15% for 10 or 20 dose vials that are opened and reused. Delivered and supplied wastage figures in the Program are below the WHO Global Standard. NCVTF engages in ongoing monitoring of wastage and implementation of wastage prevention measures utilising various channels such as Commonwealth stock management, effective use of stock, and logistical measures[17].

This section captures wastage management at two points in the supply chain:

- Wastage while stock held at warehouse and logistics service providers' warehouses (Figure 5).
- Wastage in transit from warehouses to Sites due to cold chain breaches (Figure 6).

Vaccine wastage is handled differently depending on the quantity and locations. For example:

- **At the Sites**: Site staff manage the wastage that occurs on site. Wastage is reported in disposed of locally by the Sites and reported in CVAS. s47C, s47E
- **State and territory health warehouses**: Due to the potential accumulation of large quantities of wasted vaccine products, the NCVTF arranges reverse logistics to transport the wasted

[17] Wastage metrics, comparison commentary and overview of wastage prevention measures provided by Taskforce Australian Government Department of Health

stock (beyond an established amount) back to warehouse and logistics service providers s47G sites for processing.

s47C, s47E

Key observations:

- There are established Standard Operating Procedures (SOPs) to manage the write-off and destruction of stock.

- Vaccine wastage is reported by Sites in the CVAS system through the Stock Management or Wastage reports. Sites do not report on consumable wastage. Instead, consumable waste is reported by the warehouse and logistics service providers, prior to distribution to the Sites.

- Cold chain breach incidents are recorded in VIMS and managed through the system as incidents.

- s47E, s47G

3.1.3.4 Process Group D: Reverse logistics and reallocations

This process covers the changes made to allocations after initial orders have been placed in CVAS. These include:

- **Reverse logistics**: Sites determine to reduce SOH, by returning stock to warehouse and logistics service providers' warehouses. These returns may include doses which are fit for use as well as wastage. *The reverse logistics process is detailed below:*

  - Vaccine and consumables product reverse logistics movements will be at the discretion of the Department.

  - The warehouse and logistics service provider facilitates the arrangements of the reverse logistics of any product upon request by the Department.

  - The warehouse and logistics service provider may seek a product disposition statement or confirmation from the Department ensuring the vaccine has been kept within the required storage temperature.

  - Agreed timelines for ea h reverse logistics product movement will be made on a case-by-case basis given the collection location.

  - Reverse logistics movements for cold chain vaccine products will be conducted under the warehouse and logistics service provider's Quality Management process for the transport of cold-chain medicines, including non-traditional cold-chain transport required for Pfizer vaccines.

- **Allocation adjustment**: Involves a supplementary vaccine request, change of vaccine brand allocations or request to increase /reduce allocation. This adjustment is driven by requests made by the Sites (Figure 7).

- The NCVTF used to manage a Dynamic Reallocation process (as described in Table 4) to reallocate over or under ordered stock for a cohort or Site. This was driven by the NCVTF and based on a review of internal forecasts and allocations. This process no longer takes place as ordering has reached a demand driven approach.

3.2 The current Program supply chain's capability

This section outlines key observations regarding the current Program supply chain and identifies potential areas for improvement, based on insights from stakeholder consultations. A total of 18 consultations were conducted with members of the NCVTF, the Department, cohort representatives, warehouse and logistics service providers, peak bodies, and pharmaceutical wholesalers as part of this review (please refer to Appendix A for a detailed list of stakeholders consulted). Some observations pertaining to the vaccine administration activities and the impact on the general population are out of scope for this report. However, they have been documented here to provide a comprehensive view.

As outlined in Section 2.4.1, potential improvements in the workforce and technology categories have not been assessed in detail in this report as review activities are still underway. The findings of those reviews should be considered when assessing overall supply chain capability for future models.

Table 5: Overview of key observations, stakeholder insights, potential improvement, and considerations

Observation 01	**Current processes and systems have undergone significant improvements since the Program being established**
Stakeholder Insights	▸ Initial Program challenges required rectifications or workarounds but was to be expected in a pandemic environment: It was generally agreed that the government faced an unprecedented challenge to secure vaccines, establish approval processes, manage specialised storage and transport requirements, as well oversee distribution across a geographically dispersed population against the backdrop of a global pandemic. There was agreement that standing up the Program was difficult given the circumstances, and that it was done well. ▸ The identified challenges included vaccine shortages and manual input of orders into the order system. However, it is acknowledged that this is to be expected in establishing operations in a pandemic environment, and that most of these challenges have been addressed over time. ▸ s47C ▸ Supply chain processes and partnerships with warehouse and logistics service providers are well established: The roles and responsibilities of all key parties involved in supply chain processes appear to be clear and well delineated, with clear communication channels to key stakeholders. There is integration with warehouse and logistics service provider systems (i.e., with CVAS), and clear delineation in terms of vaccines, consumables and jurisdictions managed by both s47G s47C
Observation 02	**All stakeholders are interested in continuing their involvement in the Program. The ongoing requirement for frozen and ultra-cold chain capacity and capability have the biggest impact on potential involvement.**
Stakeholder Insights	▸ All external stakeholders consulted indicated that they were interested in having an ongoing involvement in the Program. s47C ▸ There is limited capacity and capability to support frozen and ultra-cold supply chain requirements for mRNA-based vaccines: s47C

s47C

s47C

s47C

Observation 03	Clear communication was identified as a key success factor.
	▸ There were several examples of having clear communication and maintaining good relationships with key stakeholders within the Program enabling the success of the Program. For example: ▸ Daily and weekly stand-up meetings between the NCVTF and warehouse and logistics service providers s47G to manage the process. ▸ Having a dedicated VLO to triage issues that helped address urgent challenges such as vaccine shortages at Sites. s47C
s47C	▸ When clear communications were not yet established, stakeholders faced uncertainty and planning difficulties: s47C ▸ In addition, some stakeholders reported challenges in reaching the VLO. They mentioned examples of having long wait times, difficulty in identifying the right person to speak to and to address their issue with multiple transfers throughout the call to VLO. However, there was consensus that once the call was connected to the right individual, VLO personnel were supportive and helpful. ▸ Several stakeholders mentioned Sites believed they may be penalised for vaccine wastage. Consequently, these Sites did not open vaccination bookings when demand waned, given this could lead to wastage of a multi-dose vaccine vial.

s47C

s47C

Observation 04	There is potential to leverage existing networks for future supply chain models.
Stakeholder Insights	▸ s47C ▸ Furthermore, concerns were also raised in relation to the multi-dose vial packaging, as opposed to the pre-filled single use syringe packaging, as the existing NIP infrastructure is not accustomed to supplying consumables. ▸ Local networks and potential hub and spoke models can be used: ▸ Consultations have identified that when community pharmacies or clinics have insufficient vaccine stock, they reach out to other local providers to see which locations may have excess stock and arrange to pick these up. This is a commonly utilised process by immunisation providers, and guidelines have been provided in the Transfer of COVID-19 vaccines between participating primary care vaccination sites factsheet[21]. This process has been further formalised for COVID-19 vaccines, with the ability to report a transfer in the CVAS Stock Management report. However, this system of vaccine transfer relies on existing relationships between local immunisation providers. Stakeholder's feedback indicated that it would be helpful to gain visibility of excess stock / SOH within a local network in the CVAS system. A workaround has since been implemented, with the VLO acting as a liaison to assist in matching excess doses between Sites and assist with transfer scheduling, if required. ▸ Stakeholders also proposed that a local hub-and-spoke model can be established, utilising existing local infrastructure. For example, the potential use of hospitals as a temporary hub for vaccine storage in more remote areas, as well as identifying GP clinics with strong outreach activities to better reach vulnerable cohorts in the general population, such as the homeless, could be explored subject to agreements with relevant stakeholders. While there has been some utilisation of local networks in this manner, this can be extended to become a more formalised part of the distribution network.

s47C

Observation 06	There are specific access challenges for rural and remote locations which needs to be taken into consideration.
Stakeholder Insights	▸ The logistics challenge of storing and transporting ultra-cold and frozen vaccines is compounded for rural and remote locations, and locations isolated due to natural disasters (e.g., flooding / bushfires). For these locations, the limited shelf-life of thawed vaccines due to time on the road were identified as key challenges. ▸ s47C to provide support in delivering vaccines for the last leg of the distribution journey to remote or isolated locations. s47C

s47C

s47C

[21] Australian Government Department of Health, 2022, COVID-19 vaccination – Transfer of COVID-19 vaccines between participating primary care vaccination sites https://www.health.gov.au/resources/publications/covid-19-vaccination-transfer-of-covid-19-vaccines-between-participating-primary-care-vaccination-sites [accessed 30/06/2022] Australian Government Department of Health

Observation 07	The economic viability of a commercial supply chain needs to be assessed further
Stakeholder Insights	▸ Given the current ultra-cold and frozen chain requirements for mRNA vaccines, any new warehouse and logistics service providers for these vaccines will require investment to build-up capacity. However, the majority of interviewed warehouse and logistics service providers have indicated that return on investment is unlikely to be achieved unless these costs are passed on to the customer. ▸ In addition, if a 'just in-time' model is adopted, and a Site orders a single unit, the costs for the provider to thaw, pack and deliver that unit will be high s47C indicated possible synergies and efficiency gains may be achieved if vaccine delivery were to be combined with other pharmaceutical and medical goods.

s47C

4. Supply chain model and options

This Chapter explores the potential supply chain options based on current state (including key stakeholder themes described in Section 3.2) and examples from international jurisdictions. The proposed supply chain options are designed to ensure the Program's supply certainty post-2022, with the assumptions that COVID-19 vaccines will be managed in line under the public health approaches to other national notifiable infectious diseases.

4.1 Examples from other jurisdictions

4.1.1 Overview

This section explores the supply chain components which underpin the COVID-19 vaccine rollout in other countries (please refer to Table 6 for further information) with similar circumstances to Australia. The countries selected for comparison are all classified as Organisation for Economic Co-operation and Development (OECD) developed countries with similar vaccination campaigns. There are, however, differences in population densities, demographics and political systems which have consequences for the cost and delivery times of vaccines across each of their domestic vaccine distribution networks. The selected countries are:

- United States (Section 4.1.2).
- United Kingdom (Section 4.1.3).
- Canada (Section 4.1.4).

Due to differences in onshore vaccine manufacturing capacities and / or stock availability subjected to regulatory approval and recommendations, these countries utilised a variety of COVID-19 vaccines as part of their respective national vaccine rollout programs. This is illustrated below in Table 6:

Table 6: Approved COVID-19 vaccines for supply and distribution in similar OECD countries*

Approved Vaccine Manufacturer	Australia[22]	United States of America[23]	United Kingdom[24]	Canada[25]
Pfizer	✓	✓	✓	✓
Moderna	✓	✓	✓	✓
AstraZeneca	✓		✓	✓
NovaVax	✓			✓
Johnson & Johnson		✓		✓

[22] Department of Health, 2019, *Approved COVID-19 vaccines*, Available at: <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/approved-vaccines> [Accessed 2 June 2022]
[23] Federal Drug Administration, 2022, *COVID-19 vaccines*, Available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines#authorized-vaccines> [Accessed 1 June 2022]
[24] GOV.UK, *COVID-19 vaccines if you live abroad*, 2021, Available at: <https://www.gov.uk/guidance/covid-19-vaccines-if-you-live-abroad>
[25] Government of Canada, *Approved COVID-19 Vaccines*, 2022, Available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html> [Accessed 1 June 2022]
Australian Government Department of Health

**Population coverage provided by each vaccine manufacturer is subject to local regulatory approvals and recommendations*

International supply chains

There are many factors that influence the success of supply chains. An overview of the key supply chain success factors within these countries is summarised below in Table 7, with key differences to the Program highlighted in yellow. Further detail on the success factors for each selected country is discussed in respective Sections 4.1.2 – 4.1.4.

Table 7: Summary of key supply chain success factors for the selected country

Supply chain success factors	Australia	United States	United Kingdom	Canada
Demand planning	Federal	Federal	Federal	Provincial / Territorial
Enabling technology to support vaccine logistics and surveillance	Centralised system	Centralised system	Centralised system	Provincial / Territorial systems
Vaccine distribution and logistics	Centralised service provider	Centralised service provider	Centralised service provider	Centralised service provider
Use of Armed Forces	Deployed to support the Program	Deployed to support the Program	Deployed to support the Program	Deployed to support the Program
Excess vaccine supply	Donated	Donated	Donated	Donated
Manufacturing locations	Offshore	Onshore	Onshore	Offshore
Regulatory release	Standardised	Standardised	Standardised	Standardised
Warehouse and logistics requirements	Ultra-cold, frozen, and cold chain	Ultra-cold, frozen, and cold chain	Cold chain – due to the predominant supply of non-mRNA vaccines	Ultra-cold, frozen, and cold chain
Advanced Purchase Agreements (APAs) with vaccine manufacturers	Secured	Secured	Secured	Secured
Roles and responsibilities between Federal and State governments	Clear delineation	Clear delineation	Clear delineation	Clear delineation
Logistics support for ultra-cold chain requirements	Provided - investment was made into ultra-cold freezers and dry ice.	Provided - investment was made into ultra-cold freezers and dry ice.	Provided - investment was made into ultra-cold freezers and dry ice.	Provided - investment was made into ultra-cold freezers and dry ice.
Technological infrastructure	New	New / Existing	New / Existing	New / Existing

4.1.2 United States

Overview

The Federal Government is responsible for how COVID-19 vaccines are procured, transported, stored, delivered, and administered across the United States. This COVID-19 program rollout was delivered under 'Operation Warp Speed' (OWS), utilising a centralised approach to demand planning and distribution across the United States [26]. OWS involved a phased rollout approach to manage the

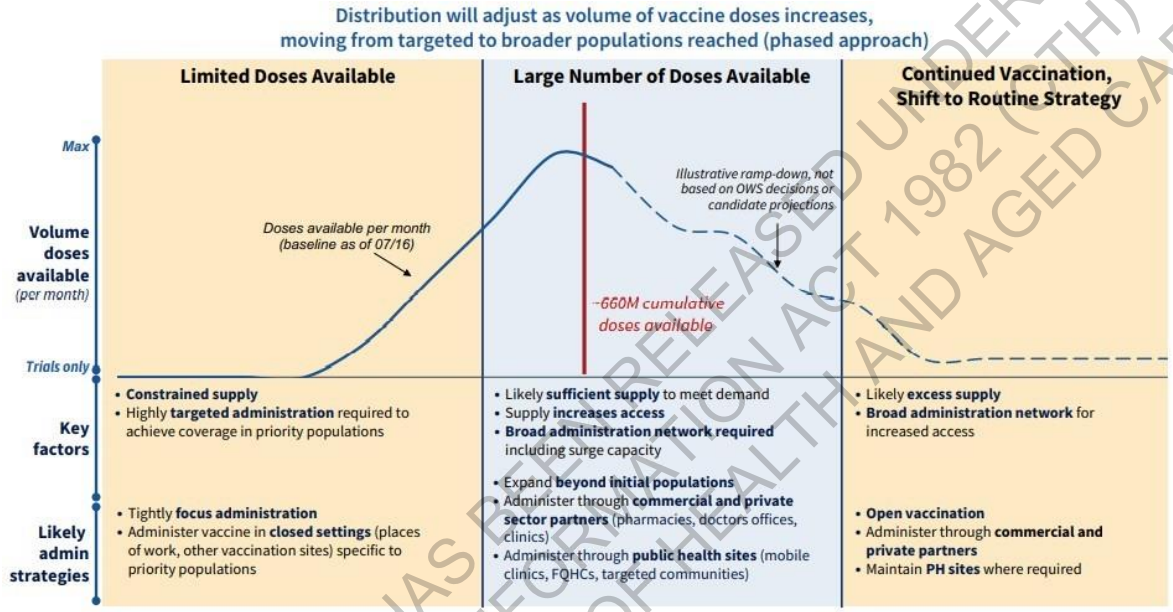
[26] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022] Australian Government Department of Health

demand against the ongoing availability of COVID-19 vaccines. This is illustrated in Figure 10 below with three different phases:

- **Phase 1**: Represented as "Limited Doses Available".
- **Phase 2**: As "Large Number of Doses Available".
- **Phase 3:** As "Continued Vaccination, Shift to Routine Strategy".

To note, it is unclear if the Federal Government has commenced Phase 3 of OWS and transitioned back into routine vaccine strategy.

Figure 10: Operation Warp Speed Phased COVID-19 Program Rollout[27]



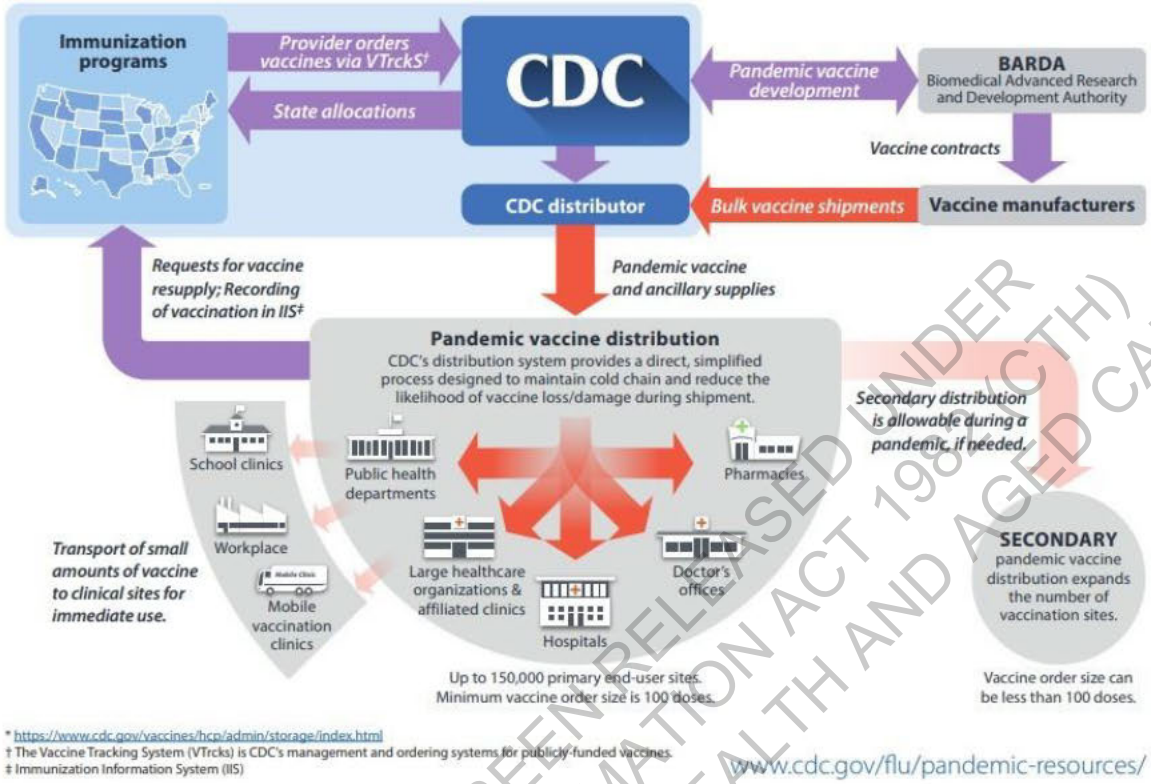
To support OWS, a number of key government agencies and private partners were involved to operationalise the vaccine rollout across the United States in a centralised manner. These included:

- **The Department of Health and Human Services:** Responsible for acting as the vaccine development lead.
- **The Food and Drug Administration (FDA):** Responsible for approving vaccine use for specific populations.
- **The Department of Defense and the Center for Disease Control and Prevention (CDC)**: Responsible for coordinating the supply, production, and distribution of vaccines across jurisdictions. This is illustrated in Figure 11 below.
- **McKesson**: Responsible for providing end to end logistical support for all COVID-19 vaccines and associated consumables as the sole distributor. This included the delivery of COVID-19 vaccines and consumables to Sites as well as storing COVID-19 vaccines in accordance with its

[27] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022] Australian Government Department of Health

cold chain requirements (e.g., refrigeration (2 °C to 8 °C), frozen (-25 °C to -15 °C), ultra-cold (-90 °C to -60 °C).

Figure 11: OWS COVID-19 Vaccine Program Distribution[28]



Key success factors for the OWS supply chain

A number of success factors underpinned the OWS supply chain. These are described below in Table 8 along with their impact to the supply chain. The success factor that is arranged differently to the Program is also highlighted in yellow.

Table 8: Success factors of the United States COVID-19 Program supply chain

Success factor	Brief description	Impact to the COVID-19 supply chain
A central body is responsible for the demand planning for all jurisdictions	▸ The CDC is responsible for the COVID-19 demand planning for all 64 jurisdictions in the United States [29].	▸ Similarly to the NCVTF, the CDC has centralised control over COVID-19 vaccine inventory at critical phases (i.e., during limited supply in Phase 1).
Centralised technology enablers are in place to support vaccine	Vaccine Tracking System (VTrckS) [30] ▸ Tracks the entire publicly funded vaccine supply chain from purchasing and ordering through distribution to participating state,	▸ Similarly to CVAS, participating vaccine providers would require onboarding onto VTrckS, enabling centralised visibility over

[28] National Center for Immunization and Respiratory Diseases, 2020, Pandemic Vaccine Program Distribution, Tracking, and Monitoring, Available at: <https://www.cdc.gov/flu/pdf/pandemic-resources/pandemic-influenza-vaccine-distribution-9p-508.pdf> [Accessed 30 May 2022]

[29] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022]

[30] Centers for Disease Control and Prevention, 2022, *Vaccine Tracking System (VTrckS)*, Available at: <https://www.cdc.gov/vaccines/programs/vtrcks/index.html> [Accessed 30 May 2022]

Success factor	Brief description	Impact to the COVID-19 supply chain
logistics and surveillance	local and territorial health departments, and healthcare providers is integrated. ▸ Includes private partners, who can also order vaccines (i.e., on top of state, local and territory allocations).	vaccine stock movement across Sites and SOH.
	Immunisation Information Systems (IIS)[31] ▸ Each of the 64 jurisdictions in the United States utilise a form of IIS. ▸ Most IISs act as data repositories for jurisdictions to maintain population vaccination information (e.g., vaccination status). This information is then transferred to VTrcks for subsequent vaccine coverage reporting and monitoring. ▸ Integration with VTrckS has permitted vaccination providers within jurisdictions to submit vaccine orders (in line with pre-allocated amounts) through their IIS. ▸ Most IISs capture vaccine related adverse event reporting and vaccine waste incidents.	▸ Similar to the Australian Immunisation Register and VIMS, IIS enabled the CDC to monitor vaccine wastage and vaccine availability across Sites by reconciling vaccines distributed versus vaccines administered. ▸ Integration of IISs into VTrckS enabled scalability by permitting vaccine orders to be performed through respective jurisdictional ISSs.
Vaccine distribution is centralised using contracted logistics partners	McKesson[32] ▸ Integration with VTrckS streamlined the supply chain process with McKesson receiving orders directly from VTrckS. ▸ Vaccine manufacturers ship vaccines directly to Sites or through McKesson distribution centres. ▸ Vaccine shipment details are transmitted from providers to VTrcks.	▸ s47E, s47G this integration streamlined processes and enabled minimal transit times for vaccine delivery and subsequent cold chain breach risks. ▸ Centralised coordination enabled the CDC to maintain control over vaccine orders and monitor demand from jurisdictions, in line with allocated vaccine amounts.
Armed Forces capacity and capability is leveraged to support the vaccine rollout	▸ The United States Federal Government deployed United States Armed Forces to leverage existing capability in logistics planning and capacity for program delivery.	▸ Similarly to the Australian Program, this has enabled existing logistics capabilities to be leveraged in delivering a national scale program to reduce the potential of vaccine wastage and appropriate allocations of vaccines to Sites. ▸ This also enabled a quicker deployment of vaccines without the need to rely on commercial partners.
Excess vaccine doses donated via the COVAX facility	▸ Excess COVID-19 vaccines are donated via the COVAX facility to neighbouring countries.	▸ Similarly to the Australian Program, this enables excess vaccines to be utilised, minimising the risk of vaccine wastage.
Onshore vaccine manufacturing capability is leveraged	▸ There is onshore capability and capacity to produce FDA approved vaccines (as outlined in Table 6) locally[33]. ▸ Vaccines with ultra-cold storage requirements may be shipped directly from the manufacturer to Sites (e.g., Pfizer).	▸ In contrast to the Australian Program, the ability to leverage onshore vaccine manufacturer capability to store vaccines (e.g., ultra-cold storage requirements) and minimise risk of cold chain breaches due to reduced handling points in the supply chain.
Standardised regulatory	▸ The FDA has implemented standardised batch testing processes which require both the FDA and the vaccine manufacturer to perform	▸ Similarly to the Australian Program, this has enabled the quick deployment of vaccines at scale across the United States.

[31] Centers for Disease Control and Prevention, 2022, *COVID-19 Vaccine IT Overview*, Available at: <https://www.cdc.gov/vaccines/covid-19/reporting/overview/IT-systems.html> [Accessed 8 June 2022]
[32] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022]
[33] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022]

Success factor	Brief description	Impact to the COVID-19 supply chain
approvals for batch testing processes	rigorous testing to comply with international standards.	
Approved vaccines required ultra-cold, frozen, and cold chain storage	▸ Approved vaccines for administration in the United States (Table 6) required ultra-cold, frozen and cold chain storage requirements.	▸ Similarly to the Australian program, this required additional investment into warehouse and logistics service providers with ultra-cold and frozen storage capacities and capabilities to deliver vaccines across the United States, as well as investment into Sites to store vaccines.
Securing APAs with vaccine manufacturers	▸ Arranging APAs with vaccine manufacturers secured access to vaccines as they became available. This included APAs with three vaccine manufacturers as seen in Table 6 [34, 35, 36]	▸ Similarly to the Australian Program, this enabled a guaranteed supply of vaccines for the United States population.
Clear delineation of roles between Federal and State governments	▸ Clear roles and responsibilities between the Federal and State governments to procure, transport, store, deliver, and administer vaccines across United States. [37]	▸ Similarly to the Australian Program, this enabled the utilisation of existing touchpoints with State governments and existing infrastructure immunisation programs within jurisdictions to ensure minimal impact to supply chains and program delivery.
States and territories were responsible for providing logistics support for cold chain requirements to Sites	▸ To support the temperature requirements of various vaccine types (i.e., ultra-cold, frozen and standard cold chain), the United States state and territorial governments invested into cold chain storage products to ensure Sites contained the capacity to store vaccines. This included ultra-cold freezers and dry ice.	▸ Similarly to the Australian Program, this enabled a capacity and capability uplift to manage the influx of vaccines into Sites across the United States at scale.
Use of new and existing technological infrastructure to support vaccine logistics and surveillance	▸ Existing jurisdictional immunisation systems (i.e., IISs) were leveraged to order and manage vaccine orders, as well as for vaccine coverage. ▸ IISs are also integrated with VTrcks.	▸ In contrast to the Australian Program, this enabled existing technological infrastructure from national immunisation programs to be leveraged and integrated to deliver a large-scale national program. ▸ The integration of IISs with VTrcks enabled a streamlined process for vaccine logistics and surveillance.

4.1.3 United Kingdom

Overview

As part of its strategy for COVID-19 vaccine deployment, the United Kingdom Federal Government created a new role within the Department of Health and Social Care to oversee the centralised program rollout. A new *Parliamentary Under-Secretary of State for COVID-19 Vaccine Deployment*

[34] USA Today, 2020, US cuts $1.95 billion deal with Pfizer for 100 million doses of COVID-19 vaccine, https://www.usatoday.com/story/news/health/2020/07/22/us-pays-1-95-billion-100-million-doses-pfizer-covid-19-vaccine/5489964002/ [accessed: 28/06/2022]

[35] CNA, 2020, US inks US$1.5 billion deal with Moderna for 100 million doses of COVID-19 vaccine, https://www.channelnewsasia.com/world/covid-19-moderna-vaccine-us-1-5-billion-deal-100-million-doses-617586#:~:text=WASHINGTON%3A%20The%20United%20States%20has%20entered%20an%20agreement,and%20White%20House%20said%20on%20Tuesday%20%28Aug%2011%29. [accessed 28/06/2022]

[36] Johnson and Johnson, 2020, Johnson & Johnson Announces Agreement with U.S. Government for 100 Million Doses of Investigational COVID-19 Vaccine, [accessed: 28/06/2022]

[37] US Department of Health and Human Services, 2020, *From the Factory to the Frontlines*, Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf> [Accessed 27 May 2022]

role was responsible for providing oversight to the Vaccine Taskforce, which was set up to provide the UK population with access to safe and effective vaccines against COVID-19.

The vaccine program rollout was performed under a phased approach, following advice from the Joint Committee on Vaccination and Immunisation, to prioritise administration to priority cohorts against the ongoing availability of COVID-19 vaccines. A major focus of the United Kingdom's rollout was to leverage onshore manufacturing capability to accelerate the supply and distribution of COVID-19 vaccines[38].

To support the United Kingdom's rollout, a number of key government agencies and private partners were involved to operationalise the vaccine rollout in a centralised manner. These included:

- **Department of Defence:** Responsible for deploying British Armed Forces in all parts of the UK to support the vaccine rollout. This included planning, construction of vaccination centres and contribution of staff to administer vaccines[39].
- **Public Health England**: Responsible for surveillance of the COVID-19 program, including assessing the risks posed by new and emerging variants, and providing support on vaccine distribution and deployment[40].
- **Medicines and Healthcare Products Regulatory Agency (MHRA)**: Responsible for providing regulatory approvals for vaccine use in the United Kingdom, and batch testing approved vaccines for deployment[41].
- **Onshore vaccine manufacturers** (e.g., Oxford Biomedica, Cobra, Wockhardt, Symbiosis): Responsible for manufacturing vaccines in Sites all-across the United Kingdom. For example, Oxford Biomedica manufactured the Oxford/AstraZeneca vaccine at scale with a rapid deployment facility underpinning its function[42].
- **Joint Committee on Vaccination and Immunisation:** Responsible for providing independent clinical expertise on priority cohorts for vaccination[43].
- **Vaccine Taskforce:** Responsible for securing access to COVID-19 vaccines for the UK population and providing centralised planning for vaccine allocations[44].

[38] UK.GOV, 2021, *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]
[39] Forces, 2021. COVID: How The Military's Been Involved In Fighting Coronavirus, Available at: < https://www.forces.net/news/coronavirus-how-military-helping> [Accessed 16 June 2022]
[40] UK.GOV, 2021. *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]
[41] UK.GOV, 2021, *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]
[42] Department for Business, Energy and Industrial Strategy, 2022, UK Vaccine Taskforce 2020 Achievements and Future Strategy, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027646/vtf-interim-report.pdf [accessed 16 June 2022]
[43] UK.GOV, 2021, *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]
[44] UK.GOV, 2021, *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]
Australian Government Department of Health

- **National Health Service (NHS):** Responsible for planning and coordinating NHS Trusts to ensure operational readiness for vaccine administration. This includes creating capacity and capability to deliver vaccines[45].

Key success factors of the United Kingdom Program supply chain

A number of success factors underpinned the United Kingdom's Program supply chain. This is described below in Table 9 along with its impact to the supply chain.

Table 9: Success factors of the United Kingdom's COVID-19 Program supply chain

Success factor	Brief description	Impact to the COVID-19 supply chain
A central body is responsible for the demand planning and vaccine allocations	▸ The Vaccine Taskforce is responsible for demand planning and vaccine allocations across NHS trusts[46].	▸ Similarly to the NCVTF, this enabled centralised control over COVID-19 vaccine inventory at critical phases (i.e. during limited vaccine supply to distribute to priority populations).
Centralised technology enablers are in place to support vaccine logistics and surveillance	National Immunisation Management System ▸ A system used by vaccination providers to record vaccination administration details and provides a central register of vaccines delivered in the full range of healthcare settings[47]. ImmForm Platform ▸ A system used by vaccination providers for existing immunisation programs (e.g., flu vaccine) to record vaccination administration details and to place orders for vaccines[48].	▸ Similarly to CVAS, this has enabled visibility over vaccine stock movement data, including SOH data at Sites (via analytics on vaccine coverage i.e., vaccines administered versus vaccines delivered).
Vaccine distribution is centralised using contracted logistics partners	Serco[49] ▸ Contracted to distribute vaccines across the United Kingdom. ▸ Works in close collaboration with Public Health England.	▸ s47E, s47G commissioning centralised logistics providers, to leverage their existing capacity and capability to ensure minimal cold chain breaches and timely delivery of vaccines to Sites. ▸ Similarly to the NCVTF, centralised coordination enabled Public Health England to maintain visibility over vaccine orders and monitor demand from jurisdictions, in line with allocated vaccine amounts.
Armed Forces capacity and capability is leveraged to support the vaccine rollout	▸ The United Kingdom Federal Government deployed British Armed Forces to leverage existing capability in logistics planning and capacity for program delivery.	▸ Similarly to the Australian Program, this has enabled existing logistics capabilities to be leveraged in delivering a national scale program to reduce the potential of vaccine wastage and appropriate allocations of vaccines to Sites.

[45] NHS, 2022, COVID-19 vaccination deployment strategy and operational readiness, https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/11/covid-19-vacc-deployment-strategy-and-operational-readiness-letter.pdf [Accessed 16 June 2022]

[46] NHS, 2022, COVID-19 vaccination deployment strategy and operational readiness, https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/11/covid-19-vacc-deployment-strategy-and-operational-readiness-letter.pdf [Accessed 16 June 2022]

[47] UK.GOV, 2021, *UK COVID-19 vaccines delivery plan*, Available at: <https://www.gov.uk/government/publications/uk-covid-19-vaccines-delivery-plan/uk-covid-19-vaccines-delivery-plan> [Accessed 31 May 2022]

[48] NHS, 2022, COVID-19 vaccination deployment strategy and operational readiness, https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/11/covid-19-vacc-deployment-strategy-and-operational-readiness-letter.pdf [Accessed 16 June 2022]

[49] Serco bags £322m contract extension, https://www.theregister.com/2021/06/28/serco_bags_a_322m_contract/ [accessed 28/06/2022]

Success factor	Brief description	Impact to the COVID-19 supply chain
		▸ This also enabled a quicker deployment of vaccines without the need to rely on commercial partners.
Excess vaccine doses donated via the COVAX Facility	▸ Excess COVID-19 vaccines are donated via the COVAX Facility to neighbouring countries.	▸ Similarly to the Australian Program, this enabled excess vaccines to be utilised, minimising the risk of vaccine wastage.
Onshore vaccine manufacturing capability is leveraged	▸ The United Kingdom Federal Government has provided funding to several Sites across the nation to secure rapid manufacturing capability of millions of doses of vaccines for the entire country's population. This included the capability uplift of these Sites to maintain the flexibility to manufacture different platforms of vaccines[50].	▸ The ability to leverage onshore vaccine manufacturer capability to store vaccines (e.g., ultra-cold storage requirements) and minimise risk of cold chain breaches due to reduced handling points in the supply chain. ▸ In contrast to the Australian Program, this enabled the vaccine supply chain (i.e., logistics) to be shortened, with relatively higher supply security and potential quicker distribution.
Standardised regulatory approvals for batch testing processes	▸ The MHRA has implemented standardised batch testing processes which require both the MHRA and the vaccine manufacturer to perform rigorous testing to comply with international standards.	▸ This has expedited regulatory approval processes and enabled deployment of vaccine shipments within 24 hours of initial testing. ▸ This has enabled the quick deployment of vaccines at scale across the United Kingdom. ▸ By comparison to the Australian Program, regulatory approvals had a 7-day turnaround.
Regular standard of cold chain requirements	▸ AstraZeneca (Vaxzevria) is the predominant vaccine distributed across the United Kingdom which required a regular standard of cold chain (i.e., 2°C to 8 °C) in comparison to heavy reliance on frozen and ultra-cold requirements of other vaccines (e.g., Pfizer, Moderna).	▸ This has enabled risks of cold chain breaches to be minimised, due to less rigorous logistics requirements during the distribution, and storage of vaccines. ▸ By comparison, Australia's high proportion of Pfizer distribution had a requirement for ultra-cold storage, handling and packaging requirements.
Securing APAs with vaccine manufacturers	▸ Arranging APAs with vaccine manufacturers secured access to vaccines as they became available. This included APAs with three vaccine manufacturers as seen in Table 6[51] [52] [53].	▸ Similarly to the Australian Program, this enabled a guaranteed supply of vaccines for the United Kingdom population.
Clear delineation of roles between Federal and local governments	▸ Clear roles and responsibilities between the Federal and local governments to procure, transport, store, deliver, and administer vaccines across United Kingdom.	▸ Similarly to the Australian Program, This enabled the utilisation of existing infrastructure immunisation programs within jurisdictions to ensure minimal impact to supply chains and program delivery.

[50] Department for Business, Energy and Industrial Strategy, 2022, UK Vaccine Taskforce 2020 Achievements and Future Strategy, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027646/vtf-interim-report.pdf [accessed 16 June 2022]

[51] World Pharma Today, 2021, Moderna Announces Amendment to Current Supply Agreement with UK Government, https://www.worldpharmatoday.com/news/moderna-announces-amendment-to-current-supply-agreement-with-uk-government-for-an-additional-2-million-doses-of-mrna-vaccine-against-covid-19/#:~:text=Moderna%2C%20Inc.%2C%20a%20biotechnology%20company%20pioneering%20messenger%20RNA,to%20the%20United%20Kingdom%20beginning%20in%20March%202021. [accessed: 28/06/2022]

[52] Reuters, 2021, AstraZeneca contract includes UK as best effort base for output to EU, https://www.reuters.com/article/uk-health-coronavirus-europe-astrazneca-idUSKBN29Y1ED [accessed: 28/06/2022]

[53] Pharmaceutical Technology, 2020, UK enters supply agreement for Pfizer and BioNTech's Covid-19 vaccine, https://www.pharmaceutical-technology.com/news/uk-covid19-vaccine-supply-deals/#:~:text=The%20UK%20Government%20has%20signed%20an%20agreement%20with,the%20delivery%20timing%20and%20the%20volume%20of%20doses. [accessed: 28/06/2022]

Australian Government Department of Health

Success factor	Brief description	Impact to the COVID-19 supply chain
Federal logistics support provided for cold chain requirements to Sites	▸ To support the temperature requirements of various vaccine types (i.e., ultra-cold, frozen and standard cold chain), the United Kingdom federal governments invested into ultra-cold chain storage products to ensure Sites contained the capacity to store vaccines. This included ultra-cold freezers and dry ice.	▸ Similar to the Australian Program, this enabled a capacity and capability uplift to manage the influx of vaccines into Sites across the United Kingdom at scale.
Use of new and existing technological infrastructure to support vaccine logistics and surveillance	▸ Existing jurisdictional immunisation systems (i.e., ImmForm Platform) were leveraged to order and manage vaccine orders, as well as for vaccine coverage. ▸ IISs were also integrated with National Immunisation Management System.	▸ In contrast to the Australian Program, this enabled existing technological infrastructure from national immunisation programs to be leveraged and integrated to deliver a large-scale national program. ▸ The integration of ImmForm with the National Immunisation Management System enabled a streamlined process for vaccine logistics and surveillance.

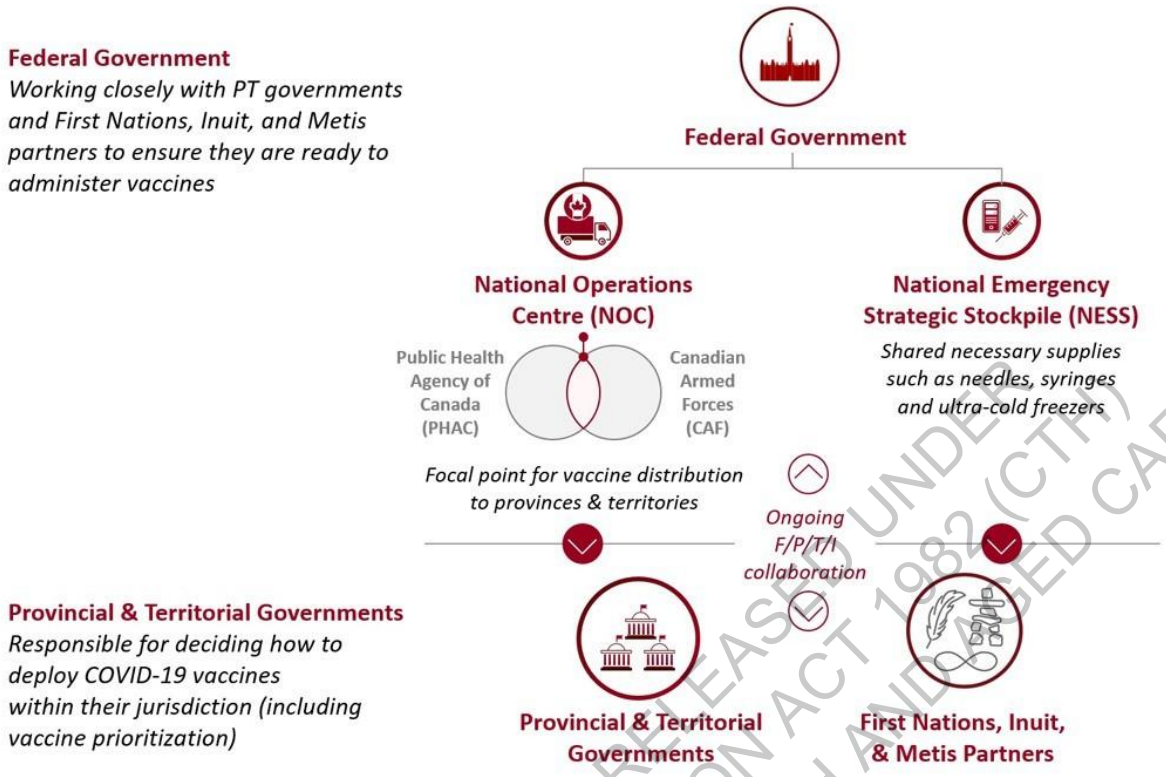
4.1.4 Canada

Overview

To deliver its response against COVID-19, Canada employed an intergovernmental response involving Federal, Provincial and Territorial governments, and Indigenous Peoples to deliver its vaccine program rollout. This involved a clear delineation of responsibilities between the Federal and Provincial / Territorial governments. Similar to the NIP program in Australia, The Canadian Federal government was responsible for the procurement and distribution of vaccines to Provincial / Territorial governments, who were then responsible for planning, storing, and administering vaccinations to their respective populations[54]. This is illustrated below in Figure 12.

[54] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]
Australian Government Department of Health

Figure 12: Roles delineation between Federal and Provincial / Territorial governments[55]



The vaccine rollout program involved a phased approach and prioritised administration of priority populations based on the ongoing availability of vaccines. To support Canada's program rollout, a number of key government stakeholders and private partners were involved to operationalise the vaccine rollout in a centralised manner[56]. This included:

- **Public Services and Procurement Canada**: Responsible for the procurement of vaccines.
- **Public Health Agency of Canada**: Responsible for coordinating the COVID-19 public health response, as well as the ongoing infectious disease control. This includes surveillance over the program rollout
- **National Operations Centre (NOC):** Responsible for tracking and monitoring vaccine delivery and distribution. This was established as the federal logistical coordination entity and focal point for managing vaccine delivery and collaboration with provinces and territories for distribution.
- **Health Canada**: Responsible for the approval and regulation of vaccines.

National Advisory Committee on Immunisation: Responsible for providing recommendations on how vaccines should be distributed, at what intervals and to which populations.

[55] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]
[56] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]
Australian Government Department of Health

- **Provincial and Territorial governments:** Responsible for planning and delivering COVID-19 vaccine programs in their respective jurisdictions. This includes storing and distributing vaccines to vaccine providers, tracking and managing vaccine shipments via jurisdictional delivery systems, ordering vaccines through the NOC, and coordinating vaccination Sites.
- **FedEx Express Canada and Innomar Strategies:** Responsible for acting as centralised contracted logistics partners to support the distribution of vaccines across Canada.
- **Canadian Armed Forces:** Responsible for supporting the vaccine program rollout.

Key success factors of Canada's Program supply chain

A number of success factors underpinned Canada's Program supply chain. These are described below in Table 10 along with their impact on the supply chain.

Table 10: Key success factors of Canada's Program supply chain

Success factor	Brief description	Impact to the COVID-19 supply chain
Demand planning and vaccine allocations is decentralised to Provincial / Territorial governments	▸ Canadian Provincial and Territorial governments were responsible for planning and delivering COVID-19 vaccine programs in their respective jurisdictions.	▸ In contrast to the Australian Program, the Canadian's arrangement enabled existing relationships with Provincial / Territorial governments and jurisdictional immunisation program infrastructure to be leveraged for the vaccine program rollout.
Existing technology infrastructure is leveraged to support vaccine logistics and surveillance	▸ With Provincial / Territorial governments responsible for delivering COVID-19 administration activities, existing jurisdictional immunisation systems were leveraged to order and manage vaccine orders, as well as for vaccine coverage.	▸ In contrast to the Australian Program, the Canadian's approach enabled existing technological infrastructure from national immunisation programs to be leveraged and integrated to deliver a large-scale national program.
Vaccine distribution is centralised using contracted logistics partners	FedEx and Innomar Strategies[57] ▸ Contracted to store and distribute vaccines across Canada's provinces and territories. ▸ Work in close collaboration with the NOC.	▸ s47E, s47G , Canada commissioned FedEx and Innomar Strategies as the centralised logistics providers, to leverage existing capacity and capability to ensure minimal cold chain breaches and timely delivery of vaccines to Sites. ▸ Similar to the NCVTF role in the Australian Program, centralised coordination in Canada has enabled the NOC to maintain visibility over vaccine orders and monitor demand from jurisdictions, in line with allocated vaccine amounts.
Armed Forces capacity and capability is leveraged to support the vaccine rollout	▸ The Canadian Federal Government deployed Armed Forces to leverage existing capability in logistics planning and capacity for vaccine distribution to Provinces / Territories.	▸ Similar to the Australian Program, leveraging the armed force capacity has enabled a quicker deployment of vaccines without the need to rely on commercial partners.
Excess vaccine doses donated via the COVAX Facility	▸ Excess COVID-19 vaccines are donated via the COVAX facility to neighbouring countries.	▸ Similar to the Australian Program, the donation to the COVAX Facility has enabled excess vaccines to be utilised, minimising the risk of vaccine wastage.

[57] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]
Australian Government Department of Health

Success factor	Brief description	Impact to the COVID-19 supply chain
Reliance on offshore vaccine manufacturing capability	▸ With no onshore capability and capacity to produce Health Canada approved vaccines (as outlined in Table 6), there is a reliance on the procurement vaccines offshore. [58]	▸ Similar to the Australian Program, APAs have been secured to ensure vaccine supply. ▸ Offshore production also required all incoming vaccine shipments to be subject to customs approval prior to its release and deployment, adding a layer of complexity and time constraint for vaccine delivery to Sites.
Standardised regulatory approvals for batch testing processes	▸ Health Canada has implemented standardised batch testing processes which require both the Health Canada and the vaccine manufacturer to perform rigorous testing to comply with international standards.	▸ Similar to the Australian Program, quick deployment of vaccines at scale across Canada, particularly since all incoming vaccines require customs approval, was enabled by standardised regulatory approvals.
Approved vaccines require ultra-cold, frozen, and cold chain storage	▸ Approved vaccines for administration in Canada (Table 6) require ultra-cold, frozen and cold chain storage requirements.	▸ Similar to the Australian program additional investment into warehouse and logistics service providers with ultra-cold and frozen storage capacities and capabilities to deliver vaccines across Canada was required.
Securing APAs with vaccine manufacturers	▸ Arranging APAs with vaccine manufacturers secured access to vaccines as they became available[59]. This included APAs with five vaccine manufacturers as seen in Table 6.	▸ Similar to the Australian Program, this enabled a guaranteed supply of vaccines and addressed concerns of having minimal onshore manufacturing capabilities.
Clear delineation of roles between Federal and State governments	▸ Clear roles and responsibilities between the Federal and Provincial / Territorial governments to procure, transport, store, deliver, and administer vaccines across Canada.	▸ Similar to the Australian program where the Federal Government were responsible for procuring vaccines and states and territories responsible for vaccine administration, this enabled the utilisation of existing infrastructure immunisation programs within jurisdictions to ensure minimal impact to supply chains and program delivery.
Federal logistics support for cold chain requirements	▸ To support the temperature requirements of various vaccine types (i.e., ultra-cold, frozen and standard cold chain), the Canadian federal government invested into cold chain products and delivered these products across Canada. This included ultra-cold freezers and dry ice, as well as investing into logistics providers with transportation options to deliver and store vaccines to remote communities. [60]	▸ Similar to the Australian Program, this enabled a capacity and capability uplift to manage the influx of vaccines into Canada at scale, and to ensure there was sufficient capability to store, deliver and administer vaccines in remote communities across Canada.
Use of existing technological infrastructure to support vaccine logistics and surveillance	▸ With Provincial / Territorial governments responsible for coordinating the vaccine administration across Canada, existing jurisdictional immunisation systems were employed to order and manage vaccine orders, as well as for vaccine coverage. [61]	▸ In contrast to the Australian Program, this enabled existing technological infrastructure from national immunisation programs to be leveraged and integrated to deliver a large-scale national program.

[58] Government of Canada, 2022, *Canada's COVID-19 vaccine supply and donation strategy*, Available at: <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines/supply-donation.html#a1> [Accessed 1 June 2022]

[59] Government of Canada, 2022, *Canada's COVID-19 vaccine supply and donation strategy*, Available at: <https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19/vaccines/supply-donation.html#a1> [Accessed 1 June 2022]

[60] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]

[61] Canada's COVID-19 Immunization Plan: Saving Lives and Livelihoods, 2020, https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/canadas-reponse/canadas-covid-19-immunization-plan.html [accessed 17 June 2022]

Australian Government Department of Health

4.2 The future Program objectives for Australia

4.2.1 Draft proposed Program objectives for post-2022

A set of high level, draft Program objectives and Program aim have been developed for the purpose of this review. The aim and objectives have been developed based on inputs from the NCVTF and other key stakeholder groups including the Immunisation & Communicable Diseases Branch within the Department. The objectives are not exhaustive or finalised with all relevant areas within the Department, however they provide useful inputs into potential forward planning activities for discussion with stakeholders to inform future supply chain models.

- **Program Aim:** Provide continued COVID-19 vaccination administration as part of a routine strategy.
- **Program Objectives:**
  - **Population immunisation coverage** through targeted coverage of relevant population cohorts and broad availability of vaccines.
  - **Efficient procurement and delivery of vaccines** through cost effective supply chain models and partnerships, improved end to end vaccine stock movement and visibility, and waste minimisation through integrated demand and supply planning.
  - **Simplified and accurate reporting mechanisms** through optimised, automated approaches to capture and collate reporting from delivery sites, and provide accurate and up to date databases of vaccines administered with details on adverse events, wastage etc.

s47C

s47C

4.2.4 Proposed supply chain options

The current Program supply chain arrangements were established amidst the pandemic, with the aim of '*ensuring that as many Australians are vaccinated as early as possible*'[63]. However, the vaccine supply was limited across the globe at the beginning of the National COVID Vaccine Campaign, and eligibility for the vaccine evolve over time. This required the public health policy to rapidly change to accommodate the supply challenge and evolving clinical and epidemiological information as they became available, considering a whole of Program perspective.

The current demand and supply landscape for COVID-19 vaccines has shifted since rollout commencement in February 2021. Over 95% of people aged 16 years and over are now up to date with their COVID-19 vaccinations[64]. In contrast to the beginning of the Program, there is a set of approved vaccines and an established network of Sites, with improved understanding of what drives spikes in vaccine demand and which elements of the supply chain needs to be scaled up to meet these spikes in demand.

Given these circumstances, the key drivers that influence the supply chain can potentially shift from *speed and coverage* now to *value for money and efficiency* in the future. Thus, any change to the supply change model could be based on the following key drivers:

- Value for money and /or performance satisfaction
- Simplification in vaccine packaging by the majority of manufacturers (e.g., move from multi-dose vials to pre filled, single use syringes)
- Innovation in vaccines resulting in different supply chain requirements
- Policy changes, such as:
  - Updated immunisation / booster requirement
  - Leveraging the setup of / as part of NIP-like program
  - Partnership with state and territory health agencies to deliver and administer the vaccines

s47C

[63] Operation COVID Shield, Australian Government Department of Health, 2021, https://www.health.gov.au/initiatives-and-programs/operation-covid-shield/about-operation-covid-shield, [accessed: 27/06/2022]
[64] Please visit ATAGI statement on defining 'up-to-date' status for COVID-19 vaccination | Australian Government Department of Health for more details on the definition of 'up-to-date' status

6. Key decisions and next steps

6.1 Key decisions

The supply chain options explored in this report provide different alternatives to the Department to continue to safeguard the supply of vaccines and consumables for the Program in the short, medium and long term. It is recommended that following key decisions are explored at the Program level, which will enable the Department to effectively evaluate these options. s47C

s47C

APPENDIX A: Stakeholder list

Category	Department/ Division/ Organisation
The Department	NCVTF – Primary Care Response Branch
The Department	NCVTF – Vaccine Logistics and Operations Branch
The Department	NCVTF – CVAS / VIMS Section
The Department	Immunisation and Communicable Diseases Branch
The Department	Therapeutic Goods Administration
The Department	Department of Health – National Medical Stockpile
State and territory health agencies	State Health Department - NSW
State and territory health agencies	State Health Department - VIC
State and territory health agencies	State Health Department - QLD
State and territory health agencies	State Health Department - ACT
State and territory health agencies	State Health Department - WA
State and territory health agencies	State Health Department – NT
State and territory health agencies	State Health Department - TAS
State and territory health agencies	State Health Department - SA
State and territory health agencies	Warehouse and Logistics Coordinator – NSW
State and territory health agencies	Warehouse & Logistics Coordinator – VIC
State and territory health agencies	Warehouse & Logistics Coordinator – QLD
State and territory health agencies	Warehouse & Logistics Coordinator – ACT
State and territory health agencies	Warehouse & Logistics Coordinator – WA
State and territory health agencies	Warehouse & Logistics Coordinator – NT
State and territory health agencies	Warehouse & Logistics Coordinator – TAS
State and territory health agencies	Warehouse & Logistics Coordinator – SA
State and territory health agencies	Department of Health – NCVTF – Commercial Team
Warehouse and logistics service providers	s47E, s47G
Warehouse and logistics service providers	
Warehouse and logistics service providers	
Pharmaceutical wholesalers	
Pharmaceutical wholesalers	
Pharmaceutical wholesalers	
Pharmaceutical wholesalers	
Peak Body	
Peak Body	
Peak Body	

APPENDIX G: Table of acronyms and abbreviations

Table 23: Table of acronyms and abbreviations

Acronym	Description
APA	Advanced Purchase Agreement
BAU	Business As Usual
CDC	Center for Disease Control and Prevention
COVAX	COVID-19 Vaccines Global Access
CVAS	COVID-19 Vaccination Administrative System
DFAT	Department of Foreign Affairs and Trade
FDA	Food and Drug Administration
GAVI	Vaccine Alliance
IIS	Immunisation Information Systems
MHRA	Medicines and Healthcare Products Regulatory Agency
NCVTF	National COVID-19 Vaccine Taskforce
NHS	National Health Service
NIP	National Immunisation Program
NOC	National Operations Centre
NSW	New South Wales
OCABR	Official Control Authority Batch Release
OECD	Organisation for Economic Co-operation and Development
OWS	Operation Warp Speed
PCR	Primary Care Response
Program	COVID-19 vaccine rollout
RDD	Required Delivery Date
RFDS	Royal Flying Doctors Service
QLD	Queensland
Site	Vaccination Administration Site

Acronym	Description
SOH	Stock on Hand
SOP	Standard Operating Procedure
The Department	Department of Health
TGA	Therapeutic Goods Administration
UNICEF	United Nations International Children's Emergency Fund
VAPP	Vaccine Administration Partners Program
VDS	Vaccine Data Solution
VIMS	Vaccine Issues Management System
VLO	Vaccine Logistics and Operations Branch
VOC	Vaccine Operations Centre
VTrckS	Vaccine Tracking System
WA	Western Australia

EY | Building a better working world

EY exists to build a better working world, helping to create long-term value for clients, people and society and build trust in the capital markets.

Enabled by data and technology, diverse EY teams in over 150 countries provide trust through assurance and help clients grow, transform and operate.

Working across assurance, consulting, law, strategy, tax and transactions, EY teams ask better questions to find new answers for the complex issues facing our world today.

EY refers to the global organization, and may refer to one or more, of the member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. Information about how EY collects and uses personal data and a description of the rights individuals have under data protection legislation are available via ey.com/privacy. EY member firms do not practice law where prohibited by local laws. For more information about our organization, please visit ey.com.

Liability limited by a scheme approved under Professional Standards Legislation.

ED 0522

Ernst & Young is a registered trademark.

Our report may be relied upon by the Australian Government Department of Health for the purpose of the engagement only pursuant to the terms of our engagement letter dated 24/05/2022. We disclaim all responsibility to any other party for any loss or liability that the other party may suffer or incur arising from or relating to or in any way connected with the contents of our report, the provision of our report to the other party or the reliance upon our report by the other party.

ey.com