

Evaluation of the 2020 Influenza Season and assessment of system readiness for a COVID-19 vaccine

Final Report
Australian Government
Department of Health
26 March 2021

Ms Brooke Bligh
Director
Immunisation Procurement and Contract Management Section
Australian Government Department of Health
PO Box 9848
Canberra ACT 2601

Transmittal of Report

Dear Brooke,

In accordance with our Engagement Agreement dated 3 November 2020 and subsequently varied on 15 December 2020 ("Agreement"), Ernst & Young ("we" or "EY") has been engaged by the Department of Health ("you" or the "Department") to produce an evaluation of the 2020 influenza vaccination program and assessment of system readiness for a COVID-19 vaccine (the "Services").

The enclosed report (the "Report") sets out the outcomes of our work. You should read the Report in its entirety. A reference to the report includes any part of the Report.

Purpose of our Report and restrictions on its use

Please refer to a copy of the Agreement for the restrictions relating to the use of our Report. We understand that the deliverable by EY will be used to inform planning for the provision of seasonal influenza vaccine in the future, and the potential annual rollout of COVID-19 vaccine as part of the National Immunisation Program (the "Purpose").

This Report was prepared on the specific instructions of the Department solely for the Purpose and should not be used or relied upon for any other purpose.

This Report and its contents may not be quoted, referred to or shown to any other parties except as provided in the Agreement. We accept no responsibility or liability to any person other than to the Department or to such party to whom we have agreed in writing to accept a duty of care in respect of this Report, and accordingly if such other persons choose to rely upon any of the contents of this Report they do so at their own risk.

Nature and scope of our work

The scope of our work, including the basis and limitations, are detailed in our Agreement, and in this Report.

Our work commenced on 3 November 2020 and this Report was completed on 18 March 2021. Therefore, our Report does not take account of events or circumstances arising after 18 March 2021.

In preparing this Report we have considered and relied upon information from a range of sources believed after due enquiry to be reliable and accurate. We have no reason to believe that any information supplied to us, or obtained from public sources, was false or that any material information has been withheld from us.

We do not imply and it should not be construed that we have verified any of the information provided to us, or that our enquiries could have identified any matter that a more extensive examination might disclose. The compressed timeframe to deliver the Services has also potentially limited the response rate of interviews and surveys. However, we have evaluated the information provided to us by the Department as well as other parties through enquiry, analysis and review and nothing has come to our attention to indicate the information provided was materially mis-stated, unrepresentative or would not afford reasonable grounds upon which to base our Report.

The work performed as part of our scope considers information provided to us and a combination of input assumptions relating to future conditions, which may not necessarily represent actual or most likely future conditions. We take no responsibility that the projected outcomes will be achieved. We highlight that our analysis and Report do not constitute investment advice or a recommendation to you on a future course of action. We provide no assurance that our analysis will be accepted by any relevant authority or third party.

Our conclusions are based, in part, on the assumptions stated and on information provided by the Department and other information sources used during the course of the engagement. The evaluation outcomes are contingent on the collection of assumptions as agreed with the Department and no consideration of other market events, announcements or other changing circumstances are reflected in this Report. Neither EY nor any member or employee thereof undertakes responsibility in any way whatsoever to any person in respect of errors in this Report arising from incorrect information provided by the Department or other information sources used.

This letter should be read in conjunction with our Report, which is attached.

Thank you for the opportunity to work on this project for you. Should you wish to discuss any aspect of this Report, please do not hesitate to contact Ben Bishop on s47F or Caitlin Francis on s47F.

Yours sincerely

s47F
Ben Bishop
Partner

s47F
Caitlin Francis
Partner

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Abbreviations

Abbreviation	Definition
3PL	Third party logistics
ACRRM	Australian College of Rural and Remote Medicine
ACT	Australian Capital Territory
ACT Health	Department of Health Australian Capital Territory
ACV	Advisory Committee on Vaccines
AEFI	Adverse Events Following Immunisation
AHCSA	Aboriginal Health Council of South Australia
AHCWA	Aboriginal Health Council of Western Australia
AHPPC	The Australian Health Protection Principal Committee
AIR	Australian Immunisation Register
AIVC	Australian Influenza Vaccination Committee
AMA	Australian Medical Association
AMSANT	The Aboriginal Medical Services Alliance Northern Territory
ARTG	Australian Register of Therapeutic Goods
ATAGI	Australian Technical Advisory Group on Immunisation
CDCD	Communicable Disease Control Directorate
CDNA	Communicable Diseases Network Australia
CWH	Chemist Warehouse
DHB	District Health Boards
dTpa	Diphtheria, tetanus and acellular pertussis
Flu	Influenza
GP	General practitioner
GSK	GlaxoSmithKline
Hib	<i>Haemophilus influenza</i> type b
HPV	Human papillomavirus
JIC	Jurisdictional Immunisation Coordinators
NCIRS	National Centre for Immunisation Research and Surveillance
NHS	National Health Services
NIC	National Immunisation Committee
NIP	National Immunisation Program
NIR	National Immunisation Register
NDSS	National Notifiable Diseases Surveillance System
NSW	New South Wales
NSW Health	Ministry of Health New South Wales
NT	Northern Territory
NT Health	Department of Health Northern Territory
OGTR	Office of the Gene Technology Regulator
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
QAIHC	Queensland Aboriginal and Islander Health Council

Abbreviation	Definition
QLD	Queensland
QLD Health	Department of Health Queensland
RACGP	The Royal Australian College of General Practitioners
RDAA	Rural Doctor Association of Australia
SA Health	Department for Health and Wellbeing South Australia
SOH	Stock on hand
SOP	Standard Operating Procedure
TAS	Tasmania
TGA	Therapeutic Goods Administration
the Department	the Department of Health
the Guild	The Pharmacy Guild of Australia
UK	United Kingdom
USA	United States
VAS	Vaccine Administration System
VIC	Victoria
VIC Health	Department of Health Victoria (formally known as 'Department of Health and Human Services Victoria')
WA	Western Australia
WHO	World Health Organization

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Executive summary

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1. Executive summary

1.1 Project outline and purpose

This report has been commissioned by the Australian Government Department of Health (the Department) to evaluate the supply of vaccines for the 2020 influenza (flu) season. Any findings and lessons learned from the evaluation will also need to be considered in light of a potential rollout of a COVID-19 vaccine on a regular basis as part of the National Immunisation Program (NIP).¹

1.2 Background

In Australia, individuals can access prescribed flu vaccines through one of two markets:

- ▶ **Public market** – Where vaccines are provided free to those eligible under the NIP
- ▶ **Private market** – Where vaccines are available at retail rates for individuals not eligible for the NIP

The government funds the NIP with the aim to increase national immunisation coverage to reduce the number of cases of diseases that are preventable by vaccination in Australia. The NIP is implemented in collaboration by the Department, and states and territories health departments, with the delivery overseen by a range of committees and advisory bodies. The key goal of the NIP is to deliver vaccinations to the right people at the right time. The Department's strategic priorities for the NIP are:

- ▶ Ensure effective governance
- ▶ Ensure secure vaccine supply and efficient use of vaccines
- ▶ Continue to enhance vaccine safety monitoring systems
- ▶ Maintain and ensure community confidence through effective communication strategies
- ▶ Strengthen monitoring and evaluation through assessment and analysis of immunisation register data and vaccine-preventable disease surveillance
- ▶ Ensure an adequately skilled immunisation workforce through promoting effective training for immunisation providers
- ▶ Maintain Australia's strong contribution to the region

All of these priorities depend on a high state of vaccine system readiness which is achieved through system-wide coordination between all levels of governments, vaccine suppliers, and immunisation providers, as well as support and cooperation from the Australian public.

The flu vaccine is funded under the NIP for the following eligible cohorts:

- ▶ People aged six months and over with certain medical risk factors
- ▶ All children six months to less than five years
- ▶ All Aboriginal and /or Torres Strait Islander people six months and over
- ▶ People aged 65 years and over
- ▶ Pregnant women

¹ This should be contrasted against the expected initial rollout of COVID-19 vaccines in 2021, which is outside of the scope of this report.

1.3 Project approach

A structured approach was implemented to evaluate the current state and performance of the 2020 flu vaccination program. The methodology involved conducting desktop research, data analysis, policy review, stakeholder consultations and social media analysis. A dynamic and varying mix of these approaches was applied to six evaluation criteria as outlined below:

- ▶ Influenza vaccination strategy
- ▶ Program governance
- ▶ Supply chain
- ▶ Immunisation provider
- ▶ Post administration documentation and reporting
- ▶ Consumer sentiment

The stakeholder consultations covered representatives from all health departments in Australia, wholesalers, distributors, peak bodies, immunisation providers and consumer advocates, through a variety of methods including interviews and surveys.

1.4 Overview of the 2020 flu season

Australia entered the 2020 flu season (April 2020) during the early stages of the COVID-19 pandemic which was an unprecedented public health event for the Australian population.

"Vaccinating against the flu will reduce the risk of a very dangerous double-up of flu and coronavirus—both diseases affecting the respiratory system."

The Hon Greg Hunt MP, Minister for Health²

Given the potential risk that if a person was to contract the seasonal flu and COVID-19 simultaneously, the severity of the combined illness could be significant. On 01 April 2020, the Australian Government encouraged all Australians to be vaccinated against the seasonal flu to reduce the likelihood of co-infection. In doing so, Australia saw a historical number of doses made available across the country (17.6 million) although the surge in demand for the flu vaccine from the general public created significant pressure on vaccine distribution. In particular, immunisation providers, such as General Practitioners (GPs), experienced stock delay during the peak of the season due to high demand and logistical challenges amidst the COVID-19 pandemic. As a consequence, although the overall stock supplied was sufficient, some perceived shortage in NIP vaccine supply was experienced by certain stakeholders, such as GPs in Tasmania and Northern Territory.

These complications surrounding the supply of the flu vaccine, regardless of being perceived or real, warranted further investigation, and are the subject of this evaluation.

1.5 Overall finding

The 2020 annual flu vaccination program was largely successful with a record 17.6 million doses of vaccines released to the Australian market between March and October 2020. Of the 17.6 million, 8.8

² Australian Government Department of Health, 2020, *Flu vaccination more important than ever during the month of April*, Available at: <<https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/flu-vaccination-more-important-than-ever-during-the-month-of-april>> [Accessed 12 December 2020]

million doses were released via the NIP, the highest volume ever released since flu was added to the program in 2009.³

In a year when demand was higher than ever before, 70% of immunisation providers who participated in EY's immunisation provider survey were satisfied that community expectations of vaccine availability were met.⁴ Immunisation providers described the season as one of their most successful ever, based on the rates in which vaccines were given and the low rates of infection. Immunisation providers felt that the driving factor of increased immunisation was the introduction of the COVID-19 virus, with the sustained advertising campaign in recent years also playing a part.⁵

Australia recorded a fraction of laboratory confirmed flu infections compared to previous years. During the 2020 season, there were 21,266 laboratory confirmed flu cases reported to the National Notifiable Diseases Surveillance System (NNDSS) which was eight times less than the five year average (163,015 cases).⁶ This can be attributed to the social distancing measures and public health communications implemented as part of the COVID-19 response as well as the availability of seasonal flu vaccines.

A key challenge faced in the 2020 flu season was the delivery of vaccine stock. While procurement lead times for the vaccine stock this season were consistent with prior years - highlighting the robustness of suppliers' processes and the effectiveness of the Department's planning process - COVID-19 related restrictions on movement, interstate travel restrictions

The higher than usual level of vaccine inventory towards the end of the 2020 season also suggests that overall supply was more than adequate to meet overall demand. With delivery timeframe being only marginally above the previous season, the likely reason for any real or perceived vaccine shortages can be attributed to the heightened demand for the flu vaccine at the beginning of the season.

While these disruptions had the potential to impair the outcome of the program, the deft implementation of workaround solutions at a jurisdiction (i.e. state and territory) level ensured that NIP vaccines were ultimately delivered effectively. These disruptions, however, highlighted vulnerabilities in the Australian vaccine supply chain that should be addressed before a COVID-19 vaccine is added to the NIP, should it be required.

1.6 Findings and recommendations

Our review presents a range of findings where the solutions cannot always be mandated by the Department and require the cooperation of a number of stakeholders. Our findings are detailed below, along with the associated recommendations where:

- Yellow squares reflect recommendations that can be directly addressed by the Department
- ▲ Grey triangles reflect recommendations that cannot be directly addressed by the Department, such as those that would require the support and cooperation of other jurisdictions, or are subject to the availability of commercial services

Strategy	
No clear national strategy	
A defined and agreed strategy for the annual flu vaccination program under the NIP does not currently exist. Without a clearly defined purpose and strategy, operational decisions are made between the Department, jurisdictions and other program participants without a key strategic platform which, in turn, leads to a lack of clarity and predictability in the	<ul style="list-style-type: none">▲ Recommendation 1: The Department and the departments of health in the jurisdictions agree to an annual flu vaccination program strategy under the NIP which includes:<ul style="list-style-type: none">a. Annual objectives for immunisation rates across the population as a whole and for specific high-risk groups, such as people over 65 years of age and Aboriginal and Torres Strait Islander people

³ Australian Government Department of Health - Australian Influenza Surveillance Report No. 17 2020. Available at: <https://www1.health.gov.au/internet/main/publishing.nsf/Content/ozflu-surveil-no17-20.htm>

⁴ Synthesis of interviews with stakeholder, survey of immunisation providers and EY analysis

⁵ Synthesis of interviews with stakeholder, survey of immunisation providers and EY analysis

⁶ Australian Government Department of Health - Australian Influenza Surveillance Report No. 17 2020. Available at: <https://www1.health.gov.au/internet/main/publishing.nsf/Content/ozflu-surveil-no17-20.htm>

Strategy	
<p>delivery of the program. This lack of a key program strategy also makes it hard to measure the success of the program.</p>	<ul style="list-style-type: none"> b. Annual timelines for the achievement of these immunisation program objectives c. Annual projections for NIP flu demand by jurisdiction d. Identification of higher risk population groups and the national strategy to increase vaccination rates among these higher risk groups e. Nationally consistent protocols for the vaccination of targeted groups to reduce confusion among vaccine suppliers, distributors and clinical administrators generated by the variability in arrangements between jurisdictions f. Nationally consistent logistical arrangements for the distribution and administration of vaccines under the NIP including the administration of flu vaccines to people living in residential aged care facilities and remote communities g. Agreed performance measures to monitor the effectiveness of the program h. The communications strategy between the Department and jurisdictions for the annual NIP flu vaccination program (see Recommendation 9 for further detail) i. A National Communications Strategy for the NIP flu vaccination program needs to be refreshed and aligned (see Recommendation 14 for further detail) <p><i>It is noted that the Department currently performs components c. and d. already.</i></p>
Inconsistent jurisdictional approach leading to eligible cohorts not adequately prioritised	
<p>While each jurisdiction determines how it rolls out public vaccines to its eligible cohorts, a lack of consistency across states and territories creates complexity for vaccine suppliers, distributors and administrators.</p> <p>Notably, only Victoria and South Australia have reported that some aged care facilities are registered flu vaccine providers. The remaining residential aged care facilities rely on the residents' general practitioners to source the vaccine themselves and it is unclear whether they have been given any special considerations taking into account the larger quantity ordered usually at the beginning of the flu season as demanded by this cohort. Anecdotal evidence suggest these orders have not been given any special considerations and potentially mistaken as unnecessarily large order that are then truncated.</p> <p>The current arrangement reflects the potential mis-alignment between vaccine distribution and duty of care to aged care residents, where the responsibility of the former rests with state and territory jurisdictions and the latter rests with the Department.</p>	<ul style="list-style-type: none"> ■ Recommendation 2: The Department refresh the flu vaccination administration program for residents of residential aged care facilities in collaboration with Primary Health networks, aged care operators and general practitioners. <p>The program refresh should take into account age care residents' risks profile in relation to flu as well as the higher potential for outbreaks in a residential care setting.</p> <p>Potentially as a mean to align care and jurisdiction for aged care residents, while recognising the complexities of the matter, the Department should commission a study into the benefits and risks of creating a priority group, such as aged care residents, within the NIP eligible cohorts, as well as informing the refresh of the flu vaccination administration program.</p>

Governance	
Role of the National Immunisation Committee	
<p>The National Immunisation Committee (NIC) played a key role in governing the operation of NIP. The NIC provided advice on the implementation, communication and strategic direction of the NIP, including policy and program advice, and represented the needs and views of vaccination providers and consumers.</p> <p>The breadth of membership on the NIC allowed for critical and diverse stakeholder input from independent parties that can observe, with great depth, the strengths and weaknesses of the current vaccination strategy, and implement new strategies in an already volatile environment further complicated by the COVID-19 pandemic.</p>	<ul style="list-style-type: none"> ■ Recommendation 3: The Department restore the NIC or a NIC-like forum with similar mandates, with the objective of seeking inputs from a range of relevant external stakeholders such as GPs, Aboriginal and Torres Strait Islander health providers and aged care providers, into the development of the annual NIP flu vaccination strategy, as well as the interaction of the program with the private flu vaccination market.

Governance	
Following positive stakeholder feedback, the restoration of the NIC, with clear agenda and objectives of each meeting, would allow for more efficient strategy implementation and post-implementation review for future decision making processes.	
Role of the Therapeutic Goods Administration	
<p>The involvement of the Therapeutic Goods Administration (TGA) in the Department's internal governance processes for the NIP was requested by TGA representatives during consultation. Currently, TGA's involvement is useful and productive. However, it is considered that the TGA is constrained from having a thorough understanding of any emerging issues in the program, as TGA tends to be involved relatively late in the decision making processes.</p> <p>A more structured and more regular involvement of the TGA in the Department's immunisation decision making processes will improve the effectiveness of the TGA's involvement in the program and improve the TGA's readiness to anticipate changes in the program and contribute in a more timely manner.</p> <p>Furthermore, the TGA chairs multiple international committees with regulatory counterparts around the world, and proactively ensures patients can report adverse events via multiple avenues. The TGA can play an intermediary role in communicating the global trend and local experience more broadly when more tightly integrated with the governance process of NIP.</p>	<p>▲ Recommendation 4: The Department consider expanding its internal governance processes used to design, approve and monitor the effectiveness of the annual NIP flu vaccination program to include formal involvement of the TGA in the decision making processes earlier. The early and more comprehensive involvement of the TGA will improve the effectiveness of the flu vaccination program.</p>

Supply Chain	
Improve planning with Australian Immunisation Register data	
<p>With AIR reporting becoming mandatory from March 2021, there is an opportunity for the Department to enhance the demand planning process by using vaccinations data recorded on AIR.</p> <p>As the data would reflect actual vaccinations performed, it would more closely reflect underlying vaccine demand, and enable for a more accurate prediction of eligible cohort sizes compared to the current practice of estimating using demographic data.</p>	<p>■ Recommendation 5: Redesign the demand planning process to incorporate AIR vaccinations data from the 2022 season.</p>
Key freight port risk	
<p>Despite supply being stable for most jurisdictions, the Northern Territory noted significant challenges in receiving their supplies. The jurisdiction experienced unstable supply deliveries for the 2020 season due to a lack of domestic commercial flights to transport vaccine stock from Sydney, the most common port for vaccine stock to arrive in Australia.</p>	<p>▲ Recommendation 6: International deliveries should be shared between more international airports across Australia to reduce the dependence on Sydney as the main port of delivery.</p>
Storage capacity	
<p>Storage capacity was identified as a key constraint at the immunisation provider level. Ineffective demand planning and ordering processes at the provider level Providers' lack of understanding of their storage capacity, coupled with weak demand planning and ordering, meant that providers often ordered in excess of what they could store and administer at their facility, resulting in vaccine wastage.</p> <p>In addition, most jurisdictions health agencies have no visibility of their providers' vaccine storage capacity. Department of Health Australian Capital Territory (ACT Health) is the only jurisdiction that has full and accurate visibility of providers' storage capacity as the ACT Health staff members are responsible for distribution and delivery, all the way to providers' fridges.</p>	<p>▲ Recommendation 7: The Department supports and encourages jurisdictions to assess and record the capacity of immunisation providers to store vaccines appropriately. The information would support the efficient and effective management of the ordering of NIP flu vaccine, or the addition of emerging vaccines, such as a COVID-19 vaccine, to be delivered alongside the annual flu vaccination program.</p>

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Reporting	
AIR adoption	
<p>Adoption of AIR by some immunisation providers to record vaccinations is low, which makes it difficult for relevant agencies to assess the level of vaccine uptake across the population. Stakeholders consulted have raised concerns over the validity of AIR, noting it is effective as a single source but large portions of under-reporting may render insights from AIR inaccurate.</p> <p>Reporting from pharmacists is of particular concern, whilst one chain indicated that all pharmacists are required to record vaccinations on AIR, consultations with jurisdictions found that there was a distinct lack of confidence in pharmacist reporting.</p> <p>Adoption of AIR is low because recording on the register is not a legislated requirement. In addition, users expressed serious concerns about AIR's usability. The historically low levels of use of the AIR amongst pharmacists highlights the need for an education/awareness campaign specifically targeted at pharmacists once the new legislation is introduced, which could be designed in consultation with the peak bodies.</p>	<ul style="list-style-type: none"> ■ Recommendation 11: The recording of NIP flu vaccination on the AIR should be mandatory for all immunisation providers to enable the assessment of the effectiveness of the program and its reach into higher risk population groups. <p>It is also recommended that improvements be made to AIR's usability to reduce manual inputs and interoperability with ICT infrastructure of immunisation providers.</p> <p><i>It is noted at the time of writing that an amendment to the Australian Immunisation Register Act 2015 has been introduced in parliament to mandate vaccination recordings on AIR. The amendment has since received parliamentary approval on 4 February 2021, where vaccination recordings will be mandatory from 1 March 2021</i></p> <p><i>The recommendation remains to highlight the importance and value of mandatory reporting on AIR.</i></p>
Streamline adverse events reporting	
<p>The adverse events reporting system meets the needs of stakeholders, but it is cumbersome due to the existence of multiple reporting pathways. It is also a substantially manual process due to the lack of digital links across the database and jurisdiction's systems.</p> <p>Stakeholders have also expressed that the limited system interoperability may become a potential issue with the COVID-19 vaccine roll out, as the system may suffer a reduction in timeliness and responsiveness in a large new vaccine rollout.</p>	<ul style="list-style-type: none"> ■ Recommendation 12: The adverse events reporting process should be streamlined among the various pathways currently operating so that all reports of adverse events are only required to be entered once into a system that will then ultimately report to the TGA's adverse event system. <p>While this recommendation is directed at the flu vaccination program, there are direct implications for the COVID-19 vaccine rollout.</p> <p>As COVID-19 vaccines are new to the market, reporting and responding to adverse events in a timely manner is important. Having an optimised reporting process for consumers and providers will support timely report and response.</p> <p><i>It is noted that the COVID-19 Taskforce is examining improvements to adverse events reporting as part of its vaccine rollout program.</i></p>
Adverse events review by NIC	
<p>It was noted that the NIC does not cover a review of adverse events as part of its Terms of Reference. Having visibility of adverse events at the NIC can assist in identifying and responding to any emerging vaccine safety risks within the NIP at a national level.</p> <p>The review of the annual adverse event trend will be beneficial for the entire NIP for all relevant parties to have a common understanding of the level and significance of adverse events within the NIP.</p> <p>This can be achieved by discussing an annual summary of adverse events as well as urgent ad-hoc discussion of any urgent trends in adverse events at the NIC or an NIC-like forum. Australia has been lucky in the last decade in that there have been relatively few adverse events in the NIP but the NIC or an NIC-like forum should be aware of the trends in adverse events.</p>	<ul style="list-style-type: none"> ■ Recommendation 13: The NIC or an NIC-like forum should review a summary of adverse event trends annually. This has implications for the COVID-19 vaccine to optimise the visibility of adverse events and any required responses at a national level.

Consumer sentiment	
National communication strategy	
<p>Success in having NIP eligible cohorts accessing program vaccines is heavily dependent on individuals' understanding their entitlements, benefits and risks.</p> <p>Furthermore, there was a misalignment in messaging to the public between the Department and jurisdictions with respect to NIP vaccine availability. The Department had encouraged the public to consider i flu vaccine uptake early, whilst the NIP stock may still be in transit. This resulted in a rush by consumers to their immunisation providers for vaccines despite a lack of public stock. This problem was further complicated by the private market advertising that flu stock was available earlier than the NIP stock.</p>	<p>■ Recommendation 14: The annual refresh of the national communication strategy must be aligned with the annual National Influenza Immunisation Strategy (referred to in Recommendation 1) and should include the following additional components:</p> <ol style="list-style-type: none"> Flu vaccine supply and why eligible consumers should wait for their NIP vaccines to be available How immunisation works in an aged care setting Consider the use the social media with tailored content as another medium of communication to reach targeted cohorts and counter misinformation <p>The program's communication strategy should be discussed at the NIC or an NIC-like forum to improve the coordination of messaging across both the NIP and the private flu vaccination market.</p> <p>The effectiveness of the communication strategy underpinning the annual NIP flu vaccination program be measured through regular formal testing of consumer and provider sentiment.</p> <p>Consultation with Indigenous councils emphasised the importance of tailored messaging to remote communities, who require Aboriginal and / or Torres Strait Islander representation and respond better to plain language, and evidence based details. This is also applicable to any future rollout of the COVID-19 vaccine to support effective uptake.</p>

1.6.1 COVID-19 Vaccine System Readiness Assessment Limitations

EY has refrained from making any COVID-19 vaccine specific recommendations due to the rapidly evolving science around its development, and all recommendations and considerations from this report would nonetheless benefit the rollout of an annual COVID-19 vaccination program under the NIP .

2

Introduction

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2. Introduction

2.1 Purpose and objectives of the evaluation and assessment

The Australian Government Department of Health engaged EY to independently evaluate the 2020 flu vaccination program. The purpose of this report is to provide a better understanding of the Australian vaccine system operations to support the rollout of future seasonal flu vaccine programs. In addition to this, a key objective was to assess the vaccine system's readiness for the potential concurrent rollout of a COVID-19 vaccination program alongside the annual flu program as part of the NIP.

The scope of this review was to:

- ▶ Conduct an end-to-end review of the components of the vaccine system, from policy development and vaccine manufacturing, to consumer uptake and waste management for both the NIP and private market
- ▶ Facilitate consultations with stakeholders involved in the Australian flu vaccine system, including policy makers, regulators, jurisdictions, suppliers, wholesaler, immunisation providers, consumer advocates and peak bodies, to understand the performance of the 2020 flu season and ensure coverage of a broad range of views and experiences
- ▶ Benchmark vaccine system practices against other developed countries
- ▶ Review existing logistics, transportation and infrastructure networks to identify capability, capacity and pain points
- ▶ Review the performance of the flu vaccine system based on the 2020 flu season, to identify the success, and to provide recommendations and considerations to address identified shortfalls or limitations
- ▶ Identify existing and emerging needs in the vaccine system that should be addressed to support the rollout of a potential COVID-19 vaccine program concurrently with the seasonal flu program

It should be noted that given the substantial uncertainty associated with COVID-19 vaccines, there are a number of aspects on the rollout of a potential COVID-19 vaccine program, as part of the NIP, that this evaluation cannot reliably comment on. The three main uncertainties are:

- ▶ Whether the COVID-19 vaccines require regular inoculations, similar to the need to administer the seasonal flu vaccine annually, in order to maintain a person's immunity and to respond to the constant mutating nature of the virus
- ▶ It is as yet unknown whether a seasonal flu vaccine can be co-administered with a COVID-19 vaccine. This is further complicated by the vast array of COVID-19 vaccines based on different platforms
- ▶ The significant difference in logistical requirements of COVID-19 vaccines, even amongst the current front runners in clinical trials

2.2 Approach

To meet the objectives of the evaluation and assessment, an Evaluation Plan was developed. This Evaluation Plan served two purposes:

1. A structured approach to evaluating the 2020 flu season
2. A framework for analysing individual components of the vaccine system, and assessing whether system components are ready for the potential implementation of a COVID-19 vaccination program as part of the NIP

As part of the Evaluation Plan, six evaluation criteria have been identified, each representing a critical component of the Australian vaccine system:

Figure 1: Evaluation criteria



Each criteria was analysed through a range of evaluation methods, including:

- ▶ Method 1 - Value chain consultations with stakeholders involved in the vaccine system
- ▶ Method 2 - Interviews with immunisation providers and consumer advocates⁷
- ▶ Method 3 - Surveys with immunisation providers⁸
- ▶ Method 4 - Social media analysis
- ▶ External research
- ▶ Review of policy governing the vaccine system
- ▶ Review of data and reports provided by vaccine system stakeholders

The Evaluation Plan criteria have been mapped against evaluation methods. This was done to illustrate how each method directly informs criteria analysis. Please refer to Appendix A for the mapping of evaluation criteria against evaluation methods. The stakeholders who were interviewed as part of Method 1 are listed in Appendix B.

A miniaturised outline of the chevrons is used to assist with the navigation of *Chapter 4 - Evaluation findings and recommendations* in this report.

⁷ A series of in-depth interviews were conducted with 11 immunisers across Australia. Participants for the interviews were sourced from peak bodies, including ACCRM, ACHSA, AMSANT, RACGP, and Winnunga Nimmityjah Aboriginal Health Service. All interviews were approximately 30-45 minutes in length and were conducted between Tuesday 12th January 2021 and Tuesday 2nd February 2021.

⁸ An online survey was used to capture insights from a total of 114 immunisers. The survey was conducted between Monday 7th December 2021 and Wednesday 3rd February 2021.

2.3 Assumptions and limitations

While all evaluations are inherently reliant on the cooperation and support of all stakeholders, this evaluation stands out in the following ways:

- ▶ Compressed timeline - delivering a substantial body of work within a compressed timeframe limited our ability to undertake extensive follow-up sessions with our stakeholders
- ▶ Evaluation timing - there were three key factors that influenced the success of the evaluation: a) conducting the evaluation during a pandemic; b) conducting the evaluation in the lead-up to Christmas and the busy trading period; and c) commencing the evaluation approximately four months after the completion of the 2020 flu season. This resulted in a number of stakeholder constraints, including:
 - ▶ Reduced availability of stakeholders to participate in the evaluation thereby reducing the breadth of stakeholder participation
 - ▶ Less ability to respond to requests to participate in a timely manner
 - ▶ Reliance on respondents' recollection may reduce respondents' ability to provide in-depth responses
- ▶ S47 [REDACTED]
- ▶ Potential bias - It is acknowledged that many of the stakeholders involved in the evaluation have high levels of professional interest in the topics of the evaluation. As such, their responses may reflect their desire to:
 - ▶ Portray their performance in a positive light, potentially resulting in participants being unwilling to consider or suggest areas for improvement or challenges relating to their role
 - ▶ Downplay the performance of other roles
- ▶ No direct consultation with consumers - which may otherwise allow for a more in-depth evaluation of the consumer sentiment criteria
- ▶ Participation of pharmacists - while we have consulted with the relevant peak bodies of pharmacists, it has not been possible to capture the views of individual pharmacists due to disruptions caused by COVID-19 as well as the Christmas New Year holiday period. This has resulted in an underrepresentation of their views in the evaluation

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.

Influenza vaccination in Australia

This document was released under the Freedom of Information Act 1982

3. Influenza vaccination in Australia

3.1 Overview of the flu virus

Influenza is a contagious respiratory infectious disease caused by orthomyxoviruses' genera types A, B and C. It infects vertebrates such as birds (avian flu), humans and other mammals. The virus is a Ribonucleic Acid (RNA) virus and has the potential to cause an endemic in certain regions, known as seasonal flu, during the winter months. Each season, the flu virus goes through a natural evolution process called antigenic shift, where the combination of two or more strains of the virus mix to form a new viral strain. The new circulating viral strain is transmitted via the air in the form of droplets from infected objects to others. The most prevalent circulating viral strain could potentially infect a greater geographic region and cause a pandemic event.

Common flu symptoms include fever, runny nose, sore throat, muscle ache and headache.⁹ It can range from mild to severe, resulting in hospitalisation or mortality. Further complications include viral pneumonia, sinus infections and secondary bacterial infection (e.g. *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Staphylococcus aureus*) which can further increase the morbidity and mortality of flu.¹⁰

3.2 Value of vaccinations

While antivirals are available to treat flu, vaccination remains one of the most effective preventative measures to combat the flu virus.¹¹ The flu vaccine induces antibody development after approximately two weeks of vaccination, and provides protection against the pre-selected circulating flu viral strains contained in the vaccine.

Vaccine strains for the Southern Hemisphere are forecasted and recommended each year by the World Health Organization (WHO) in September, and adopted for Australia by the Australian Influenza Vaccination Committee (AIVC) in October¹² ahead of the upcoming flu season. As the strains recommendation is a prediction of what the circulating strains will be in the upcoming season, there can be a mismatch between the recommendation and what is in circulation due to antigenic shift. In addition, the egg based growing of viruses for vaccines can also result in antigenic shift. Both these factors lead to a lower vaccine efficacy rate compared to other common viral disease immunisations and an annual update of the vaccines, to match with the predominated circulating strains.

Co-administration of flu and COVID-19 vaccines

Co-infection of flu and COVID-19 together has been determined to sufficiently increase the risk of mortality. Evidence emerged from the United Kingdom (UK), a 20% increase of mortality rate is associated with co-infection of the two viruses (43%), compare to COVID-19 positive (20%) only, for those hospitalised, which represents the patients with the most severe illness.¹³ UK health officials have recommended that individuals should be immunised against both seasonal flu and COVID-19 when vaccines become available and as deemed appropriate by medical professionals.

⁹ HEALTH, N. Z. M. O., 2018, *Influenza*, Available at: <<https://www.health.govt.nz/your-health/conditions-and-treatments/diseases-and-illnesses/influenza>> [Accessed 6th December 2020].

¹⁰ ROTHBERG, M. B., HAESSLER, S. D. & BROWN, R. B., 2008, Complications of viral influenza. *Am J Med*, 121, 258-64.

¹¹ Australian Department of Health, 2011, *Antivirals & Vaccines*. Available at:

<<https://www1.health.gov.au/internet/main/publishing.nsf/Content/panflu-avail-anti-vacc-1>> [Accessed 2020].

¹² * A meeting of the AIVC was held on the 9th October 2019, where the committee expert reviewed and evaluated data related to influenza epidemiology, antigenic and genetic characteristic of recent circulating influenza strains in Australia and the southern Hemisphere. This also includes the serological response to the prior season's (2018 - 2019) influenza vaccines, as well as the availability of candidate vaccines virus and reagents. Followed by a recommendation to TGA, should adopt the WHO recommendations of the 2020 flu seasons.

¹³ Boseley, S, 2020, *Flu and Covid-19 at same time significantly increases risk of death*, The Guardian, Available at: <<https://www.theguardian.com/world/2020/sep/22/flu-and-covid-19-at-same-time-significantly-increases-risk-of-death>> [Accessed 27 January 2021]

Uncertainty however remains over whether the two vaccines can be administered concurrently.¹⁴ There is no data at the time that this report is written, to support or object to the co-administration of the COVID-19 vaccine with other vaccines (including the seasonal flu vaccine). The guideline varies internationally with considerations taken based on the technology used for the COVID-19 vaccine. For example:

In the UK

National Health Services (NHS) England has updated its *Standard Operating Procedure (SOP) - COVID-19 local vaccination services deployment in community settings* on 14 January 2021, with the view that the COVID-19 vaccine should not be administered if 'any other vaccination has been received within the last 7 days'.¹⁵ However, a further complementing guideline was also added as below:

- ▶ 'However, adjacent or co-administration can occur where this would cause delay or reduce access to either flu or COVID-19 vaccine for certain patient groups e.g. care homes, housebound patients and hard to reach or vulnerable groups'.

The current Green Book¹⁶ suggest that there is no evidence of safety concerns when co-administering the COVID-19 vaccines with other vaccines. The advice of seven days gap is to 'avoid incorrect attribution of potential adverse events'. The updated guideline only applies to eligible patients and the same advice applies for other vaccines where the COVID-19 vaccine is received first. There is no further comment distinguishing the different type of vaccine technologies (i.e. mRNA).

In the United States (USA)

Similarly, the Centres for Disease Control and Prevention (CDC) in the USA acknowledged that there is a lack of data on the safety and efficacy of co-administration of flu and COVID-19 mRNA vaccines.¹⁷ The guideline has suggested not to co-administer the two vaccines but they are able to be administered with a minimum interval of 14 days, before or after the administration of any other vaccines.

It is however advised that, timeframes shorter than a 14 day interval may occur based on clinical other clinical considerations, where greater benefits are deemed to outweigh the potential unknown safety and efficacy risks. Examples given are¹⁸:

- ▶ 'To avoid barriers or delays to mRNA COVID-19 vaccination in long-term care facility residents or healthcare personnel who received flu or other vaccinations prior to / upon admission or onboarding'
- ▶ 'Tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak'

In Australia

In Australia, the rollout of the 2021 COVID-19 vaccination is managed by the Department, with support and consultation from the state and territory health departments. The current advice by the Australian Technical Advisory Group on Immunisation (ATAGI) on the relative timing of administering flu and COVID-19 vaccines in 2021¹⁹ includes:

¹⁴ Public Health England, 2021, *COVID-19: the green book, chapter 14a*, Available at:

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955548/Greenbook_chapter_14a_v6.pdf> [Accessed 27 January 2021]

¹⁵ NHS, 2021, *Novel coronavirus (COVID-19) standard operating procedure: COVID-19 local vaccination services deployment in community settings*, Available at: <<https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/12/C1038-covid-19-vaccine-deployment-in-community-settings-lvs-sop-v3.2.pdf>> [Accessed 27 January 2021]

¹⁶ Public Health England, 2021, *COVID-19: the green book, chapter 14a*, Available at:

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/955548/Greenbook_chapter_14a_v6.pdf> [Accessed 27 January 2021]

¹⁷ CDC, 2021, *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States*, Available at: <<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>> [Accessed 27 January 2021]

¹⁸ CDC, 2021, *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States*, Available at: <<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>> [Accessed 27 January 2021]

¹⁹ Australian Technical Advisory Group on Immunisation (ATAGI), 19 January 2021, *Advice on the relative timing of administering influenza and COVID-19 vaccines in 2021*, Prepared by NCIRS for the ATAGI COVID-19 Working Group. Available at: <https://www.health.gov.au/sites/default/files/documents/2021/01/atagi-advice-on-influenza-and-covid-19-vaccines.pdf>

- ▶ Routine scheduling and giving of an flu vaccine with a COVID-19 vaccine on the same day is not recommended
- ▶ The preferred minimum interval between a dose of seasonal flu vaccine and a dose of BNT162b2 or ChAdOx1-S is 14 days
- ▶ There may be circumstances where co-administration or near administration (within days) of an flu vaccine with a COVID-19 vaccine may be considered
- ▶ There is no particular requirement regarding the order of receiving a dose of flu vaccine and either the first or second dose of a COVID-19 vaccine
- ▶ If an flu vaccine has been inadvertently co-administered or administered within an interval shorter than 14 days with a COVID-19 vaccine, revaccination with either vaccine is not considered necessary

Post-2021, in the case where the COVID-19 vaccination has become an annual activity similar to flu (with similar rollout time, system requirements and the potential for the same or a greater quantity), it is noted that the immunisation plan against COVID-19 may complicate the flu vaccine rollout or vice versa. The potential risks, impact and recommendations are discussed in *4.9 COVID-19 system readiness assessment*.

3.3 Vaccine approval and governance

AIVC's decision on the matching circulating strains are passed on to the TGA for the purposes of new vaccine approval. In parallel, vaccine suppliers work with the TGA to register their vaccine products on the Australian Register of Therapeutic Goods (ARTG). The TGA goes through a multiple staged evaluation and assessment of vaccine applications and consults with the Advisory Committee on Vaccines (ACV) on the safety and efficacy of vaccine applicants.²⁰

If the TGA is satisfied with the safety and efficacy of the vaccine that is the subject of the application, the vaccine can be provisionally registered on the ARTG, provided the benefits outweigh the risks. This grants the supplier the right to supply the vaccine in Australia, where it will continue to be monitored for adverse effects.

As part of the TGA's regulatory role, it is responsible for reviewing and assuring the quality of vaccines. This includes:

- ▶ **Prior to approval for Australian use** - Assessing the results of submitted clinical trials with respect to minimum size and length, representative groups, and ensuring the vaccine's benefits outweigh the associated risks²¹
- ▶ **Following batch release** - Conducting batch monitoring to assess the quality of every batch of vaccine before shipment into Australia
- ▶ **Post supply into Australia** - Periodically testing vaccines and releasing results at least 6 months after testing publicly to assess for adverse events and safety

3.4 Vaccine supply and access

In Australia, individuals can access approved flu vaccines through one of two markets:

- ▶ **Public market** - Where vaccines are provided free to those eligible under the NIP
- ▶ **Private market** - Where vaccines are available to non-eligible consumers at retail rates

²⁰ Australian Government Department of Health, 2020, *COVID-19 vaccine approval process*, Available at: <<https://www.tga.gov.au/covid-19-vaccine-approval-process>> [Accessed 29 December 2020]

²¹ Australian Government Department of Health, n.d., *National Immunisation Program (NIP) vaccine listing process*, Available at: <<https://www.health.gov.au/sites/default/files/nip-vaccine-listing.pdf>> [Accessed 29 December 2020]

3.4.1 Public market vaccine supply and access

3.4.1.1 National Immunisation Program

The NIP is a series of immunisations, ranging from birth through to adulthood, recommended to be given at specific times throughout one's lifetime.²² The NIP began in 1997, with vaccine preventable diseases being included in the as evidence became available and where clear benefits can be demonstrated to the public health. For example:

- ▶ Funding for individuals aged 65+ was introduced nationally in 1999²³
- ▶ Human papillomavirus (HPV) vaccination - Australia was the first country in the world to initiate a fully funded HPV vaccination program in 2007 and is set to eliminate cervical cancer by 2035 combining the effort of routine screening²⁴

All vaccines recommended in the NIP are free for individuals who are eligible for Medicare benefits. Examples of diseases that are immunised for both non-Indigenous and all Aboriginal and Torres Strait Islander people are:

- ▶ **Childhood** - hepatitis B, Diphtheria, tetanus and acellular pertussis (dTpa), polio, *H. influenza* type b (Hib), rotavirus, pneumococcal and meningococcal (B and ACWY)
- ▶ **School programs** - in-school vaccinations for year seven (or age equivalent, 11-13 years of age) in all states and territories, except South Australia and Western Australia, for HPV and dTpa
 - ▶ **South Australia and Western Australia:** the school program will take place in year eight and year ten respectively
- ▶ **Adulthood:** annual flu vaccine, shingles, pneumococcal and pertussis

Seasonal flu vaccination in the public market

Seasonal flu vaccines are provided through the NIP for eligible cohorts. The NIP is an immunisation initiative funded by the Australian Government to increase national immunisation rates against flu. Various arrangements for the funding and management of the NIP have been in place since its inception in 1997. The NIP is governed in collaboration by the Department, states and territories, with the delivery of the program overseen by a range of committees and advisory bodies.

The key goal of the NIP is to deliver vaccinations to the right people at the right time. The Department's strategic priorities for the NIP are:

- ▶ Improve immunisation coverage
- ▶ Ensure effective governance
- ▶ Ensure secure vaccine supply and efficient use of vaccines
- ▶ Continue to enhance vaccine safety monitoring systems
- ▶ Maintain and ensure community confidence through effective communication strategies

²² Australian Government Department of Health, 2021, *National Immunisation Program*, Available at: <<https://www.health.gov.au/initiatives-and-programs/national-immunisation-program>> [Accessed 27 January 2021]

²³ Kassianos G, Banerjee A, Baron-Papillon F, Hampson AW, et al., 2021, *Key policy and programmatic factors to improve influenza vaccination rates based on the experience from four high-performing countries*, DOI: 10.7573/dic.2020-9-5, Drugs in Context, Available at: <<https://www.drugsincontext.com/wp-content/uploads/2021/01/dic-2020-9-5.pdf>> [Accessed 27 January 2021]

²⁴ Cancer Council, 2018, *Australia set to eliminate cervical cancer by 2035*, Available at <<https://www.cancer.org.au/media-releases/2018/australia-set-to-eliminate-cervical-cancer-by-2035>> [Accessed 27 January 2021]; Hall, M, Simms, K, Lew, J, Smith, M, Brotherton, J, Saville, M, et al., 2018, *The projected timeframe until cervical cancer elimination in Australia: a modelling study*, The Lancet Public Health, Vol. 4, Issue 1, pp. 19 - 27, Available at: <[https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667\(18\)30183-X/fulltext](https://www.thelancet.com/journals/lanpub/article/PIIS2468-2667(18)30183-X/fulltext)> [Accessed 27 January 2021]

- Strengthen monitoring and evaluation through assessment and analysis of immunisation register data and vaccine-preventable disease surveillance
- Ensure an adequately skilled immunisation workforce through promoting effective training for immunisation providers
- Maintain Australia's strong contribution to the region

All of these depend on a high state of vaccine system readiness achieved through system-wide coordination between all levels of governments, vaccine suppliers and immunisation providers, as well as support and cooperation from the Australian public.

The table below shows how the Australian program compares with similar programs overseas in terms of eligibility criteria to receive a publicly funded flu vaccine. It is evidenced that Australia's target cohorts are similar to New Zealand and England. However, unique to Australia, all Aboriginal and Torres Strait Islander at six months and over are covered by the NIP. This demonstrates the Government's initiative to closing the gap on the health and wellbeing outcomes between Indigenous and non-Indigenous Australians.

Table 1: Eligible cohorts to receive a free flu vaccine under overseas public programs

Eligible cohorts	Australia (2020)	New Zealand (2020) ²⁵	England (2020/21) ²⁶
Children	Aged six months to less than five years	Four years or under who have been hospitalised for respiratory illness or have a history of significant respiratory illness	Aged two to ten (but not 11 years or older) on 31 August 2020
All Aboriginal and/or Torres Strait Islander people six months and over	✓		
Aged 65 years and over	✓	✓	✓
Pregnant women	✓	✓	✓
People in long-stay residential care homes			✓
Carers			✓
Close contacts of immunocompromised individuals			✓
Health and social care staff employed by a registered residential care /nursing home, registered domiciliary care provider, or a voluntary managed hospice provider			✓

²⁵ The Immunisation Advisory Centre, 2020, *Influenza information for health professionals*, Available at: <<https://www.influenza.org.nz/eligibility-criteria>> [Accessed 26 January 2021]

²⁶ NHS, 2021, *Flu vaccine*, Available at: <<https://www.nhs.uk/conditions/vaccinations/flu-influenza-vaccine/>> [Accessed 26 January 2021]

Eligible cohorts	Australia (2020)	New Zealand (2020) ²⁵	England (2020/21) ²⁶
People aged six months to 65 years with eligible medical conditions			
Example of conditions include:			
▶ Heart disease			
▶ Severe asthma (requiring frequent medical consultations or use of multiple medications)			
▶ Chronic lung conditions	✓	✓	✓
▶ Diseases of the nervous system which affect your breathing			
▶ Impaired immunity			
▶ Diabetes			
▶ Kidney disease			
▶ Haemoglobinopathies			
▶ Children aged six months to 10 years on long-term aspirin therapy			

Jurisdictions distribute NIP vaccines to immunisation providers who then ensure they are administered to those people that meet the eligibility criteria.. Some state and territory immunisation schemes provide additional funded vaccines to cohorts that are deemed higher risks. For example:

- ▶ New South Wales provides free flu vaccinations to healthcare workers in the primary healthcare settings
- ▶ Victoria funds vaccines to healthcare workers in the primary healthcare setting and school vaccination program

When asked through the online survey, 31% of immunisation providers indicated that the eligibility criteria for state government immunisation programs was confusing. A similar proportion (27%) also found the NIP eligibility criteria confusing.

3.4.1.2 Process for vaccines to be listed on the NIP

In order for vaccines to be considered for inclusion on the NIP, a supplier must submit the vaccine for registration by the TGA. A positive TGA delegate's overview must be provided in order for the Pharmaceutical Benefits Advisory Committee (PBAC) to recommend a solution. The supplier will also seek pre-submission advice from the ATAGI on vaccine effectiveness and use in Australia prior to submission to the PBAC. Eligibility is determined by the PBAC. Systems are in place for parallel application to the ARTG and PBS by suppliers for faster approval and implementation.²⁷

Following PBAC recommendation for vaccine adoption, the Department sources and agrees on an initial price with the vaccine supplier. Pricing may be further negotiated as the vaccine procurement process progresses. Post initial price agreement, the Department then seeks Ministerial or Cabinet approval to fund the new vaccine as part of the NIP. If successful, the vaccine must be listed on the *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No. 1)*.²⁸ After listing, a contract for supply can then be executed, and the vaccine can be distributed for immunisation in Australia.

3.4.1.3 Governance of the NIP

The governance of the NIP is spread across the Department, state and territory departments and federal and state and territory laws locally. The Australian Health Protection Principal Committee (AHPPC) has overall responsibility in ensuring immunisation is within health advisory arrangements. This is achieved through delegating responsibility to various state and territory governments, through their Jurisdictional

²⁷ The Pharmaceutical Benefits Scheme, 2018, *TGA and PBAC Parallel Process and Requirements*, Available at: <<https://www.pbs.gov.au/info/publication/factsheets/shared/tga-pbac-parallel-process>> [Accessed 29 December 2020]

²⁸ Australian Government Federal Register of Legislation, 2020, *National Health (Immunisation Program – Designated Vaccines) Determination 2014 (No.1)*, Available at: <<https://www.legislation.gov.au/Details/F2020C00816>> [Accessed 29 December 2020]

Immunisation Coordinators (JIC), and subsequently local councils.²⁹ Multiple legislative frameworks govern immunisation in Australia, including:

- ▶ National Health Act 1953
- ▶ A New Tax System (Family Assistance) Act 1999
- ▶ Australian Immunisation Register Act 2015
- ▶ Public health Acts in states and territories
- ▶ Poisons Acts in states and territories

Consequently, governance of the immunisation program is quite broad and allows individual states and territories to implement strategies best suited to them. In contrast, protocols for action have been agreed on with the states and territories to ensure a consistent, national response to safety concerns regarding NIP vaccines.

The following subsections outline the different mechanisms local health departments use to track, monitor and govern their respective NIP vaccine rollouts, noting that at the time of writing New South Wales, South Australia, Northern Territory and Queensland were unable to provide information on governance mechanisms for the report.

S47E(d)

²⁹ Commonwealth of Australia, 2018, *National Immunisation Strategy For Australia 2019-2024*, Available at: <https://www.health.gov.au/sites/default/files/national-immunisation-strategy-for-australia-2019-2024_0.docx> [Accessed 16/12/2020]

* It should be noted that the Australian Capital Territory and Tasmania are the two geographically smallest jurisdiction in Australia, hence their operation may not be comparable to other larger jurisdictions.

This document was released under the Freedom of Information Act 1982

The National Immunisation Committee

The National Immunisation Committee (NIC) played a key role in governing the NIP. The NIC provided advice on the implementation, communication and strategic direction of the NIP, including policy and program advice, and represented the needs and views of vaccination providers and consumers. In addition, the NIC collaborated with other peak immunisation related committees, including ATAGI, JIC and the CDNA.

The NIC included bodies and members that represented Aboriginal and Torres Strait Islander, pharmaceutical, GP, Government and Ministerial interests.³⁰ They used to meet regularly, twice a year in Canberra for 1-day out of a 3-day forum involving JIC and NIC conferences to discuss the current vaccination environment, and share information between key stakeholders and associate bodies. However, the NIC has not met in the past two years.

Jurisdictional Immunisation Coordinators

While their roles differ between jurisdictions, JICs are the key coordinators for the states and territories, mediating communications between the Department, stakeholders and suppliers. NIP operations are supported by JICs who are responsible for forecasting demand as well as monitoring NIP compliance. The JICs are representatives from states and territories who meet twice a year in Canberra for a three-day forum to discuss the current vaccination environment. The JICs are currently meeting with the Department weekly to plan and implement the COVID-19 vaccination program.

3.4.1.4 Vaccine supply chain

The public market has its own distinct supply chain, with the Department, states and territories, suppliers and immunisation providers involved in the delivery of vaccines to consumers. The supply chain consists of five major components:

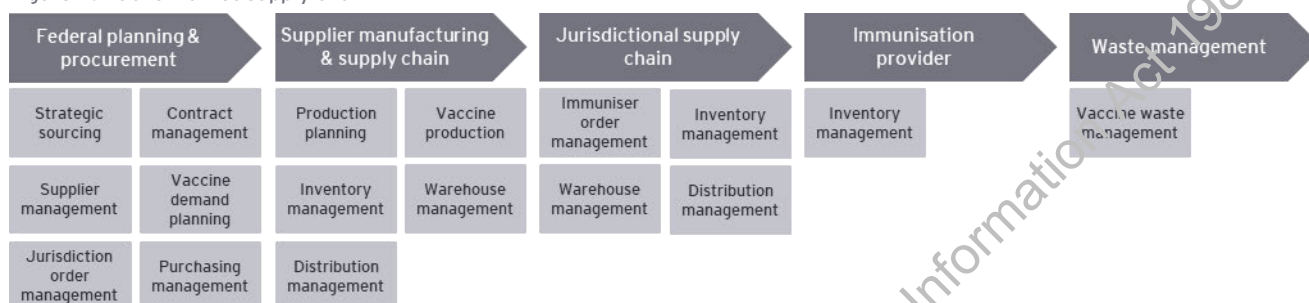
- **Federal planning and procurement** - Activities linked with demand planning for vaccines and the procurement of vaccines from suppliers to meet vaccine demand

³⁰ Department of Health, 2020, *National Immunisation Committee*, Available at: <<https://www.health.gov.au/committees-and-groups/national-immunisation-committee>> [Accessed 17/12/2020]

- **Supplier manufacturing and supply chain** - Activities associated with production and the fulfilment of vaccine orders from jurisdictions
- **Jurisdictional supply chain** - Activities relating to the fulfilment of vaccine orders from immunisation providers
- **Immunisation provider** - Storage of vaccines by the immunisation provider
- **Waste management** - Disposal of vaccines due to expiry or cold chain breach

The entirety of the public market supply chain is depicted below and explored in further detail.

Figure 2: Public market supply chain



Federal Planning and Procurement for the public market

The Department conducts regular procurement activities to source vaccines for the NIP, including flu, with contracts in place for the provision of vaccines for a three year period. From the most recent tender, the three suppliers for flu vaccine to the NIP are:

- **Seqirus** - Second largest flu vaccine manufacturer globally. It is the only onshore manufacturer and their manufacturing facility is located in Parkville, Victoria. Seqirus utilise Toll as a 3PL provider, operating out of a central warehouse in Altona, Victoria with branch facilities in other states.³¹
- **Sanofi Aventis** - Has two primary production facilities in USA and France. Sanofi Aventis utilises Linfox as their 3PL provider. Stock is imported into Australia through Sydney where Sanofi Aventis has a central warehouse, with stock further distributed to warehouses in Queensland, Victoria and Western Australia. Linfox subcontracts to other logistic suppliers to enable greater remote area coverage.³²
- **GlaxoSmithKline (GSK)** - Manufactures in Germany, with packaging, fill and finish and shipment out of Belgium. GSK employs DHL as its 3PL provider which subcontracts to Toll for the Northern Territory.³³

Over the course of the contract, the Department works with jurisdictions to plan out yearly demand for flu vaccines. Demand planning begins in October in the year prior to the flu season. Through a collaborative planning process, the Department and jurisdictions develop a demand forecast for each eligible cohort group taking into account Australian Bureau of Statistics (ABS) demographic data, ATAGI advice, prior year data and estimated uptake of flu that year.

A non-binding preliminary demand forecast is shared with suppliers in October, per the public market supply contracts agreed to between the Department and suppliers, with confirmed orders for vaccines placed in March of the following year.

Jurisdictions place vaccine orders using the Vaccine Administration System (VAS), a Salesforce based solution that incorporates purchase requisitioning, requisition approval and issuance of purchase orders to

³¹ Meeting Minutes, Seqirus, 26/11/2020

³² Meeting Minutes, Sanofi, 27/11/2020

³³ Meeting Minutes, GSK, 27/11/2020

suppliers. When order quantities exceed what was agreed to in the demand forecast, a control is in place in VAS for the Department to review the order before it is approved.

Supplier Manufacturing and Supply Chain in the public market

Vaccine production is a year round process with suppliers alternating production between the Northern and the Southern Hemisphere flu seasons. As one hemisphere's flu season ends, manufacturing of vaccines for the other hemisphere's flu season begins.³⁴ For the Southern Hemisphere, production planning typically begins 18 months prior.

Once orders are received in March, suppliers fulfil their orders from March to May based on the agreed upon supply plan between the Department and the suppliers.

Suppliers must ensure cold chain integrity as part of their jurisdictional deliveries. Cold chain integrity is tracked using a temperature monitoring device which logs vaccine temperature to provide information on whether the cold chain is breached during transportation. If a cold chain breach is detected, suppliers must replace stock free of charge for the customer (jurisdictions). Stock ownership is subsequently transferred from supplier to the jurisdiction upon receipt of stock and confirmation that the cold chain breach did not occur.

Jurisdictional Supply Chain for public markets

Jurisdictions manage immunisation provider vaccine orders and onward delivery to immunisation providers. Approaches to immunisation provider order management varies by jurisdiction. Currently, five out of eight jurisdictions outsource their order management process to a 3PL provider, while the rest manage this in-house within its health agency. Half of the jurisdictions manage ordering online, while the other half manage ordering using a paper-based system. Some jurisdictions also impose additional rules to order management and approval to reduce the risk of vaccine wastage. Examples of this include:

- ▶ Review of prior immunisation provider order history prior to the approval of new orders (Queensland and Western Australia)
- ▶ Review of immunisation provider fridge capacity to determine whether order sizes are acceptable (Queensland and the Australian Capital Territory)

Table 2: Order management by jurisdiction

Jurisdiction	Service provider	Online or paper based ordering	Jurisdiction specific order management processes
Australian Capital Territory	In-house	Paper based by email or fax	<ul style="list-style-type: none"> ▶ Orders reviewed against immunisation provider fridge capacity
New South Wales	Outsourced: Toll	Online	<ul style="list-style-type: none"> ▶ Order is place by immunisation providers ▶ Due to the high demand during the 2020 flu season, New South Wales surveyed immunisation providers' capacity and publicise such information for the ease of assessing vaccine availability
Northern Territory	In-house	Paper based by email or fax	<ul style="list-style-type: none"> ▶ None noted
Queensland	In-house	Paper based by email or fax	<ul style="list-style-type: none"> ▶ To commence the yearly flu program a first round of flu vaccines is distributed to all immunisation providers. The quantity of flu vaccines each provider receives is determined by the Queensland Immunisation Program based on historical immunisation provider order data and fridge capacity ▶ After first round orders are complete immunisation providers can order directly from the Queensland Immunisation Program ▶ Ordering history reviewed before orders are approved ▶ Orders reviewed against immunisation provider fridge capacity. Should a fridge size be too small, the jurisdiction will not allow the immunisation provider to increase the quantity or frequency of their orders ▶ Immunisation providers required to report vaccine expiry dates of stock on hand as part of ordering process

³⁴ Meeting Minutes, Sanofi, 27/11/2020

Jurisdiction	Service provider	Online or paper based ordering	Jurisdiction specific order management processes
South Australia	Outsourced: Toll	Online	► Limits are placed on what a provider can order. System will flag an order for review if a provider exceeds their limit. Orders below limit are automatically approved
Tasmania	Outsourced: Toll	Online	► None noted
Victoria	Outsourced: Onelink	Paper based by email or fax	► Pre-allocation of vaccine stock to medical clinics is performed based on prior year's usage for the over 65 cohort
Western Australia	Outsourced: Toll	Online	► Ordering history reviewed before orders are approved

Source: EY Consultations with Jurisdictions, Department of Health

The majority of jurisdictions also outsource their inventory management, with Toll being the most commonly used provider. A central warehouse is managed by the 3PL provider from which stock is picked and packed for distribution. Australian Capital Territory and Northern Territory are the two exceptions to this rule.

Table 3: Inventory management by jurisdiction

Jurisdiction	Service provider	Storage facility type	Number of storage locations
Australian Capital Territory	In-house	Cold storage room	One in the Australian Capital Territory
New South Wales	Outsourced: Toll	Warehouse	One in New South Wales
Northern Territory	In-house	Hospital storage	Four in the Northern Territory: Royal Darwin, Alice Springs, Katherine and Gove
Queensland	Outsourced: Toll	Warehouse	One in Queensland
South Australia	Outsourced: Toll	Warehouse	One in South Australia
Tasmania	Outsourced: Toll	Warehouse	One in Victoria
Victoria	Outsourced: Onelink	Warehouse	One in Victoria
Western Australia	Outsourced: Toll	Warehouse	One in Western Australia

Source: EY Consultations with Jurisdictions, Department of Health

Finally, most jurisdictions outsource vaccine distribution. 3PL providers typically deliver to metropolitan areas using their own fleet, while relying on jurisdictions to organise deliveries to rural and remote locations which can require multiple transportation modes.

Table 4: Distribution management by jurisdiction

Jurisdiction	Service provider	Distribution method
Australian Capital Territory	In-house	► Delivered using eskies ► Delivery personnel will deliver stock all the way to the immunisation provider fridge
New South Wales	Outsourced: Toll	► Deliveries sent in insulated vehicles
Northern Territory	In-house	► Local couriers and chartered flights used for the delivery of vaccine stock to rural communities from the four storage locations
Queensland	Outsourced: Toll	► Metropolitan deliveries sent in insulated vehicles ► Regional and remote deliveries delivered in an esky containing ice bricks, freeze indicator and heat monitor ► Extreme remote deliveries in export eskies which are viable for three to four days after being packed
South Australia	Outsourced: Toll	► Deliveries sent in insulated vehicles
Tasmania	Outsourced: Toll	► Deliveries are first flown from Victoria to Tasmania by air, then delivered using insulated vehicles
Victoria	Outsourced: Onelink	► Deliveries sent in insulated vehicles
Western Australia	Outsourced: Toll	► Deliveries sent in insulated vehicles

Source: EY Consultations with Jurisdictions, Department of Health

Where vaccinations take place and how are vaccines stored by immunisation providers

Public flu vaccine administration primarily occurs in GP practices. In some states, such as Australian Capital Territory, Victoria and Western Australia, flu vaccinations can take place in pharmacies. In

residential aged care settings, immunisation is generally provided by GPs and nursing staff acting under the supervision of a GP.

In general, vaccines are stored on-site in the (vaccine) refrigerators once delivered to the immunisation providers' facilities (GP practices and pharmacies). The Department has published guidelines on vaccine storage, known as "Strive for 5"³⁵, which recommends that vaccines be stored at 5°C to protect vaccines from damage when stored outside of the optimal 2-8°C temperate range. The guidelines describe the best approach to ensuring that consumers receive effective and potent vaccines and provides advice on how immunisation providers should respond in the event of a cold chain breach.

Public Vaccination Waste Management

Cold chain breach and vaccine expiry are the two main reasons for vaccine wastage. For cold chain breaches, all jurisdictions require immunisation providers to complete and submit a cold chain breach form documenting the reason for the breach and the number of affected vaccines.

Jurisdictions also have documented procedures for isolating cold chain damaged stock to ensure immunisation providers do not incorrectly use damaged stock for vaccinations. With the exception of the Australian Capital Territory which handles the disposal of expired vaccines for its immunisation providers, all other jurisdictions rely on their immunisation providers to dispose of any wasted or damaged vaccines.

No returns of unused vaccines were noted in the public market due to an inability to maintain cold chain integrity effectively as part of a returns management process.

3.4.2 Private market vaccine supply

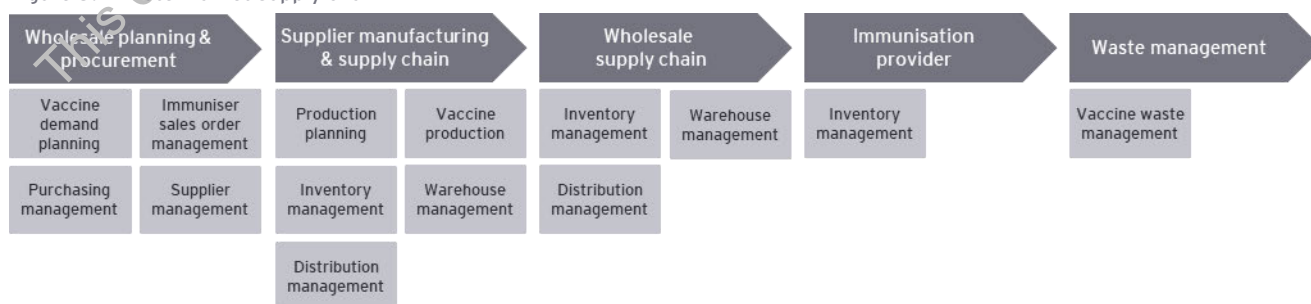
3.4.2.1 Vaccine supply chain

The private market has its own vaccine supply chain, with suppliers, wholesalers and immunisation providers involved in the delivery of vaccines to consumers. The supply chain consists of five major components:

- ▶ **Wholesale planning and procurement** - Activities linked with demand planning for vaccines and the procurement of vaccines from suppliers to meet vaccine demand
- ▶ **Supplier manufacturing and supply chain** - Activities associated with the production and fulfilment of vaccine orders from wholesalers
- ▶ **Wholesale supply chain** - Activities relating to the fulfillment of vaccine orders from immunisation providers
- ▶ **Immunisation provider** - Storage of vaccines by the immunisation provider
- ▶ **Waste management** - Disposal of vaccines due to expiry or cold chain breach

The entirety of the private market supply chain is depicted below.

Figure 3: Private market supply chain



³⁵ Australian Government Department of Health, 2020, *National Vaccine Storage Guidelines 'Strive for 5'*, Available at: < <https://www.health.gov.au/resources/publications/national-vaccine-storage-guidelines-strive-for-5> > [Accessed 15 March 2021]

One unique feature of the private market is that market participants can participate across multiple parts of the supply chain. As an example, Australian Pharmaceutical Industries (API), an integrated pharmacy retail group, operates its own wholesale supply chain which it uses to serve both its own pharmacy banners as well as other external customers. Additional examples of how participants participate across the private market supply chain is shown below.

Figure 4: Examples of market participants and how they participate in private market supply chain

Company	Company overview	Supply chain participation				
		Wholesale planning & procurement	Supplier manufacturing & supply chain	Wholesale supply chain	Immunisation provider	Waste management
Australian Pharmaceutical Industries	Integrated pharmacy group which performs wholesale planning, procurement and distribution of vaccines to its pharmacy banners which include Priceline and Soul Pattinson. It also acts as a 3PL provider to other external customers.	✓		✓	✓	✓
Team Medical	Online vaccine wholesaler which serves medical centres, aged care facilities and pharmacies.	✓		✓		✓
Arrotex	Online vaccine wholesaler which sells vaccines through its APOAccess site. It uses both a wholesaler and its own supply agreements to obtain vaccine supplies, and distributes supplies through other wholesalers. It also performs vaccinations by providing immunisation to retail pharmacies, aged care homes and companies.	✓			✓	✓
Mylan	Private market vaccine supplier.		✓			
Chemist Warehouse	Australia's largest pharmacy retail chain. It mainly performs immunisation, but also plays a wholesale planning and procurement role as it procures vaccines direct from supplier and has this distributed through a 3PL provider.	✓			✓	✓

Wholesale Planning and Procurement in the private market

Demand planning in the private market takes place between June and September in the year prior, much earlier than the public market. During this time, suppliers and wholesalers obtain immunisation provider customer orders for vaccines to understand vaccine demand for the upcoming season.

There are two types of wholesalers in the private market:

- **Wholesalers who manage supply chain in-house** - These companies have an in-house supply chain function, and also act as a 3PL provider to other wholesalers and immunisation providers. Examples of companies who perform wholesale and distribution include API, EBOS, Sigma Healthcare and Team Medical
- **Wholesalers who outsource their supply chain** - These companies outsource their supply chain management to a third party. An example of this is Arrotex which manages a wholesale vaccine

business known as APOAccess. Arrotex uses API, EBOS and Sigma Healthcare to deliver vaccines to its customers

Despite the difference in approach to supply chain management, both types of wholesalers still follow the same wholesale supply chain as shown in Figure 3.

Once customer orders are aggregated, confirmed orders are sent to suppliers by no later than November. Deliveries are made to wholesalers by February/March in time for delivery to immunisation providers for vaccinations to begin in March.

From a procurement perspective, there are three distinctive features of the private market:

- ▶ While the majority of immunisation providers use a wholesaler to procure vaccines, large immunisation providers such as Chemist Warehouse have sufficient purchasing power to purchase vaccines directly from a supplier. Vaccine stock purchased directly from suppliers are then fulfilled using a wholesaler's distribution network, with the wholesaler functioning as a 3PL provider for the immunisation provider
- ▶ Wholesalers and immunisation providers use annual supply agreements, rather than multi-year supply agreements. Wholesalers and immunisation providers believed they needed the flexibility of an annual agreement as vaccine products changed too frequently for them to commit to a multi-year agreement. While using an annual supply agreement increases the risk of wholesalers and immunisation providers not being able to obtain supply, wholesalers and immunisation providers EY consulted with were confident of their ability to obtain supply, citing strong supplier relationships
- ▶ Unlike the public market which requires PBAC recommendation and ministerial approval to introduce new vaccines to the public market in addition to the standard regulatory approval process, wholesalers in the private market can more easily introduce new vaccine products to the private market, such as cell based vaccines. Cell based vaccines are seen as more effective than egg based vaccines as they are not affected by antigenic shift which can occur during egg based vaccine production³⁶

Supplier Manufacturing and Supply Chain in the private market

Supplier manufacturing and distribution follows the same process as the public market. In addition to the three suppliers used in the public market, the private market has one additional supplier: **Viatis** (formerly Mylan). Viatis manufactures vaccines offshore in the Netherlands and imports vaccines to Australia via Queensland. The company manages its own distribution using a central warehouse in Queensland.³⁷

Private Wholesale Supply Chain

In contrast to the public market where states and territories are managed individually by their JIC, the wholesale supply chain is managed by the wholesaler at a national level. where individual wholesalers operate multiple warehouses across the country to allow them to serve customers in a timely manner. One wholesaler EY consulted with, for instance, operates four warehouses across Australia from which vaccines are sent from, each with a cool room where vaccines are picked and packed for delivery. Chemist Warehouse, which outsources supply chain management to EBOS, has access to EBOS' national supply chain network which enables daily vaccine stock deliveries to pharmacies across its retail network during the flu season.³⁸

Another point of difference between the public and the private market is the difference in drivers influencing how their respective supply chains are managed. In the public market, ensuring adequate, uninterrupted supply is critical as local health agencies are driven to improving vaccination rates for the vulnerable and improving public health outcomes. In contrast to wholesalers who are for profit, there is a strong commercial incentive to minimise wastage cost and the amount of unsold vaccines through conservative demand planning and ongoing inventory management. If required, excess inventory will be

³⁶ Centers for Disease Control and Prevention, 2020, Cell-Based Flu Vaccines, Available at: <<https://www.cdc.gov/flu/prevent/cell-based.htm>> [Accessed 18 January 2021]

³⁷ Meeting Minutes, Mylan, 17/12/2020

³⁸ Meeting Minutes, Chemist Warehouse (CWH), 25/11/2020

moved from one warehouse to another to meet local demand. An advantage of this approach to supply chain management is that at the end of the season there is little obsolete stock remaining – from EY’s consultation with two wholesalers it was noted that annually less than 1,000 vaccines remain at the end of the season. The issue with this approach however is that wholesalers may underestimate demand for the season which has been the case in recent years.

In terms of transportation and distribution of vaccines, wholesalers have the option to either perform this in-house using their own fleet or outsource this to a 3PL provider. In the case of one wholesaler, it used a mixed model of both in-house and outsourced distribution, with in-house used for metropolitan areas and a 3PL provider used for non-metropolitan and regional areas.

Private Immuniser

In addition to GP practices and pharmacies, the private market has a number of additional avenues through which consumers can receive their vaccines. These include:

- ▶ Workplace vaccination programs
- ▶ Aged care facilities

Vaccines are transported to private immunisation providers from cold chain warehouses by wholesalers in conjunction with contracted 3PL distributors. They are either transported in refrigerated trucks for metropolitan deliveries, or in eskies for regional areas. Vaccines are then transferred directly to fridges for storage until use.

Survey participants were asked to select the ways they store vaccines, with survey participants being able to select multiple responses (to allow the reflection of multiple ways of vaccine being stored). Results indicate that survey participants used more than one method to store vaccines, including secure fridges on site (78%), on-site general access fridge (26%) and/or a transfer device (16%).

Temperature trackers were used to alert clinics if the temperature was too high for a certain period of time. Vaccines were discarded if the temperature was too high for too long, or if the vaccine was not used in a certain time frame. In storing private and public flu vaccines, immunisation providers distinguished between the two by storing them in different locations (83%) and / or via their different packaging / brands (51%).

New service offerings have since emerged within this space, expanding on how the private sector provides immunisations. Arrotex, an Australian pharmaceutical company and a service provider for immunisation clinic service. In addition, their model provides workforce service to assist with administering vaccinations in corporate and aged care facilities.³⁹

Private Vaccination Waste Management

Consistent with the public market, wastage for the private market stems from cold chain breaches and end of season expiry. No returns were noted for the private market.

³⁹ Meeting Minutes, Arrotex, 12/01/2021

4

Evaluation findings and recommendations

This document was released under the Freedom of Information Act 1982

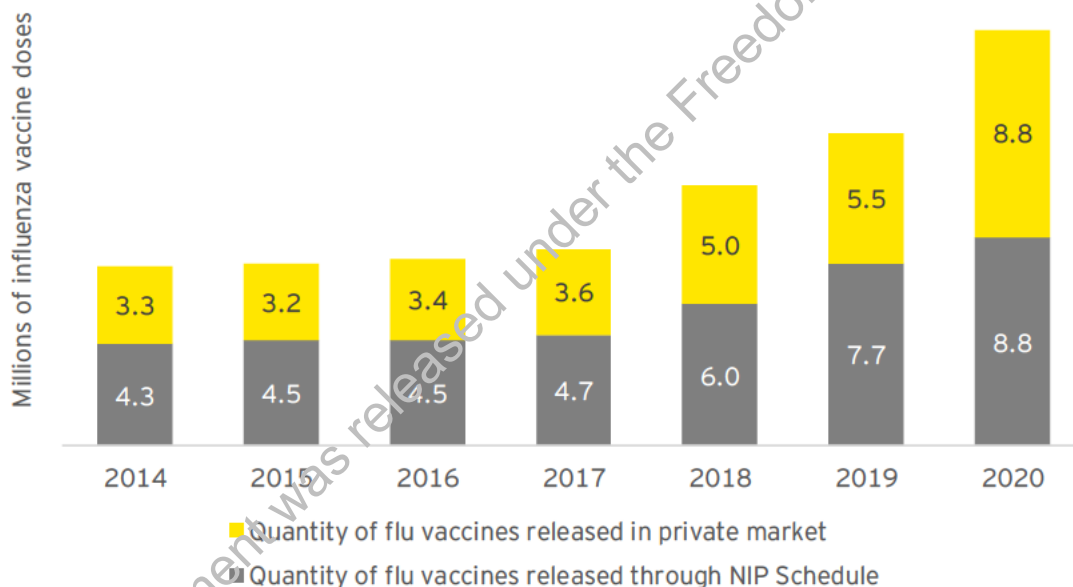
4. Evaluation findings and recommendations

4.1 Overview of the 2020 season

Each flu season is unique because of the changing nature of flu viruses in circulation each year. However, 2020 was an unprecedented season due to record demand and the added complication of the COVID-19 pandemic. The pandemic, coupled with the Federal Minister of Health's appeal to the public to be vaccinated against flu,⁴⁰ encouraged consumers to seek vaccination early in the season as part of the preventative measures.

The Department made a record quantity of flu vaccine available (as illustrated in Figure 5 below) in both the public (the NIP market where the vaccine is funded by the Australian Government) and private (the non-NIP market where the vaccine is not funded by the Australian Government) markets in response to the overwhelming consumer demand. This resulted in 17.6 million (33% increase compared to 13.2 million in 2019) doses of vaccine being made available across both the public and private markets. Of these, 8.8 million doses were provided as part of the NIP, demonstrating a 14% increase over the 7.7 million administered the year prior.⁴¹ Mirroring these results, 97% of immunisation providers who participated in the online survey rated demand for flu vaccinations in 2020 to be higher than previous years. This is in alignment with the findings from immunisation provider interviews that more people than ever before asked to receive the flu vaccine.

Figure 5: Annual flu doses released in Australia between 2014 and 2020



Source: Australian Government Department of Health

⁴⁰ Australian Government Department of Health, 2020, *Flu Vaccination More Important Than Ever During The Month Of April*, Available at: <<https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/flu-vaccination-more-important-than-ever-during-the-month-of-april>> [Accessed 14 December 2020]

⁴¹ Based on TGA doses released provided by the Australian Government Department of Health

4.2 Overall finding

The 2020 flu season proved to be largely successful, weathering significant logistical disruptions. Commonwealth have made 17.6 million doses of flu vaccine available in the Australia market, which represents the highest ever number of doses of flu vaccine ordered under the NIP. States and territories, as well as the vaccine supply industry, deftly implemented creative solutions to overcome these challenges, and ensured sufficient vaccine delivery for administration. In a year when demand was higher than ever before, 70% of immunisation providers who participated in the online survey were satisfied that community expectations in terms of vaccine availability were met.

Despite a largely successful year, a number of opportunities for improvement were recognised

The lack of a current and clearly defined flu vaccination strategy or cohort specific targets prevents accurate benchmarking of the program, and effectively creates a decentralised program. Variations between states further exacerbates this, particularly in relation to aged care flu immunisation strategy and the limitation on Aboriginal health workers providing vaccinations in some jurisdictions.

The JICs and NIC meetings have demonstrated their ability to make crucial contributions to the governance process, and should maintain their regular meetings to ensure key stakeholders and associated peak bodies can provide their valuable insights.

The public supply chain faced issues with late confirmed / additional ordering, border closures which caused disruptions to supply delivery to immunisation providers. General practitioners continued to play a crucial role as an immunisation avenue, while pharmacists grew their outreach and immunisation provider capacity. Seven in ten (70%) immunisation providers who participated in the EY immunisation provider survey agreed that it took too long for vaccine stock to be delivered at the beginning of 2020 flu season. There was a delay in receiving their initial order and the majority of orders received were incomplete. This is the case for both NIP and private vaccine stock. For instance:

- ▶ Government funded flu vaccine order:
 - ▶ Sixty-three per cent of surveyed providers received 50% or less of their initial orders
 - ▶ Thirty-six per cent of surveyed providers received more than 50% of their initial orders
- ▶ Non-government funded flu vaccine order:
 - ▶ Half (51%) received 50% or less of their initial order
 - ▶ The other half (49%) received more than 50% of their initial order

Lastly, the slow adoption of AIR by immunisation providers, and in particular pharmacies, created difficulties for departmental agencies in assessing the level of vaccine uptake, necessary for accurate benchmarking of the program and the evaluation of its success to the public health system.

The following section provides a detailed analysis of the aforementioned issues, structured in accordance to the six evaluation criteria, followed in turn by the relevant recommendations to ensure a consistently successful flu program, and system readiness for the potential inclusion of COVID-19 vaccine in the NIP.

4.3 Criteria 1 - Influenza vaccination strategy



4.3.1 National and jurisdiction immunisation strategy

The national and jurisdiction immunisation strategy sets the overall direction for the NIP flu program. It identifies key outcomes to be achieved through vaccination, such as reductions in flu infection rate or the severity of flu in Australia.

From EY's public market stakeholder consultations, it is evident that all participants are in alignment on the aim and purpose of the NIP, and see value of vaccinations as a preventative measure against vaccine preventable diseases and in particular, the seasonal flu. However it was noted through EY's work that a defined and agreed strategy for the annual flu program does not currently exist. This is because the NIP in its current form, has grown organically over the years based on Ministerial directives to centralise vaccine purchases nationally for each of the cohorts. Prior to this, flu vaccines were individually purchased by states and territories. Similarly, all jurisdictions consulted did not have a separate flu immunisation strategy in place.

Without a clearly defined and articulated purpose and strategy, operational decisions are made between the Department, jurisdictions and other program participants without a common strategic platform, potentially leading to a lack of clarity and predictability in the delivery of the program. This lack of a key program strategy also makes it hard to measure the success of the program.

4.3.2 Measurements of consumer participation and target population coverage

Currently there are no flu specific immunisation targets for NIP eligible cohorts, nor is there a mandatory requirement⁴² to report vaccinations into the AIR. Non-reporting of vaccinations means vaccine uptake across NIP cohorts cannot be effectively measured by both the Department and jurisdictions. This also has negative implications on subsequent year demand forecasting and other relevant public health planning.

The WHO and European Council recommended that countries shall achieve the target flu vaccine coverage rate (VCR) of 75% for ones at risk of medical complications and ones that have greater chance of transmitting flu to such populations.^{43 44} The WHO Global Influenza Strategy 2019 - 2030 has further emphasized the aim for the highest possible level of flu prevention, control and preparedness to protect the wellbeing of all, with the key aspect being to improve the global VCR. It is also recognised that achieving higher VCRs can reduce the burden on health systems and societies induced by flu infection. To better achieve so, an annual flu vaccination program strategy under the NIP will be beneficial. In comparing to countries who have similar vaccination programs as Australia, there are various degrees of comprehensiveness of flu vaccination program. For example:

- ▶ **Canada** has a clear and targeted strategy for seasonal flu including annual coverage goals and targets for 2025, for the population as a whole in addition to vulnerable groups, which have been endorsed by provinces and territories via the Pan-Canadian Public Health Network Council. It has also developed an extensive Pandemic Influenza Preparedness strategy document. These elements are both key factors for ensuring high flu vaccine coverage rates⁴⁵
- ▶ **New Zealand's** flu immunisation strategy has outlined the key programme goals. To vaccinate 75% of people 65+ years of age and 80% of healthcare workers, which is in alignment with WHO's Global Influenza Strategy.⁴⁶

⁴² It is noted that as of 01 March 2021 reporting of influenza immunisation to AIR will be mandatory

⁴³ European Union Council. Council recommendation of 22 December 2009 on seasonal influenza vaccination (2009/1019/EU). <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:348:0071:0072:EN:PDF>.

⁴⁴ European Centre for Disease Prevention and Control. Risk groups for severe influenza. <https://ecdc.europa.eu/en/seasonal-influenza/prevention-and-control/vaccines/risk-groups>.

⁴⁵ Kassianos G, Banerjee A, Baron-Papillon F, Hampson AW, et al., 2021, Key policy and programmatic factors to improve influenza vaccination rates based on the experience from four high-performing countries, Drugs in Context, Available at: <dic-2020-9-5.pdf (drugsincontext.com)> [Accessed 21 January 2021]

⁴⁶ The Immunisation Advisory Centre, New Zealand Immunisation Strategy. Available at: <https://www.influenza.org.nz/new-zealand-immunisation-strategy>

- **The United Kingdom** has issued a detailed Flu Plan - Winter 2017 / 18 by Public Health England, Department of Health and NHS England. The Plan has provided clear guidance and clarification of elements associated with the flu. For example, it layout the roles and responsibility in the NHS and public health system, the context of flu and flu virus, strategic objectives, elements of the flu programme and communications. In addition, it provides further information specific to the vaccination improvement plan, manufacturing, supply and safety concerns⁴⁷

4.3.3 Aged care

While each jurisdiction determines how it rolls out public vaccines to its eligible cohorts, a lack of consistency in rules across states and territories creates complexity for vaccine suppliers, distributors, administrators and immunisation providers. Notably, only Victoria and South Australia have reported that some residential aged care facilities are registered flu vaccine providers. The remaining residential aged care facilities rely on the residents' general practitioners to source the vaccine themselves and it is unclear whether they have been given any special considerations, taking into account the larger quantity ordered usually at the beginning of the flu season as demanded by this cohort. Anecdotal evidence suggest these orders have not been given any special considerations and potentially mistaken as unnecessarily large order that are then truncated. Given the complexities, the Department should consider commissioning a study into the benefits and risks of creating a priority group, such as aged care residents, within the NIP eligible cohorts, as well as informing next steps.

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- ▲ **Recommendation 1** The Department and the departments of health in the jurisdictions agree to an annual flu vaccination program strategy under the NIP which includes:
- Annual objectives for immunisation rates across the population as a whole and for specific high-risk groups, such as people over 65 years of age and Aboriginal and Torres Strait Islander people
 - Annual timelines for the achievement of these immunisation program objectives
 - Annual projections for NIP flu demand by jurisdiction
 - Identification of higher risk population groups and the national strategy to increase vaccination rates among these higher risk groups
 - Nationally consistent protocols for the vaccination of targeted groups to reduce confusion among vaccine suppliers, distributors and clinical administrators generated by the variability in arrangements between jurisdictions
 - Nationally consistent logistical arrangements for the distribution and administration of vaccines under the NIP including the administration of flu vaccines to people living in residential aged care facilities and remote communities
 - Agreed performance measures to monitor the effectiveness of the program
 - The communications strategy between the Department and jurisdictions for the annual NIP flu vaccination program (see Recommendation 9 for further detail)
 - A National Communications Strategy for the NIP flu vaccination program needs to be refreshed and aligned (see Recommendation 14 for further detail)

It is noted that the Department currently performs components c. and d. already.

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- **Recommendation 2** The Department refresh the flu vaccination administration program for residents of residential aged care facilities in collaboration with Primary Health networks, aged care operators and general practitioners.

⁴⁷ Public Health England, March 2017, *Flu Plan Winter 2017 / 18*, London. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/600532/annual_flu_plan_2017to2018.pdf

The program refresh should take into account age care residents' risks profile in relation to flu as well as the higher potential for outbreaks in a residential care setting.

Potentially as a mean to align care and jurisdiction for aged care residents, while recognising the complexities of the matter, the Department should commission a study into the benefits and risks of creating a priority group, such as aged care residents, within the NIP eligible cohorts, as well as informing the refresh of the flu vaccination administration program.

4.4 Criteria 2 - Program governance

4.4.1 Role of the National Immunisation Committee

The NIC played a key role in governing the NIP. The NIC provided advice on the implementation, communication and strategic direction of the NIP, including policy and program advice, and represented the needs and views of vaccination providers and consumers. In addition, the NIC collaborated with other peak immunisation related committees, including the ATAGI, JICs and the Communicable Diseases Network Australia (CDNA).

The NIC included bodies and members that represented Aboriginal, pharmaceutical, GP, government and ministerial interests.⁴⁸ They used to meet regularly, twice a year in Canberra for one-day out of a three-day forum involving JIC and NIC conferences to discuss the current vaccination environment, and share information between key stakeholders and associated bodies. Consults with stakeholders found that these meetings in previous years were largely ineffective due to the large number of players and personal agendas, and consequently the committee meetings were ceased since two years ago.⁴⁹

The NIC has not convened for an extended period of time, which means the Australian Government Department of Health is missing out on external stakeholder input into the Program. Having external stakeholder input will be crucial for the 2021 flu season, recognising that the season is likely to occur at the same time as when the COVID-19 vaccine will be rolled out into the community.

The breadth of membership on the NIC allowed for critical and diverse stakeholder input from independent parties that can observe, with great depth, the strengths and weaknesses of the current vaccination strategy, and implement new strategies in an already volatile environment further complicated by the COVID-19 pandemic.

For instance, the RACGP, one organisation represented on the NIC, reported that local mechanisms were implemented to redistribute vaccine demand to practices with excess supply, and that ineffective communication with the general public led to some eligible individuals receiving the private instead of NIP funded vaccine.

Communicating with NIP eligible consumers about vaccination when only private stock was available led to confusion, with potential insufficient dosage of vaccines being administered to certain cohorts.⁵⁰ This was supported by the Australian Medical Association (AMA), another member of the NIC, who also noted consultations with GPs are necessary to ensure they possess the training and storage capacity for the COVID-19 vaccine rollout.⁵¹

Feedback has also been provided by both JICs from South Australia and Victoria concerning the effectiveness of the NIC. They cited that the NIC had been inefficient due to representatives from participating organisations strongly advocating for their preferred agenda.

The restoration of the NIC or an NIC-like forum, with clear agenda and objectives of each meeting, would facilitate discussion and sharing of findings between the Department, key stakeholders and associated

⁴⁸ Department of Health, 2020, *National Immunisation Committee*, Available at: < <https://www.health.gov.au/committees-and-groups/national-immunisation-committee> > [Accessed 17/12/2020]

⁴⁹ Meeting Minutes, SA Health, 25/11/2020

⁵⁰ Meeting Minutes, RACGP, 25/11/2020

⁵¹ Meeting Minutes, Australian Medical Association, 01/12/2020

bodies. This will allow for more efficient strategy implementation and post-implementation review for future decision making processes.

- **Recommendation 3** The Department restore the NIC or a NIC-like forum with similar mandates, with the objective of seeking inputs from a range of relevant external stakeholders such as GPs, Aboriginal and Torres Strait Islander health providers and aged care providers, into the development of the annual NIP flu vaccination strategy, as well as the interaction of the program with the private flu vaccination market.

4.4.2 Role of the Therapeutics Goods Administration

Therapeutic Goods Administration

It was noted that the TGA is seldom involved early in governance and decision making with respect to the program whilst being the key stakeholder of the ecosystem. The TGA chairs multiple international committees with regulatory counterparts around the globe, and proactively ensures patients can report adverse events via multiple avenues. It is important for the TGA to play the intermediary role in communicating the global trend and local experience more broadly.

The TGA also receives reports via the National Adverse Events Following Immunisation (AEFI) form, as well as active surveillance information from the National Centre for Immunisation Research and Surveillance (NCIRS). This information is used to conduct causality assessments on the vaccine in order to verify that the benefits of continuing with a vaccine outweigh the associated risks. Their weekly adverse events review, fortnightly statistical analysis, and bi-monthly disproportionality analysis ensure that the TGA is consistently up to date with potential adverse events from vaccines, and can communicate this information to relevant JICs and the NCIRS.

Preserving TGA's role as an independent regulator, and more frequent and structured interactions with the TGA, is critical to ensure officials at different levels of the Department are also informed of the latest information relate to vaccine safety and effectiveness.⁵²

The involvement of the Therapeutic Goods Administration (TGA) in the Department's internal governance processes for the NIP was requested by the TGA representatives during the consultation with EY. Currently, TGA's involvement is useful and productive. However, it is considered that the TGA is constrained from having a thorough understanding of any emerging issues in the program, as TGA tends to be involved relatively late in the decision making processes.

A more structured and more regular involvement of the TGA in the Department's immunisation decision making processes will improve the effectiveness of the TGA's involvement in the program and improve the TGA's readiness to anticipate changes in the program and contribute in a more timely manner.

- ▲ **Recommendation 4** The Department consider expanding its internal governance processes used to design, approve and monitor the effectiveness of the annual NIP flu vaccination program to include formal involvement of the TGA in the decision making processes earlier. The early and more comprehensive involvement of the TGA will improve the effectiveness of the flu vaccination program.

4.5 Criteria 3 - Supply chain

4.5.1 Public market

4.5.1.1 Federal Planning and Procurement

Current method of planning is appropriate given the lack of actual vaccinations data

Given the lack of mandatory vaccination reporting on AIR for the 2020 season, and the lack of historical vaccinations data by cohort to support demand planning, the current method of collaborative demand planning performed by the Department and jurisdictions using demographic data, ATAGI advice and

⁵² Meeting Minutes, TGA, 27/11/2020

estimated uptake is an appropriate alternative. The success of the demand plan saw a record number of vaccines offered to the public through the NIP.

In contrast, in New Zealand, demand planning is performed by the contracted supplier, Seqirus, rather than by the New Zealand Government itself. The New Zealand Government, through its Pharmaceutical Management Agency (PHARMAC), provides Seqirus with data to perform a public market forecast, taking into consideration factors similar to what the Department currently accounts for such as population growth, the total number of doses distributed in recent seasons, flu vaccination target, the severity of previous seasons and any early reports about the Northern Hemisphere flu season.⁵³ However the New Zealand context is unique in that its population is much smaller and it relies on only one flu vaccine supplier in contrast to the three used by Australia. Given the number of suppliers involved in the provision of the Australian NIP, and the close working relationship the Department has fostered with jurisdictions, the use of a supplier planned demand plan is not seen as feasible in an Australian context.

With AIR reporting becoming mandatory from March 2021, there is an opportunity for the Department to enhance the demand planning process by using vaccinations data recorded on AIR. As the data would reflect actual vaccinations performed, it would more closely reflect underlying vaccine demand, and enable for a more accurate prediction of eligible cohort sizes compared to the current practice of estimating using demographic data. Having actual vaccinations data would also allow the Department to test the accuracy of its assumptions for vaccine uptake.

■ **Recommendation 5** Redesign the demand planning process to incorporate AIR vaccinations data from the 2022 season.

Suppliers expressed desire for early order commitment

Through consultation, it was noted that global demand for flu vaccines significantly outweighed suppliers' ability to supply, with production of northern hemisphere vaccines commencing directly after they conclude production of southern hemisphere products. In addition, demand and production is planned at a global level, with northern and southern hemisphere customer demand planned as early as March in the year prior.⁵⁴ This leaves little room for flexibility to accommodate new orders, and it is highly challenging for suppliers to meet additional orders part way through the flu season, as stock volumes have already been finalised and allocated for that season.⁵⁵

Because of this, all NIP suppliers expressed a desire for the Department to commit to vaccine orders by a November / December timeframe in the year prior to both align with current private market practice and to provide certainty to suppliers on quantities needed for the upcoming season. However, from discussions with the Department it is understood that the current contractual process is for firm orders to be submitted by no later than March of the flu season, and it is up to the Department's discretion on whether it wishes to align with private market practice.

Finally, it was noted in consultations that suppliers preferred supplying to the northern hemisphere as the market attracted higher volume, demand and price (Note: determining whether current pricing for vaccines is appropriate is out of scope for this evaluation). Notwithstanding, suppliers remain committed to working closely with the Department to supply to the public market.⁵⁶

4.5.1.2 Supplier Manufacturing & Supply Chain

Strong supply stability observed

Suppliers fulfilled their public market orders from March to July for the 2020 Influenza Season, with little to no disruption to supply chains noted by both local and overseas public market suppliers. This was particularly noteworthy given there was a global shortage of air freight capacity to ship vaccines to

⁵³ PHARMAC, 2020, *Flu vaccines: PHARMAC's role*, Available at: <<https://pharmac.govt.nz/medicine-funding-and-supply/what-you-need-to-know-about-medicines/flu-vaccines-pharmacs-role/>> [Accessed 18 January 2021]

⁵⁴ Meeting Minutes, GSK, 27/11/2020

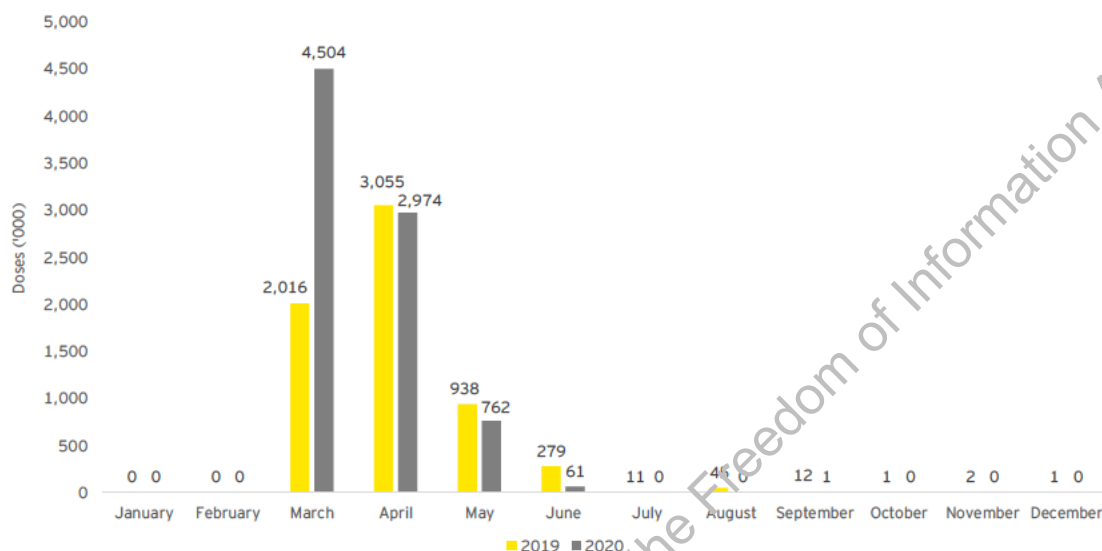
⁵⁵ Meeting Minutes, Sanofi Aventis, 27/11/2020

⁵⁶ Meeting Minutes, Sanofi Aventis, 27/11/2020

Australia due to a reduction in international flights, the presence of border restrictions domestically between jurisdictions in Australia, and physical restrictions to movement internally within a jurisdiction.

The supplier observations on supply stability was supported by an analysis of data from the Department's Vaccine Administration System (VAS) which showed that the delivery pattern for 2020 was consistent with the 2019 season. This is shown in Figure 6. VAS data also indicated that volumes delivered to jurisdictions were significantly higher for 2020 compared to 2019, peaking first on 12 March 2020 (646,900 doses), then on the 24th (709,450 doses) and the 26th (699,820 doses), reflecting strong yearly growth in vaccine demand. The largest peak in the 2019 season was on the 21 March with 532,865 doses delivered. Compared to the total doses delivered throughout the month of March, 2020 was 123% higher than 2019 (4,504,180 doses compared to 2,015,830).

Figure 6: Doses delivered to the public market for the 2019 and 2020 flu seasons



Source: VAS

Despite supply being stable for most jurisdictions, the Northern Territory noted significant challenges in receiving their supplies. The jurisdiction experienced unstable supply deliveries for the 2020 season due to a lack of domestic commercial flights to transport vaccine stock from Sydney, the most common port for vaccine stock to arrive in Australia. This resulted in multiple cold chain breaches which disrupted the onward vaccine supply chain to immunisation providers. The challenges experienced by the Northern Territory suggests that it may be worthwhile spreading deliveries across multiple airports in Australia to reduce the dependence on Sydney as the main port of delivery should future internal transport disruptions occur.

Recommendation International deliveries should be shared between more international airports across Australia to reduce the dependence on Sydney as the main port of delivery.

Increased lead time for stock observed across all jurisdictions

It was noted that the average lead time for stock to arrive at a jurisdiction has increased for every jurisdiction as shown in Figure 7. Jurisdictions mentioned that they faced storage capacity constraints at their respective storage facilities. With demand for flu vaccines rising across all jurisdictions, jurisdictions needed to further stagger their supplier deliveries such that they could distribute out their stock on hand first before replenishing their stock, pushing lead times up. As seen below, whilst Tasmania observed the overall longest lead time in 2020, Western Australia saw their lead time increase by 6.7 days from 2019 to 2020, the largest experienced by all jurisdictions. Queensland experienced the smallest increase in lead time of 0.8 days, compared to the average increase across all jurisdictions of 3.3 days.

State/Territory	2019	2020
QLD	14.7	15.5
TAS	10.2	16.6
WA	7.8	14.5
SA	8.1	13.5
NSW	10.6	11.4
VIC	6.5	9.7
ACT	8.0	9.7
NT	6.8	7.9

This upward trend in supplier lead times is expected to continue in future years as the NIP adds additional vaccines to its program, such as a COVID-19 vaccination program. Without expansions to jurisdiction storage capacity, a lack of vaccine storage will become a bottleneck for suppliers to deliver vaccines to states and territories.

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Significantly higher inventory observed post flu season peak

Analysis of monthly stock on hand data for each jurisdiction shows that for the 2020 season, most jurisdictions are carrying significant amounts of vaccine stock beyond August into October, past the peak of the winter flu season, as shown in Figure 8. This was confirmed by immunisation providers in the EY immunisation provider survey, where 73% of immunisation providers reported having leftover government-funded vaccine, and 54% having leftover non-government funded vaccine. Common reasons

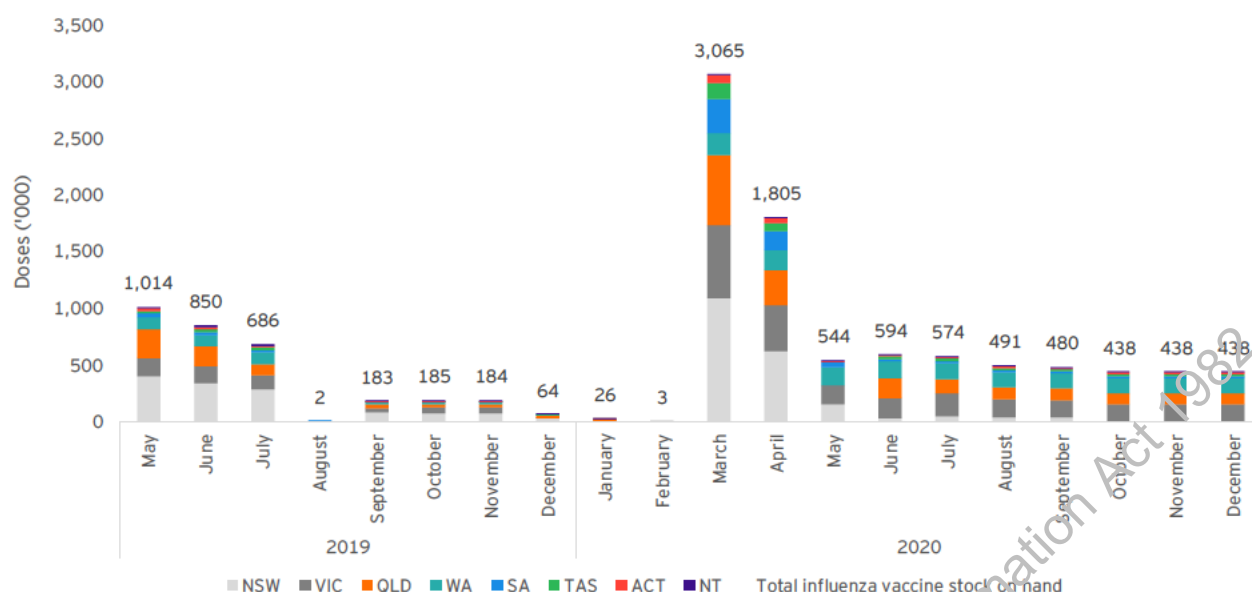
⁵⁸ Meeting Minutes, Tasmania, 23/11/20

for leftover stock includes stock arrived too late, ordered too much vaccine, and people visiting pharmacies instead. The breakdown for paediatric, adult and 65+ NIP vaccine stock are:

- ▶ **Paediatric flu vaccine (survey respondents = 30): 60% were located in metro and 40% were in regional / rural region**
 - ▶ Stock arrived too late (50%)
 - ▶ Overall demand was lower than expected (30%)
 - ▶ Ordered too much vaccine (17%)
 - ▶ Keeping supply for second dose, children turning six months after winter
 - ▶ People visited a pharmacy instead (3%)
 - ▶ Still using the vaccines as they are in date (3%)
- ▶ **Adult flu vaccine (survey respondents = 36): 56% were located in metro and 44% were in regional / rural region**
 - ▶ Stock arrived too late (53%)
 - ▶ Ordered too much vaccine (22%)
 - ▶ Overall demand was lower than expected (17%)
 - ▶ People visited a pharmacy instead (6%)
 - ▶ Keep a few for those who come in later in the season, and / or pregnant women (3%)
- ▶ **Adult (65+) flu vaccine (survey respondents = 31): 61% were located in metro and 39% were in regional / rural region**
 - ▶ Stock arrived too late (65%)
 - ▶ Ordered too much vaccine (26%)
 - ▶ Overall demand was lower than expected (6%)
 - ▶ People visited a pharmacy instead (6%)
 - ▶ Keep a few for those who come in later in the season (3%)

This is in contrast to the 2019 season, where minimal stock was held beyond August till the end of the season in February 2020 (in 2020 there were 917,830 doses on hand across September and October in all jurisdiction and 363,286 doses for 2019 in comparison). This suggests that jurisdictions may have ordered more stock than what is required for the 2020 season, indicating the potential for a large stock write-off at the end of the current season.

Figure 8: Monthly doses of flu vaccine on hand by jurisdiction



Source: VAS

Note: The June 2019 figure was extrapolated based on the average of May 2019 and July 2019 figures as no data was provided for this month. This same method was also applied for April 2020 as no data was provided for this month.

Need for improved demand planning and ordering at the immunisation provider level

Storage capacity was identified as a key constraint at the immunisation provider level (e.g. at GP premises and at pharmacies). Ineffective demand planning and ordering processes at the provider level meant that providers often ordered in excess of what they could store and administer at their facility resulting in vaccine wastage.

"We ended up with quite a lot we didn't use, partly because we didn't know what the longer term demand was. We were busy, busy, busy, and then it [requests for vaccinations] all dried up."

A GP during interview

To minimise wastage, some GP clinics spoke with other providers in the area and managed the re-distribution of vaccines amongst themselves.

Immunisation providers varied their approach to ordering flu vaccines, with their approach largely dependent on whether they were ordering a government funded or non-government funded vaccine. For government-funded vaccines, only one in three (36%) immunisation providers reported ordering enough vaccine to meet anticipated demand for the whole season, while 45% ordered enough to meet anticipated demand for the first month. Immunisation providers spoke of the challenges associated with predicting demand.

"It's always hard to predict demand, there's enormous variability between years. If someone dies from the flu, there's panic uptake from everybody."

A GP during interview

Several Aboriginal health care services speculated that ordering may have been based on need in previous years rather than the directive to focus on vulnerable cohorts as a result of the COVID-19 pandemic.

The way in which immunisation providers managed NIP demand over the peak of the 2020 flu season also varied.

- ▶ Eighty-five per cent of immunisation provider respondents ordered more vaccine when stock depleted to a certain level, but before stock ran out entirely
- ▶ Twelve per cent of immunisation providers ordered more vaccine once stocks ran out
- ▶ Only three per cent of immunisation providers reported that they did not need to order stock at all after the initial order

Finally, it is worth recognising that most jurisdiction health agencies have no visibility of their providers' vaccine storage capacity. ACT Health is the only jurisdiction that has full and accurate visibility of providers' storage capacity as the ACT Health staff members are responsible for distribution and delivery, all the way to providers' fridges. Benefiting from clear visibility of storage capacity, ACT Health could better control orders placed by providers and minimise the risk of overordering and wastage incurred.

.....
▲ **Recommendation 7** The Department supports and encourages jurisdictions to assess and record the capacity of immunisation providers to store vaccines appropriately. The information would support the efficient and effective management of the ordering of NIP flu vaccine, or the addition of emerging vaccines, such as a COVID-19 vaccine, to be delivered alongside the annual flu vaccination program.
.....

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Distribution to remote locations is a challenge

Distribution to remote locations was noted as a challenge in general, and it was further impacted in the 2020 season due to the COVID-19 pandemic. The pandemic resulted in the closure of smaller airlines and / or interrupted domestic flight, which delayed the delivery of vaccines to non-metropolitan areas and states which have limited storage infrastructure. For example, a South Australian clinic spoke of running out of adult (65+) vaccinations, and were told by distributors that it would take 1.5 weeks to receive more doses.

Delays also resulted in multiple cold chain breaches. For example:

- ▶ **Tasmania Health** experienced significant delay (three weeks) of flu vaccine stock at the beginning of the flu season. All stock were delivered from their Victorian warehouse, which was delayed due to local lockdown restrictions and interrupted flight
- ▶ **Northern Territory Health** reported that flight disruptions increased the number of stopovers required to deliver their stock. This exceeded cold chain packaging limits and resulted in the breaching of multiple batches of vaccines

4.5.1.4 Waste Management

New South Wales, Queensland, South Australia and Tasmania reported wastage levels of between 0.4% to 2.0% as at November 2020 as shown in Table 5. The current wastage figures are likely to be understated as vaccine write-offs do not occur until February, when the vaccine season has formally concluded.

Table 5: Vaccine wastage by jurisdiction for 2019 and 2020

	Benchmark ⁵⁹	New South Wales	Queensland	South Australia	Tasmania
2019	5% or lower	Not available	11.1%	10.9%	6.9%
2020	5% or lower	0.4%	2.0%	1.2%	1.3%

Source: VAS and Jurisdiction Wastage Data

Based on the stock on hand balances data as at October 2020 in Figure 8, vaccine wastage due to end of season expiry is expected to be high for Queensland, Victoria and Western Australia as these jurisdictions are carrying significantly higher levels of inventory in October, when demand for vaccines is low, compared to the same period in 2019. Improved demand planning in future years as recommended in Recommendation 5 will assist with reducing vaccine wastage.

As part of EY's jurisdictional supply chain analysis, EY also analysed supply chain data from seven jurisdictions to understand how key aspects of each jurisdiction's supply chain operated for the 2020 influenza season. This analysis is presented in Appendix C.

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⁵⁹ Australian Institute of Health and Welfare, 2020. *National Partnership on Essential Vaccines: performance report 2018-19*. p.1.

The need for Government facilitation and in-season orders shows that private market immunisation providers, in seeking to minimise its commercial exposure from excess obsolete vaccines at the end of the flu season, may be under planning the amount of vaccines it requires for a flu season.

To support improved demand planning in the private market, the Department should publish vaccination rates for non-funded cohorts once sufficient data is reported on AIR. Published vaccination rates would help the private market to better gauge demand, beyond its current means of demand sensing through customer orders an upcoming flu season.

Recommendation 10 The Department publish vaccination rates for both NIP eligible and non-funded cohorts based on AIR vaccination data from 2022 onwards.

4.6 Criteria 4 – Immunisation providers

The workforce behind immunisation can be segregated into two primary groups. The first is the General Practitioners, who are often represented by peak bodies such as the Australian Medical Association, the Royal Australian College of General Practitioners (RACGP), the Rural Doctors Association of Australia (RDAA) and the Australian College of Rural and Remote Medicine (ACRRM). The second are pharmacists, and pharmacy based immunisation providers, represented by peak bodies such as the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia. Additional key workforce members include Aboriginal health workers in some states (e.g. New South Wales and Western Australia) and qualified registered nurses.

Depending on location and size, health services / clinics varied significantly in the types of patients seen and the demographics of those patients. Patients spanned all age groups, ethnicities and reasons for visiting the clinic or health service.

4.6.1.1 Differing immunisation approaches

Public market immunisation

The primary method for immunisation in the public market was through GPs. The AMA stated that GPs administered approximately ten million doses of flu vaccines in 2020, demonstrating their capability to rollout mass vaccinations.

Consultations with Chemist Warehouse outlined that currently 250 out of 450 pharmacies nationwide can provide immunisation services. However, this is planned to increase to 350 in 2021. Chemist Warehouse was also engaged to provide immunisation services to several aged care organisations in the case the relevant NIP stock was available and allowed in the jurisdiction (i.e. Australian Capital Territory, Victoria and under trial in Western Australia).⁶¹ Chemist Warehouse is also providing financial assistance to eligible staff for continuous training and development. The goal is to have half of the eligible workforce registered as immunisation providers in 2021.

Private market immunisation

Private market immunisation occurs primarily through GPs, pharmacies, and corporate vaccination programs. It often takes place earlier than public market immunisation.⁶² For example, in-store immunisation services offered by Chemist Warehouse commenced in late March and ran through to June nationally.⁶³

The Pharmacy Guild of Australia estimated that the number of pharmacy vaccinations increased to three million in 2020, a 50% increase from the 2019 season when two million pharmacy vaccinations were administered. The increase in pharmacy vaccinations was attributed to the following factors:

⁶¹ Meeting Minutes, Chemist Warehouse, 25/11/2020

⁶² Meeting Minutes, GSK, 27/11/2020

⁶³ Meeting Minutes, Chemist Warehouse, 25/11/2020

- ▶ Statements from the Department encouraging Australians to get the flu vaccine as part of the COVID-19 mitigation strategy, despite NIP vaccine supply not yet being available. This reportedly led to many consumers visiting pharmacies to obtain the flu vaccine
- ▶ The convenience of often allowing walk-in inoculation with no pre-bookings; seen to be particularly crucial to consumers during the COVID-19 pandemic.

GPs expressed frustration at private market immunisations occurring before public market vaccinations. They felt that it contradicted advice from state and federal jurisdictions, as well as peak bodies, as to when in the flu season that vaccinations should be administered (i.e. in recent years, it was reported that clinics were told to delay immunising until April/May so that the vaccine provides immune coverage throughout the entirety of the flu season).

"There were lots of pharmacies immunising earlier, even though the recommendation was to wait."

A GP during interview

4.6.1.2 Accessibility

Clinics spoke of aiming to vaccinate as many vulnerable people as possible in 2020; either via the NIP/state immunisation program in the first instance, followed by the purchase of private vaccinations directly from the supplier. In 2020, clinics offered consumers a number of ways in which they could organise access to the flu vaccination, including booking an appointment over the phone (88%), online (56%), a specific flu vaccination booking system (50%), visiting the clinic in person to make an appointment (50%) and walk in visits (18%).

Vaccines were administered in one of the following two scenarios:

- ▶ Patients proactively requested the vaccine
- ▶ Opportunistic vaccinations, whereby patients were offered the vaccine as part of routine check-ups and/or when visiting for other reasons

Several challenges relating to accessibility were identified:

- ▶ Aged care facilities in rural areas lacked nursing assistance, and consequently GPs are required to bring nurses with them from their own practices for immunisations in remote aged care facilities.⁶⁴
- ▶ Indigenous communities currently rely on nurses for inoculations. South Australia forbids Aboriginal Health Care Workers from being able to perform inoculations, despite having received the necessary training.⁶⁵ This creates congestion in inoculation waiting lists, and the rate of immunisations across remote areas, as only nurses and trained pharmacists have the ability to perform immunisations

Immunisation providers working with Indigenous communities reported that the majority of vaccinations that occurred in 2020 were opportunistic in nature. Peak bodies recognised a clear increase in effort to protect vulnerable communities through flu vaccinations, resulting in more opportunistic vaccinations than ever before.

4.6.1.3 Supply

The majority of surveyed immunisation providers (73%) reported running out of NIP stock at some stage during the 2020 flu season. This tended to be at the start of the flu season where the majority of immunisation providers reported some form of delay to their first order of the vaccine. Delays appeared to be more prevalent for government-funded vaccines (62% reported partial or full order delays for government funded vaccines, vs 41% for non-government funded vaccines). First orders also tended not

⁶⁴ Meeting Minutes, RDAA, 25/11/2020

⁶⁵ Meeting Minutes, Aboriginal Health Council of South Australia, 14/12/2020

to be received in full (61% of government-funded vaccine orders and 48% of non-government funded vaccine orders were reportedly only partially delivered).

When NIP stock ran out, common strategies included:

- ▶ Re-scheduling the appointment to when new stock arrived (90%)
- ▶ Administered a private vaccine instead, paid for by the consumer (41%)
- ▶ Directed the person to another vaccination location (34%)

4.6.1.4 Demand

The COVID-19 pandemic provided a unique set of challenges to immunisation providers, including:

- ▶ Increased demand for the flu vaccine
- ▶ Social distancing protocols introduced to counter COVID-19 occurred at about the same time as the commencement of the flu season, and clinics were mindful of limiting the number of patients/consumers in the space available, which potentially limited the pace of flu vaccinations.

Immunisation providers largely attributed the increased demand in 2020 to fear and uncertainty around the COVID-19 pandemic (98% of survey participants felt that heightened awareness due to the COVID-19 pandemic contributed to increased demand). It was felt that in a time of great uncertainty and with limited alternatives available to proactively protect themselves, patients sought out the flu vaccine as a way of feeling like they were “doing something”.

Other factors reported to have led to an increased demand include:

- ▶ Legislation changes (63% of survey participants felt this contributed to an increase in demand) – such as needing to be vaccinated before visiting aged care facilities
- ▶ Increased communication to consumers encouraging flu vaccination (50%)
- ▶ Increased focus on personal health (35%)

4.6.1.5 Workforce capacity and availability

Capacity to administer the flu vaccine differed amongst clinics; one clinic spoke of being able to vaccinate ten patients an hour, while another reported as many as 30-40. In general, workforce availability was considered adequate, with only 12% of survey participants indicating that they had not been able to meet demand because they did not have enough staff to administer the vaccine.

4.6.1.6 Communication

Immunisation providers obtained information about the 2020 flu vaccination program from a variety of sources, including the immunisation information pack provided by the Department (76%), peak bodies (64%), state / territory health authority websites (56%), colleagues (39%), the Department's website (38%) and professional development / information sessions (38%).

At the time of survey (December 2020 – January 2021), immunisation providers report feeling “in the dark” about the COVID-19 vaccine rollout and 2021 flu season. They reported receiving minimal information to date, which has led them to worry as to if and how their service and clinic will cope with these vaccination programs. It should be noted that these concerns would largely be addressed with the release of new guidance from relevant authorities starting in January 2021. Nonetheless, these concerns relate to:

- ▶ **Workforce capacity** – if immunisation providers are administering both the flu and COVID-19 vaccines, will they have enough staff? In South Australia, it was strongly suggested that legislation be updated so that Aboriginal Health Workers have the ability to vaccinate in order to support the flu and COVID-19 vaccination programs

- **Space** – will they have space at their clinic to vaccinate everyone? Space was a concern generally, but particularly so if social distancing measures are in place. Immunisation providers requested further guidance from the government on what's appropriate and not appropriate in terms of location and setup of vaccination clinics. Concerns were raised about the safety of in-car vaccinations, given it may be difficult to remove the patient from the car if an adverse reaction occurs. It was suggested that if in-car vaccination clinics are established, guidelines are needed as to the training required of those administering the vaccinations, and requirements as to what equipment is needed to be on standby in the event of an adverse reaction (e.g. adrenaline, resuscitative equipment).
- **Storage** – do clinics have both a) the space and b) the facilities/equipment required to meet cold chain requirements and store the vaccine appropriately, while still catering to demand?
- **Communication with consumers** – immunisation providers recognised the critical role that the government plays in informing the community about vaccination programs, stating the challenges associated with rolling out programs are greater if the federal or state governments are not promoting them widely, or not promoting them in a consistent manner.

Immunisation providers urge the Department to consider developing COVID-19 protocols in consultation with peak bodies (in addition to, or instead of state jurisdictions) as peak bodies are seen to have the most in-depth understanding of the differing contexts in which clinics and health services operate (e.g. previous rules relating to the storage of medicines were only relevant to public hospitals, not general practice).

While a recommendation has not been developed specifically for this evaluation criteria, Consideration 1 and Recommendation 9 address findings raised under this section.

4.7 Criteria 5 - Post administration documentation and reporting

4.7.1 Australian Immunisation Register

The AIR is the national recommended tool for reporting and documenting vaccinations administered in Australia. However, consultations revealed the importance of the data collection and the support on mandating its use from jurisdiction departments.

A NCIRS 2020 review found that vaccinations administered by pharmacists accounted for only 2.7% of total encounters recorded in AIR from all providers in 2019. Given the number of pharmacies registered as offering vaccination services, 2019 data indicated that only half were supplying valid vaccination data to AIR.

Specific to the flu vaccine, in 2018 pharmacy peak bodies reported that over one million flu vaccinations were administered and over two million in 2019. This was ten and four times greater than what was reflected in AIR respectively.⁶⁶ Adoption of AIR is low because recording on the register is not a legislated requirement in 2020's flu season. As of 01 March 2021, reporting of vaccination will be legislated to be mandatory. In addition, users expressed serious concerns about AIR's usability.

Adoption of AIR by some immunisation provider groups to record vaccinations is low, making it difficult for relevant departmental agencies to assess the level of vaccine uptake across the population. Stakeholders, noted that the AIR is effective as a single source but large portions of underreporting may render insights inaccurate.

Reporting from pharmacists is of particular concern. Consultations with jurisdictions found that there was a distinct lack of confidence in pharmacist reporting. A NCIRS 2020 review found that vaccinations administered by pharmacists accounted for only 2.7% of total encounters recorded in AIR from all providers in 2019. Given the number of pharmacies registered as offering vaccination services, 2019 data indicated that only half were supplying valid vaccination data to AIR.

Most (75%) immunisation providers who stated in the survey that they used AIR found it 'very' or 'somewhat' easy to update the AIR. However, it is important to note that no pharmacists participated in

⁶⁶ NCIRS, 2020, *Review of pharmacist vaccination reporting to the Australian Immunisation Register*, Available at: <[https://www.ncirs.org.au/sites/default/files/2020-06/Review of pharmacist vaccination reporting to the AIR_Final report_May 2020.pdf](https://www.ncirs.org.au/sites/default/files/2020-06/Review%20of%20pharmacist%20vaccination%20reporting%20to%20the%20AIR_Final%20report_May%202020.pdf)> [Accessed 15 December 2020]

the online survey, and it is this cohort who have markedly lower rates of AIR use. As such, it is important to understand challenges amongst the AIR cohort (such as awareness of the AIR, resourcing constraints and functionality).

Immunisation providers are cognisant of the importance of the AIR in successfully rolling out the COVID-19 vaccine, particularly if a multi-dose vaccine is utilised – both from the perspective of:

- ▶ Being able to view the immunisation history of consumers (knowing which vaccine they were administered previously and when); and also
- ▶ Reducing administration burden at health centres and clinics, where staff would otherwise need to spend time handling requests for vaccination history and printing vaccination records.

Immunisation providers in Victoria reported that the Victorian Government is developing a standalone system for immunisation providers to record details of COVID-19 vaccines administered. They urged federal and state governments to work together to reduce the administrative burden on health centres and clinics, as well as reducing the need for effort to be duplicated wherever possible.

Immunisation providers understand the need for COVID-19 vaccine batches and individual doses to be QR-coded, but are also aware that this will increase the administrative side of COVID-19 vaccinations. They suggest clinics and health centres will need extra administrative and non-administrative staff to cope with demand.

Reporting vaccination is not made mandatory in New Zealand. District Health Boards (DHBs), GPs and pharmacists can record the flu vaccination in the National Immunisation Register (NIR), however it is not mandated. Pharmacists were only able to record vaccines to NIR from 2017 when the Ministry of Health developed an application called ImmuniseNow which was able to 'talk' to NIR. Occupational health nurses are currently unable to record vaccines without doing so manually, which is not expected, and are also unable to claim reimbursement for eligible vaccinations.⁶⁷ The overall lack of reporting results in insufficient data which impacts the identification of target populations and forecasting ability.

■ **Recommendation 11** The recording of NIP flu vaccination on the AIR should be mandatory for all immunisation providers to enable the assessment of the effectiveness of the program and its reach into higher risk population groups.

It is also recommended that improvements be made to AIR's usability to reduce manual inputs and interoperability with ICT infrastructure of immunisation providers.

It is noted at the time of writing that an amendment to the Australian Immunisation Register Act 2015 has been introduced in parliament to mandate vaccination recordings on AIR. The amendment has since received parliamentary approval on 4 February 2021, where vaccination recordings will be mandatory from 1 March 2021.

The recommendation remains to highlight the importance and value of mandatory reporting on AIR.

4.7.2 Adverse events

Australia is well regarded internationally for highly regulated therapeutic goods. The TGA is responsible for regulating the lawful supply of therapeutic goods in Australia. Adverse event reporting is another important element of the vaccination program and is regulated by TGA. There are several avenues that exist for which providers can provide reporting, as outlined below:

⁶⁷ Ministry of Health, 2019, *Recording adult vaccines on the National Immunisation Register*, Available at <<https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/national-immunisation-register/questions-and-answers-recording-adult-vaccines-national-immunisation-register>> [Accessed 18 January 2021]

- ▶ TGA
- ▶ Jurisdiction health departments
- ▶ AusVaxSafety

This includes reporting directly to the TGA, through jurisdiction health departments and AusVaxSafety, all of which feed data into TGA's database. There were no vaccines in 2020 which experienced a serious adverse event requiring the TGA to issue a recall.

The table below describes these pathways in more detail.

Table 6: Adverse events pathways

Adverse event reporting pathway	Description
TGA	<ul style="list-style-type: none"> ▶ Suppliers regularly meet up with the TGA to ensure vaccines are safe, effective and compliant⁶⁸ ▶ Both consumers and providers are able to report adverse events directly to the TGA ▶ This is typically done electronically within the TGA portal, but can also be submitted by email or over the phone ▶ Reports are collated centrally, in TGA database, which allows TGA staff to analyse and identify potential emerging problems requiring detailed investigation <ul style="list-style-type: none"> ▶ In the case of a safety concern is identified, TGA can further investigation to determine relevant regulatory action if required
Jurisdiction health departments	<ul style="list-style-type: none"> ▶ Immunisation providers report adverse events to respective local health network or health departments <ul style="list-style-type: none"> ▶ Legislation differs across states and territories as to whether this avenue is mandated ▶ Adverse event reports are reviewed and communicated to the TGA ▶ Patients who experienced adverse events can receive follow ups if required
AusVaxSafety	<ul style="list-style-type: none"> ▶ Established in 2014, which is led by NCIRS and its contract managed by the Immunisation branch within the Australian Government Department of Health ▶ Vaccination providers are able to sign up for the SmartVax program (or other AusVaxSafety surveillance tools such as Vaxtracker), which automatically sends an SMS to patients three to five days after vaccination with an optional survey to report any adverse effects ▶ The surveys are forwarded on to the providers to allow for appropriate follow ups and optional automatic notifications to be sent to state authorities ▶ Using SmartVax as their main data monitoring tool, AusVaxSafety analyse the de-identified data to report to the TGA, federal and state governments <ul style="list-style-type: none"> ▶ 2019 summary report, it was reported that the network continues to grow, with over 330 participating immunisation clinics and over 470,000 SMS messages sent over the calendar year

The adverse events reporting system meets the needs of stakeholders, but is cumbersome due to the existence of multiple reporting pathways. There are multiple pathways being enabled for reporting purposes. However, it is a rather manual process due to the lack of digital links across the database and jurisdiction department's systems. Stakeholders have also expressed that the limited system interoperability may become a potential issue with the COVID-19 vaccine rollout.

In general, jurisdictions consulted preferred all adverse events to be reported through respective jurisdiction health departments. It was suggested this would allow for appropriate review and follow up on all events in a timely manner, at a local level.

In communicating adverse events, jurisdiction representatives commonly attend TGA and AusVaxSafety meetings. These help make them highly aware of the situation at hand and well placed to review reported adverse events.

Reporting of adverse events and the associated follow ups are inconsistent across Australia. This is due to different legislation requirements in states and territories around reporting. It is commonly agreed by consulted stakeholders that a single source of data can enhance effective communication between

⁶⁸ Meeting Minutes, Seqirus, 26/11/2020

immunisation providers and consumers. It can also increase an understanding of jurisdiction vaccine safety which cannot be achieved with a small dataset. This will also allow health authorities to follow up on adverse events and ensure the referred care is being administered.

Similarly, in New Zealand, adverse events are reported in line with the National Adverse Events Reporting Policy 2017. Adverse event reports are sent to the Centre for Adverse Reactions Monitoring (CARM), which in turn inform Medsafe and the Medicines Adverse Reactions Committee if they identify a potential issue with a vaccine.⁶⁹

In the 2020 flu season, 15% of immunisation providers who participated in the online survey indicated that they had reported at least one of their patients had experienced an adverse reaction to the vaccine, either by downloading the ADR template or lodging a report online via the Users Medical Device Incident online form.

4.7.2.1 Future enhancement

A knowledge gap has been identified by stakeholders, suggesting that pharmacists in particular can improve the documenting and reporting of vaccination induced adverse events. The new large role pharmacies play in the administration of the flu vaccine presents an issue when it comes to reporting.

In addition, it was noted that the NIC does not cover a review of adverse events as part of its terms of reference. Having visibility of adverse events at the NIC or an NIC-like forum can assist in identifying and responding to any emerging vaccine safety risks within the Program at a national level and improve the vigilance and responsiveness of immunisation providers to vaccine safety issues. This will be very important for any future novel vaccines introduced into the NIP such as the COVID-19 vaccines.

Recommendation 12 The adverse events reporting process should be streamlined among the various pathways currently operating so that all reports of adverse events are only required to be entered once into a system that will then ultimately report to the TGA's adverse event system.

While this recommendation is directed at the flu vaccination program, there are direct implications for the COVID-19 vaccine rollout.

As COVID-19 vaccines are new to the market, reporting and responding to adverse events in a timely manner is important. Having an optimised reporting process for consumers and providers will support timely report and response.

It is noted that the COVID-19 Taskforce is examining improvements to adverse events reporting as part of their vaccine rollout program.

Recommendation 13 The NIC or an NIC-like forum should review a summary of adverse event trends annually. This has implications for the COVID-19 vaccine to optimise the visibility of adverse events and any required responses at a national level.

4.8 Criteria 6 - Consumer sentiment

4.8.1 Messaging to consumers

Success in having NIP eligible cohorts accessing program vaccines is heavily dependent on eligible individuals understanding their entitlements, benefits and risks. Consumer sentiment in relation to the program should be regularly measured.

⁶⁹ MedSafe, 2019, *Safety Information*, Available at <<https://www.medsafe.govt.nz/Consumers/Safety-of-Medicines/Vaccine-safety.asp>> [Accessed 18 January 2021]

4.8.1.1 Reasons for not having the flu vaccine

During the 2020 flu season, immunisation providers reported that the most common reasons for not wanting to get the flu vaccine, and also the COVID-19 vaccine, related to:

- ▶ Safety - for the flu vaccine, consumers had read reports or known someone that have had an adverse reaction to the vaccine. For the COVID-19 vaccine, consumer concerns were that the vaccine:
 - ▶ Had not been properly tested / had been rushed through the approval processes. Immunisation providers stated that some Aboriginal patients had voiced concerns about reports that Aboriginal communities would be among the first to receive the COVID-19 vaccine, believing they were being used as "guinea pigs" to test an unreliable vaccine
 - ▶ The efficacy of the vaccine in the long term is unknown
- ▶ Low levels of trust with government - immunisation providers described Aboriginal populations having a degree of mistrust with government bodies due to historical trauma events. Fears included the government using vaccination programs to genocide the Indigenous population. Aboriginal health care clinics found it challenging to administer vaccinations when the immunisation provider was not local and/or known to the local community. They described the critical role of Aboriginal health care workers in:
 - ▶ Being present at outreach clinics or in-home vaccination visits to allay fears

"Often, they're more comfortable with an Aboriginal health practitioner than a white nurse"

- ▶ Proactively going out and finding those who would not otherwise access healthcare

"It was clear when we arrived that they weren't regular health services attendees. There was no way we would have found them without [local elder and Aboriginal health worker]'s knowledge."

- ▶ Wanting to leave it for others - in speaking with consumers as part of regular check-ups/pre-existing appointments, immunisation providers found that some older Australians did not wish to have the vaccine as they wanted to leave it for others.

Immunisers recounted several strategies for handling consumer concerns. This included using anecdotes to convey the importance of the vaccine, and giving consumers information to go away and read and ask questions about, rather than pressuring to receive the vaccine on the spot.

"Rather than being pushy, we empower people to make informed decisions."

4.8.1.2 Consumer behaviour in 2020

Stakeholders noted that uptake was significantly earlier than usual in both 2019 and 2020 which they reasoned was largely due to an increase in consumer awareness and government messaging.

In 2020, providers also noted that a large driver of the early uptake was the COVID-19 pandemic, which coincided with the start of the season, instilling fear over the potential to contract both diseases and the inability to access the vaccine later due to potential lockdowns.

This aligns with the results of a social media analysis. That is, when looking at the 2020 volumes of mentions on social media platforms related to the flu vaccine, public discussions began spiking in February, much earlier than previous years. This appears to have been driven by discussion around the effectiveness of the flu vaccine in protecting the public against COVID-19.

In 2019, volumes of discussions were considerably lower than what was observed in 2020, even with flu deaths being the key topic of discussion. Discussions in 2019 also did not start picking up until later in the season, towards the end of March / start of April, and trended down after the singular peak. The higher volumes in 2020 when compared to 2019 can likely be attributed to an increased focus on the flu vaccine as a result of the COVID-19 pandemic. Another contributing factor may also be associated with lower levels of community awareness.

4.8.1.3 Communication

There was a reported misalignment in messaging to the public between the Department and jurisdictions with respect to NIP vaccine availability. The Department encouraged the public to consider flu vaccine uptake early, whilst the NIP stock was still in transit. This resulted in a rush by consumers to their immunisation providers for vaccines despite a lack of public stock. This problem was further complicated by the private market advertising that flu stock was available earlier than the NIP stock. Immunisation provider reported feeling that this also contradicted advice that the vaccine should be administered in April/May to maximise the chances of the vaccine being effective throughout the length of the flu season.

Providers also suggested that the misaligned messaging led to consumer panic and significant increases in direct communication, either through email or over the phone, to check on vaccine stock. This caused additional frustration for GPs which received stock later than surrounding pharmacies, and were told to delay administering the flu vaccine. GP clinics reported their receptionists receiving verbal abuse in person and via phone as a result of the mis-alignment in communication, and urged politicians, the Department and the state governments to be consistent in their messaging in future seasons, ensuring that communication aligns with the supply and availability of NIP flu vaccine.

Based on an analysis of social media, and supported by the findings from consultations, immunisation provider interviews and the online survey, there appears to be an opportunity for the Department to better influence the public narrative relating to the flu vaccine on social media.

In 2020, the increase in the volume of posts and mentions online suggests that the community are using social media as a news source in relation to the flu program. This was supported by immunisation provider interviews, where those who were hesitant to receive the vaccine were reported to have quoted social media influencers or accounts as their source of information relating to safety concerns. At the same time, however, it was posts from social commentators and members of the public that had the highest reach⁷⁰ in relation to the flu vaccine, rather than news outlets or official Department accounts.⁷¹

Social media was also suggested as an ideal communication channel for Indigenous communities, with a focus on Indigenous-specific social media streams. Immunisation providers spoke of seeing a rise in the use of social media amongst the indigenous community, resulting in a rise in the number of consumers raising questions or concerns about the vaccine based on stories or posts read on social media. Immunisers suggested targeting senior Indigenous community members in marketing strategies, as they have a high degree of influence on others in the community.

"In the past, the approach was - 'The doctor is god, if he said it's important, I do it.' Now, they quote things they looked up on the internet."

Immuniser in SA

There may be an opportunity for the Department to capitalise on public interest in the COVID-19 vaccine to reach a larger proportion of the general public online with regards to the flu season. For example, the VIC Health Twitter account saw a significant and sustained increase in followers during the COVID-19 pandemic and lockdown. The increase was related to the use of Twitter to announce daily COVID-19 infections in Victoria in the morning, ahead of the daily press conference (during the second-wave lockdown). Since then, the account has seen increased engagement on posts relating to other programs and campaigns (e.g. thunderstorm asthma) compared to previous years.

⁷⁰ Reach is an estimation about how many users be would likely see a post on average, on the basis of the likes, retweets and shares that content tends to get on Twitter per amount of followers.

⁷¹ Further details of the social media analysis undertaken can be found in Appendix D

■ **Recommendation 14** The annual refresh of the national communication strategy for the NIP flu vaccination program must be aligned with the annual National Influenza Immunisation Strategy (referred to in Recommendation 1) and should include the following additional components:

- a. Flu vaccine supply and why eligible consumers should wait for their NIP vaccines to be available
- b. How immunisation works in an aged care setting
- c. Consider the use of the social media with tailored content as another medium of communication to reach targeted cohorts and counter misinformation

The program communication strategy should be discussed at the NIC or an NIC-like forum to improve the coordination of messaging across both the NIP and the private flu vaccination market.

The effectiveness of the communication strategy underpinning the annual NIP flu vaccination program be measured through regular formal testing of consumer and provider sentiment.

Consultation with Indigenous councils emphasised the importance of tailored messaging to remote communities, who require Aboriginal and/or Torres Strait Island representation and respond better to plain language and evidence base details. This is also applicable to any future rollout of the COVID-19 vaccine to support effective uptake.

4.9 COVID-19 Vaccine System Readiness Assessment

4.9.1 Overview

In addition to EY's work in evaluating the performance of the Australian vaccine system for the 2020 influenza season, EY was also engaged to assess whether the vaccine system is ready from a capability and capacity perspective to handle the addition of a COVID-19 annual vaccination program as part of the NIP, in the case that COVID-19 requiring annual immunisation activity similar to seasonal flu vaccinations, post 2021.

The assessment was performed using the same Evaluation Criteria developed for the flu season evaluation, together with the existing knowledge of COVID-19 and its vaccine candidates (monovalent) at the time of this report is drafted.

4.9.2 Limitations

It should be noted that given the relatively limited understanding of the novel coronavirus SARS-CoV-2 or COVID-19, compared to virus such as human immunodeficiency virus, flu and hepatitis, and the rapidly evolving science around vaccination against it, the following uncertainties exist:

- It is unclear whether COVID-19 require annual vaccination similar to flu, which would support its inclusion within the NIP
- If annual immunisation against circulating COVID-19 strain(s) is required, it is unclear the type of vaccine manufacturing technology will be adopted. Different vaccine technology may result in different supply chain, clinical and administration requirements

As such, EY has refrained from making any COVID-19 vaccine specific recommendations, and all recommendations and considerations from this report would nonetheless benefit the rollout of an annual COVID-19 vaccination program under NIP.

4.9.3 COVID-19 vaccination strategy and program governance

The current Australian COVID-19 vaccination strategy focuses on vaccinating as much of the Australian population as possible through the free provision of COVID-19 vaccines. This includes all:

- ▶ Medicare-eligible Australians
- ▶ Visa-holders, excluding visa sub-classes 771 (Transit), 600 (Tourist stream), 651 (eVisitor) and 601 (Electronic Travel Authority).

Following this, the Australian Government has also defined the order of vaccination, with the following rollout strategy in order of priority⁷² ⁷³:

Table 7: Australian vaccination rollout strategy

Phase	Population group
1A	<ul style="list-style-type: none">▶ Quarantine and border workers▶ Frontline health care worker▶ Aged care and disability care staff▶ Aged care and disability care residents
1B	<ul style="list-style-type: none">▶ Elderly adults aged 80 years and over▶ Elderly adults aged 70-79 years▶ Other health care workers▶ Aboriginal and Torres Strait Islander people aged over 55▶ Younger adults with an underlying medical condition, including those with a disability▶ Critical and high risk workers including defence, police, fire, emergency services and meat processing
2A	<ul style="list-style-type: none">▶ Adults aged 60-69 years▶ Adults aged 50-59 years▶ Aboriginal and Torres Strait Islander people aged 18-54▶ Other critical and high risk workers
2B	<ul style="list-style-type: none">▶ Balance of adult population

Depending on the efficacy of the vaccines selected by Australia in reducing transmission risk and providing protection against current and emerging strains of COVID-19, the current eligible groups listed under the Australian COVID-19 vaccination strategy may need to be varied by the Department as it transitions the vaccination program into a business as usual (BAU) NIP vaccination program. As with the current NIP annual flu program which focuses on specific eligible cohorts, an annual COVID-19 vaccination program may also be one that only focuses on those cohorts. Having cohorts defined, together with vaccine uptake targets as part of a COVID-19 program strategy, will be key to vaccine system readiness.

Another important consideration is the vaccine supply chain to be used in a BAU context. Currently, the COVID-19 vaccine system is designed and managed chiefly by the Australian Government with the support of its technology and supply chain partners. This is markedly different to the NIP flu vaccine supply chain which is jointly managed between the Department and jurisdictions. The Department will need to decide on whether:

- ▶ **Option 1** - Current COVID-19 vaccine supply chain established by the COVID Taskforce should continue to be used in a BAU capacity, or
- ▶ **Option 2** - If the traditional NIP supply chain should be used for BAU vaccine roll out

This will also directly impact the parties involved from a program governance perspective, with the Department having primary oversight and governance responsibilities under Option 1, and joint responsibilities with jurisdictions under Option 2. Being able to shortlist a preferred supply chain option will also be important for COVID-19 vaccine system readiness.

⁷² Australian Government, January 2021, *Australia's COVID-19 vaccine national rollout strategy*. Available at: <https://www.health.gov.au/sites/default/files/documents/2021/01/australia-s-covid-19-vaccine-national-rollout-strategy.pdf>

⁷³ Australian Government, December 2020, *Australian COVID-19 Vaccination Policy*. Available at: <https://www.health.gov.au/sites/default/files/documents/2020/12/australian-covid-19-vaccination-policy.pdf>

4.9.4 Supply chain

In addition to selecting the preferred overall supply chain option, the Department will also need to consider how key supply chain activities will operate the supply chain option will function.

From a planning and procurement perspective, the number of approved vaccine suppliers available in the market will be an important factor in how the Department goes to market to procure vaccine supply. Currently, there are three potential suppliers for COVID-19 vaccines to the Australian market as shown in Table 8 below.

Table 8: Current COVID-19 vaccine candidates

Supplier	Vaccine name	Vaccine type	Phase of testing	Secured doses	Storage and transport temperature
Pfizer and BioNTech	BNT162b2	mRNA	Provisionally approved	10 million	-70°C ⁷⁴
University of Oxford / AstraZeneca	AZD1222	Adenovirus	2 and 3	53.8 million	2-8°C ⁷⁵
Novavax	NVX-CoV2373	Protein	3	51 million	2-8°C ⁷⁶

Source: EY Analysis

One of the current advantages the Department enjoys from an flu perspective is the number of vaccine suppliers and production capacity available in the market, which allows the Department to enjoy a level of price competition between suppliers. However this is unlikely to occur with COVID-19 vaccines in the short term as global demand for vaccines will significantly outweigh suppliers' current ability to supply until more suppliers enter the market, or if existing suppliers expand production to better meet global demand. If the Department, through the assistance of the OGTR and the TGA is able to introduce additional suppliers into the market, it can give the Department more options to procure vaccines and obtain value for money.

In addition, vaccine storage and transportation temperature requirements are likely to also factor into the Department's decision making when it comes to vaccine planning and procurement. Common across the three vaccines listed in Table 8, is the need to store and transport them in a cold chain controlled manner, akin to the flu vaccine. Of note is the Pfizer and BioNTech (Pfizer) vaccine which has a temperature requirement of -70°C, significantly beyond what jurisdictions can manage from a cold chain infrastructure perspective based on consultations with states and territories. To meet the Pfizer vaccine's unique temperate requirement, the Department has contracted DHL Supply Chain and Linfox to provide the supply chain infrastructure required to store, track temperature and transport the vaccine.⁷⁷ Longer term in a BAU NIP context, the Department may opt to only procure the University of Oxford / AstraZeneca vaccine and the Novavax vaccine due to its less onerous temperature requirements. The Department's ability to do so will depend on the level of global vaccine supply available to meet the Department's anticipated demand.

Finally, given the limited supply of COVID-19 vaccines globally and its high value, the tracking of vaccine inventory across the supply chain will be of utmost importance to maximise vaccination rates and to minimise wastage. Under the Department's contract with Accenture, a system will be developed to offer point in time visibility of COVID-19 vaccines across the supply chain. Having the ability to use that system in a BAU context would further strengthen vaccine system readiness, as currently visibility of vaccine stock after it leaves a jurisdiction warehouse is generally poor based on EY's consultations with states and territories.

⁷⁴ Pfizer, 2020, *Pfizer and BioNTech Conclude Phase 3 Study of COVID-19 Vaccine Candidate Meeting All Primary Efficacy Endpoints*, Available at: <<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>> [Accessed 15/12/2020]

⁷⁵ AstraZeneca, 2020, *AZD1222 vaccine met primary efficacy endpoint in preventing COVID-19*, Available at: <<https://www.astrazeneca.com/media-centre/press-releases/2020/azd1222h1r.html#:~:text=The%20vaccine%20can%20be%20stored,administered%20within%20existing%20healthcare%20settings>> [Accessed 15 December 2020]

⁷⁶ Novavax, 2020, *Novavax Announces Positive Phase 1 Data for its COVID-19 Vaccine Candidate*, Available at: <<https://ir.novavax.com/node/14891/pdf>> [Accessed 15 December 2020]

⁷⁷ Australian Government Department of Health, 24 December 2020, *Contracts signed for rollout of COVID-19 vaccine*. Available at <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/contracts-signed-for-rollout-of-covid-19-vaccine>

4.9.5 Immunisation providers

The experience of the 2020 flu season and the record number of vaccinations performed during this time shows that the current immunisation provider workforce across Australia is sufficient in meeting the surge in demand for vaccines brought on by the COVID-19 pandemic. However, depending on the size and number of cohorts eligible for a COVID-19 vaccination program under the NIP, that immunisation provider workforce may find its capacity to deliver vaccines stretched due to the sheer number of additional COVID-19 vaccinations it needs to perform in addition to the current suite of vaccinations performed, recognising that all of the COVID-19 vaccines Australia has procured thus far requires two doses. A lack of timely access to vaccinations may discourage consumers from being vaccinated or encourage consumers to only seek out certain vaccines, leading to reduced vaccination rates and poorer health outcomes.

Further, as the COVID-19 vaccines that will be available under a potential NIP vaccination program will still be new to the market, their potential to create adverse events in consumers will need to be monitored carefully. Having the capacity to monitor and record adverse events effectively as immunisation providers will be critical to consumer safety.

5

Appendices

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5. Appendices

Appendix A Evaluation criteria

Evaluation criteria	Rationale for the criteria	Considerations	Evaluation method						
			Method 1 - VCC	Method 2 - ICI	Method 3 - IS	Method 4 - SMA	External research	Policy review	Data / Report
a. Vaccination strategy and governance	Supports in understanding current jurisdictional capacity and capabilities in administering and managing public vaccination programs	<ul style="list-style-type: none"> ▶ Extent to which the National Immunisation Strategy has been implemented for the 2020 season ▶ Extent to which individual state and territory immunisation strategy has been implemented for the 2020 season ▶ Eligibility for free vaccines across the National Immunisation Program and States and Territories schemes, particularly for priority and vulnerable groups ▶ Measurements of health care consumer participation and target population coverage ▶ Estimated immunisation provider participation rate ▶ Estimated potential weekly vaccine administration capacity ▶ Locations and modes of vaccinations - e.g. pop-up vaccination site, school immunisation programs, pharmacy, GP clinics, aged care facilities ▶ Routine immunisation programs being conducted concurrently that may affect throughput (a consideration that is specific to COVID-19 vaccine) ▶ Lessons learned from the previous strategy 	✓				✓	✓	✓
b. Vaccine supply chain	Supports in understanding current supply chain capacity, capabilities and limitations in both public and private markets	<p>Ordering</p> <ul style="list-style-type: none"> ▶ Lead time for ordering for public and private market supplies ▶ Current order management processes and systems used for both public and private market ▶ Lead time for importation and quarantine clearance, if applicable <p>Manufacturing</p> <ul style="list-style-type: none"> ▶ Capacity for manufacturers to fulfil ordering for public and private market supplies <p>Allocation</p> <ul style="list-style-type: none"> ▶ Level of visibility federal and jurisdictions have on the allocation process <p>Distribution</p>	✓	✓	✓		✓	✓	✓

Evaluation criteria	Rationale for the criteria	Considerations	Evaluation method						
			Method 1 - VCC	Method 2 - ICI	Method 3 - IS	Method 4 - SMA	External research	Policy review	Data / Report
		<ul style="list-style-type: none"> ► Distribution channels for vaccines ► Distribution channels for ancillary supplies, if applicable (i.e. if pre-filled syringe (pfs) are not delivered) ► Cold-chain capabilities and ensuring cold chain integrity ► Potential bottlenecks in transportation and distribution Inventory Management <ul style="list-style-type: none"> ► Current inventory management processes and systems used for both public and private market ► Cold storage capabilities across jurisdictions, wholesalers and immunisation providers ► Days of inventory on hand across jurisdictions, wholesalers and immunisation providers Returns and Waste Management <ul style="list-style-type: none"> ► Returns management process ► Cost of waste management - including biohazardous and sharp waste, as well as recycling (if applicable) ► Turnover time on return process ► Common causes of stock return / waste return 							
c. Immunisation providers	Supports in understanding current capacity, capabilities and limitations at the immunisation provider level	<ul style="list-style-type: none"> ► Training and annual renewal to be eligible to provide immunisation services ► Separation of public and private stock for eligible individuals ► Public vaccination program - adequate compensation on service delivered ► Private vaccination program - fee-for-services, demand and market dynamic ► Policy efficiency and compliance, for example, the upload of immunisation record for consumers ► System readiness - e.g. vaccine ordering system (for both private and public stocks) and easy of navigate of Australian Immunisation Register (AIR) ► Lead time and completeness of order placed (both public and private markets) ► Effectiveness of communication with immunisation providers (potential measures: consistency of message, awareness) 		✓	✓		✓		✓
d. Post administration	Supports in understanding the current level of administration documentation and reporting	<ul style="list-style-type: none"> ► Current practices for documenting and reporting on vaccine administrations (e.g. AIR) ► Level of compliance with local and national guidelines ► Capacity of immunisation providers to facilitate timely updates (e.g. on AIR) 	✓	✓	✓		✓	✓	✓

Evaluation criteria	Rationale for the criteria	Considerations	Evaluation method						
			Method 1 - VCC	Method 2 - ICI	Method 3 - IS	Method 4 - SMA	External research	Policy review	Data / Report
documentation and reporting	performed by immunisation providers	<ul style="list-style-type: none"> ▶ The Department's capacity to monitor reporting for vaccine administration for future programs such as a COVID-19 vaccination program ▶ Current practices for adverse events reporting 							
e. Consumer sentiment	Supports understanding of consumer concerns from the perspective of stakeholders, with regards to vaccine availability and safety	<ul style="list-style-type: none"> ▶ Willingness to participate in seasonal flu immunisation program ▶ Concerns over safety and efficacy of the seasonal flu vaccine ▶ Ability to access the relevant vaccine (from both private and public market) in a timely manner with little effort required ▶ Discomfort or concerns post-vaccination ▶ Ability of consumers to obtain evidence of vaccination for work, visitation (e.g. aged care facility) and social welfare purposes 				✓			✓
f. Immunisation information systems and other supporting systems	Supports in understanding current system capabilities and limitations, and the ramifications this has for the implementation of a COVID-19 vaccination program	<ul style="list-style-type: none"> ▶ Ability to pre-register or enrol priority groups for COVID-19 vaccination at various stage ▶ Ability to handle data volume and not negatively impact other relevant / associated databases within the same environment ▶ Place orders for COVID-19 vaccine ▶ Manage and report vaccine inventory ▶ Report vaccine spoilage or waste ▶ Report adverse events ▶ NIP and provide reminders to COVID-19 vaccine recipients of the need to obtain a second-dose reminders 	✓						

Appendix B Stakeholders interviewed

Stakeholder category	Stakeholder
Value Chain Consultation	<p>Australian Government Department of Health</p> <ul style="list-style-type: none"> ▶ S47F, Director, Immunisation Procurement and Contract Management Section ▶ S47F, Assistant Director, Immunisation Procurement and Contract Management Section
Value Chain Consultation	<p>Office of Gene Technology Regulator</p> <ul style="list-style-type: none"> ▶ Michael Dornbursch, Assistant Secretary, Evaluation Branch ▶ S47F, Director, Plant Evaluation Section
Value Chain Consultation	<p>COVID-19 Digital Integration</p> <ul style="list-style-type: none"> ▶ S47F, Acting Director Digital Initiatives
Value Chain Consultation	<p>COVID-19 Taskforce</p> <ul style="list-style-type: none"> ▶ S47F, Director, COVIS-19 Vaccine Strategy Taskforce
Value Chain Consultation	<p>Tasmania Department of Health</p> <ul style="list-style-type: none"> ▶ S47F, Nurse Manager Immunisation
Value Chain Consultation	<p>Queensland Health</p> <ul style="list-style-type: none"> ▶ S47F, Team Leader, Vaccine Coordination ▶ S47F, Manager ▶ S47F, Clinical Nurse Consultant
Value Chain Consultation	<p>Northern Territory Department of Health</p> <ul style="list-style-type: none"> ▶ S47F, Director of Immunisation and Notifiable Diseases
Value Chain Consultation	<p>Pharmacy Guild Australia</p> <ul style="list-style-type: none"> ▶ S47F, Senior Pharmacist and National Manager PBS Operations and Strategy
Value Chain Consultation	<p>Royal Australian College of General Practitioners</p> <ul style="list-style-type: none"> ▶ S47F ▶ S47F ▶ S47F
Value Chain Consultation	<p>South Australia Health</p> <ul style="list-style-type: none"> ▶ S47F, Business Manager ▶ S47F, MPH Nursing Director Immunisation Section, Communicable Disease Control Branch
Value Chain Consultation	<p>Chemist Warehouse</p> <ul style="list-style-type: none"> ▶ S47F, National Immunisation Coordinator - Professional Services Department ▶ S47F, Professional Services Education and Development Manager
Value Chain Consultation	<p>NSW Health</p> <ul style="list-style-type: none"> ▶ S47F, Manager - Immunisation Unit, Health Protection NSW ▶ S47F, State-wide Director NSW Rural Generalist Training Program ▶ S47F, Project Officer - Immunisation Unit
Value Chain Consultation	<p>Seqirus</p> <ul style="list-style-type: none"> ▶ S47F, Executive Director ▶ S47F, Associate Director
Value Chain Consultation	<p>GlaxoSmithKline</p> <ul style="list-style-type: none"> ▶ S47F, NIP - Supply and Contract Manager ▶ S47F, Vaccine Tenders Manager ▶ S47F, Supply Chain Operations Lead ▶ S47F, Vaccines Director
Value Chain Consultation	<p>Therapeutic Goods Administration</p> <ul style="list-style-type: none"> ▶ S47F, Medical Officer - Signal Investigation Unit ▶ S47F ▶ S47F, Principal Advisor - Pandemic and Vaccines
Value Chain Consultation	<p>Sanofi Aventis</p> <ul style="list-style-type: none"> ▶ S47F, Commercial Manager ▶ S47F, Public Immunisation Policy Manager

Stakeholder category	Stakeholder
Value Chain Consultation	Australian Medical Association
	► S47F, General Manager - Policy
	► S47F, Policy Advisor
Value Chain Consultation	► S47F, Policy Advisor
	Victoria Department of Health and Human Services
	► S47F, Manager, Immunisation Operations - Communicable Disease Section
Value Chain Consultation	ACT Health
	► S47F, Director Immunisation
	► S47F, Assistant Director
Value Chain Consultation	► S47F, Database Administrator
	Northern Territory Top End Health Services
	► S47F, Clinical Nurse Manager, Immunisation - Centre for Disease Control
Value Chain Consultation	Rural Doctors Association of Australia
	► S47F, Chief Executive Officer
Value Chain Consultation	Aboriginal Health Council of Western Australia
	► S47F, Executive Manager Public Health
	► S47F, Public Health Medical Officer
Value Chain Consultation	Western Australia Department of Health
	► S47F, Senior Program Officer, Vaccines
	► S47F, Senior Policy and Planning Officer (Communicable Disease Control)
Value Chain Consultation	► S47F, Program Manager - Indigo Junction
	Avant
	► S47F, Chief Medical Officer
Value Chain Consultation	► S47F, Medical Advisor
	► S47F, Special Counsel - Employment Law
Value Chain Consultation	Anonymous, Vaccine wholesaler
	► Anonymous
Value Chain Consultation	Australian College of Rural and Remote Medicine
	► S47F
	Royal Darwin Hospital
Value Chain Consultation	► S47F, Pharmacy Operations Manager - Pharmacy Department, Royal Darwin Hospital
	► S47F, Pharmacist
	► S47F, Director of Immunisation and Notifiable Diseases
Value Chain Consultation	► S47F, Executive Director Medicines Management: Research, Transformation and Change
	► S47F, Director of Pharmacy (Alice Springs Hospital)
Value Chain Consultation	Aboriginal Health Council of South Australia
	► S47F, Public Health Medical Officer
Value Chain Consultation	Queensland Aboriginal and Islander Health Council
	► S47F, Immunisation Coordinator
Value Chain Consultation	Services Australia
	► S47F
	► S47F, Director
Value Chain Consultation	► S47F
	► S47F
	► S47F
Value Chain Consultation	Mylan
	► S47F, General Manager
Value Chain Consultation	Arrotex
	► S47F, General Manager - Marketing
	► S47F, Operations Manager Programs
Value Chain Consultation	► S47F, APOAccess
	► S47F
	► S47F

Stakeholder category	Stakeholder
Value Chain Consultation	Aspen
	▶ S47F , Business Development Manager
	▶ S47F , Practice Lead

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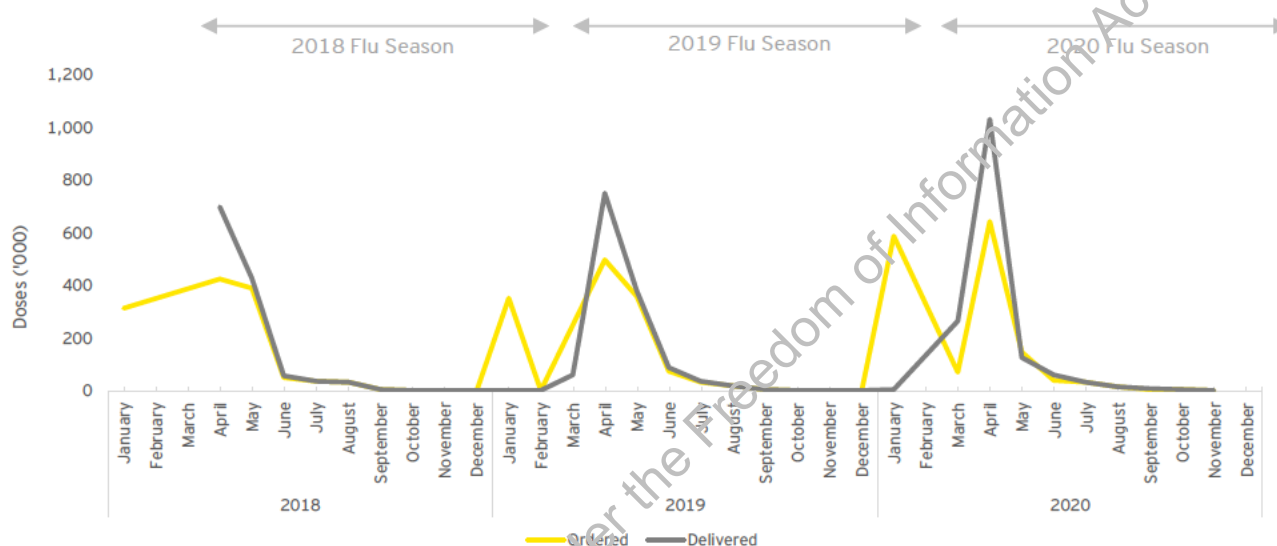
Appendix C Supply chain analysis by jurisdiction

Queensland

Orders and deliveries over time

As can be observed in the figure below (Figure 9), the delivery volumes of flu vaccines in Queensland illustrate similar trends in 2018 and 2019, and across all years there is a consistent annual peak deliveries in the month of April. However, in 2020 this peak was significantly higher than the previous two years, at 1,033,800, representing a 37% increase from 2019. This high peak in April is compensated by much lower deliveries in the subsequent four months; in particular the volume delivered in May 2020 (125,215) is 67% less than delivery volumes in May the previous year (381,637).

Figure 9: Monthly flu vaccine orders and deliveries in Queensland (2018 to 2020)



Source: Queensland order and delivery data

s47

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Further, flu vaccines ordered at the start the 2020 calendar year were significantly higher than previous years, with orders placed for 587,780 units in January 2020, representing a 66% increase when compared to the Orders placed in January of the previous year (354,020). The peak in deliveries described above could be attributed to the large volume of upfront orders placed in January. Higher volumes across both orders and deliveries could also be attributed to higher forecasts developed for the year of 2020, resulting in a greater or more urgent need for vaccine deliveries.

Top providers

In Queensland, there appeared to be a high priority placed on vaccination of healthcare workers throughout 2020. Of the top ten service providers ordering flu vaccines by supply quantity, seven were major metropolitan hospitals purchasing for their Health Care Worker Vaccination program Table 9. Under this program delivered by Queensland Health, seasonal flu vaccines are not mandatory, but are strongly recommended for all workers; however, due to concerns about infection prevention and control in 2020,

healthcare worker flu vaccinations may have been mandated or strongly recommended by the federal and state governments. This observation is further supported by the fact that although the Queensland Health Care Worker Vaccination program has been in effect since 2016, there were no orders recorded for the program in the previous two years of data. Whilst the high order quantities in 2020 may demonstrate an increase in the program activity and uptake of worker vaccinations, the differences observed between 2020 and the previous years' records could alternatively be an indication that there are gaps in the data, the provider's name has been re-classified, or the way that the vaccine is being ordered for this program has changed over the time period of data collection.

Table 9: Top 10 Queensland service providers by flu vaccine supply quantity (2018 to 2020)

Provider	2020 supply quantity	2019 supply quantity	2018 supply quantity
Health Care Worker Program Royal Womens Hospital	7,600		
Health Care Worker Program Toowoomba Hospital	7,500		
Health Care Worker Program Gold Coast Uni Hospital	7,420		
Health Care Worker Program Princess Alexandra Hospital	6,800		
Health Care Worker Program Sunshine Coast University Hospital	6,750		
Health Care Worker Program The Townsville Hospital	6,000		
Condamine Medical Centre	4,600	3,885	3,414
Gold Coast Public Health Unit	4,460	2,780	2,815
Health Care Worker Program Queensland Childrens Hospital	4,350		
Redcliffe Peninsula Seven Day Medical Centre	4,330	3,970	3,250

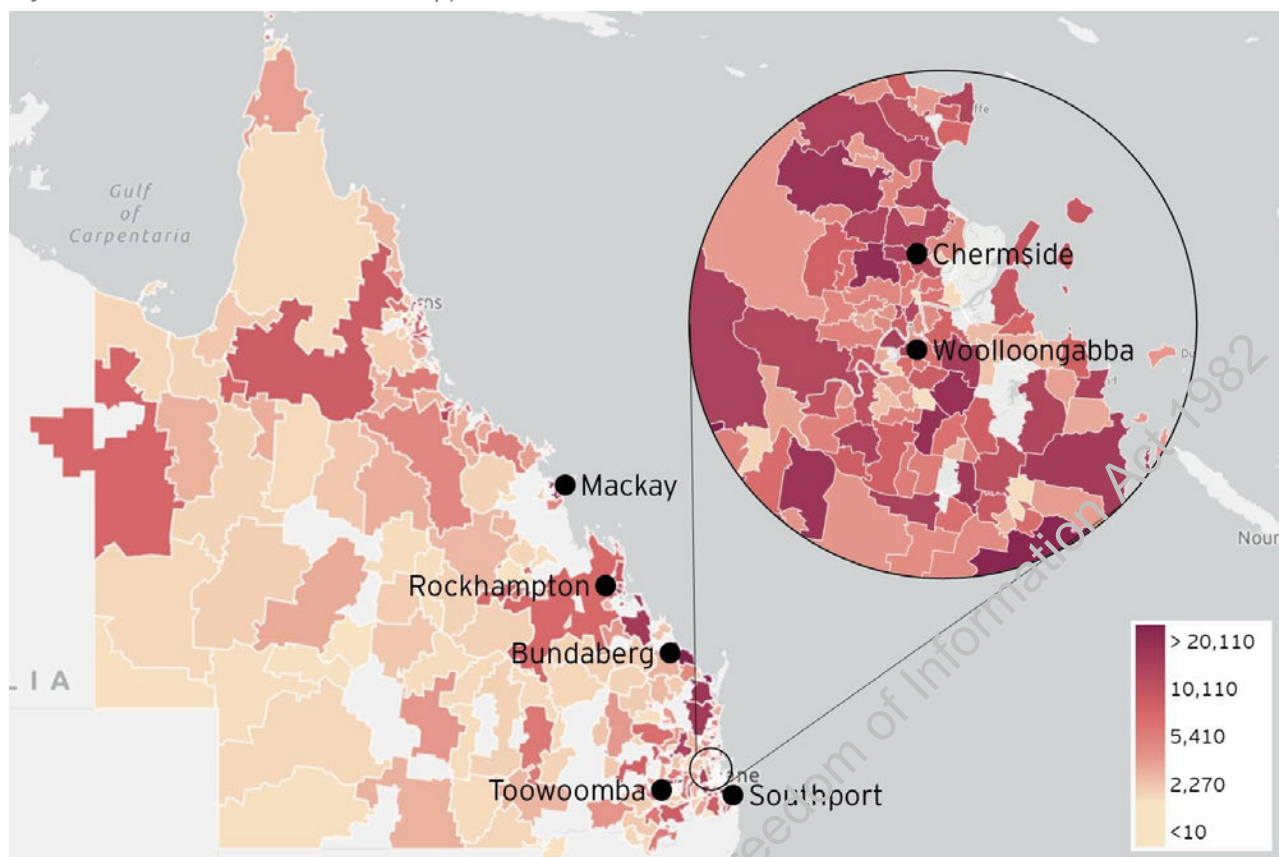
Source: Queensland order and delivery data

Of the remaining three top requisitioners, one was a public hospital and two were general practice medical centres. All three of these providers saw a notable increase in 2020 purchase volumes in comparison to 2019. The Gold Coast Public Health Unit increased their order quantity by 60%, from 2,780 in 2019 to 4,460 in 2020, while Condamine Medical Centre and Redcliffe Peninsula 7 Day Medical Centre increased their order volumes over the same period by 18% and 9% respectively.

Location of orders

Influenza vaccine allocation and distribution was delivered comprehensively and widespread across the State, as illustrated in Figure 10. As anticipated, a large portion of the orders were made by service providers in metropolitan areas, including suburbs such as Chermside and Woolloongabba. However, the distribution was not highly concentrated in greater Brisbane alone, but was broadly distributed outside of the metropolitan areas to the more regional and remote regions, including Toowoomba, Bundaberg, Southport, Mackay, and Rockhampton, which together account for eight per cent of the total flu vaccine orders in Queensland. These figures are representative of the widespread population in Queensland. However, for some of the more regional areas, that appear to have large volumes in comparison to a small population, further analysis could be undertaken to ensure that that ordering and distribution volumes were allocated correctly to ensure proper usage and avoid wastage. Further, having large volumes of vaccines distributed to rural and remote areas could create challenges and longer lead times in product distribution.

Figure 10: Queensland flu vaccine orders by postcode (2020)



Source: Queensland order and delivery data

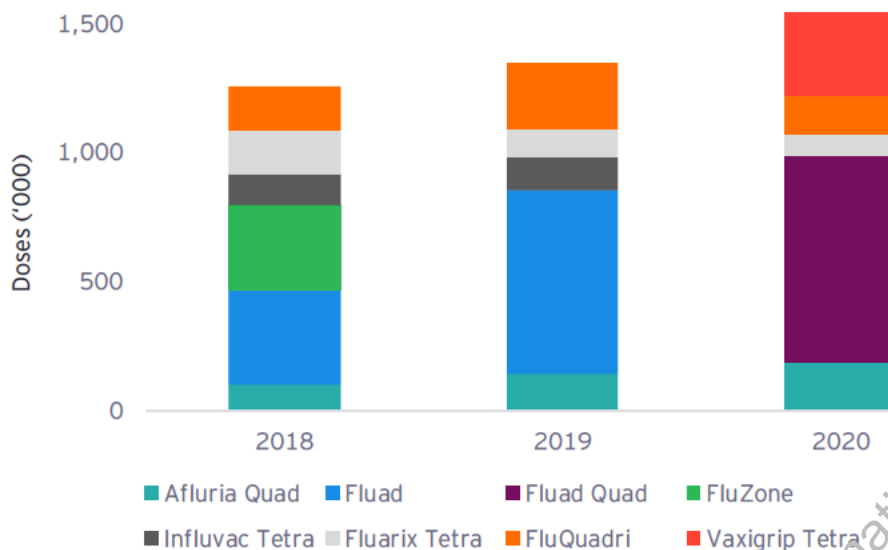
Some of the increases in ordered volumes between 2020 and the previous two years can be attributed to the Queensland Health Care Worker Vaccination programs. For instance, the locality of Birtinya had previously ordered a total of 3,750 and 3,605 units in 2018 and 2019 respectively; however, in 2020 the Sunshine Coast University Hospital located in Birtinya placed orders for 6,750 units of the vaccine as part of this program, bringing the total ordered annual volume for this region to 11,150 units; approximately triple the previous two years ordered volume.

Products ordered

As observed in the graph below (Figure 11), the composition of the seasonal flu vaccines ordered in Queensland in 2020 was somewhat dissimilar to that of 2018 and 2019. The Fludax Quadrivalent vaccine, accounting for approximately half of the total vaccine orders in 2020, replaced the trivalent Fludax vaccine used in the previous years. Both Fludax and Fludax Quadrivalent are indicated for use on persons of 65 years of age and older, illustrating the large portion of elderly population receiving the vaccine in 2020.

Another vaccine that was introduced into Queensland's orders was Vaxigrip Tetra, which represented the second-highest vaccine in terms of order volumes in 2020 (approximately 20%). It is intended for use for adults and children from six months of age and older. The vaccine was newly registered for use in 2020, and appears to have taken some of the ordering volumes of the FluQuadri and Fluarix Tetra vaccines. Due to the delay in its approval for use in comparison to the other vaccines that were readily available in the first quarter of 2020, orders for Vaxigrip Tetra were not placed until April, and in this month it accounted for approximately a third of the total units ordered in Queensland.

Figure 11: Annual flu vaccine orders in Queensland by product name (2018 to 2020)



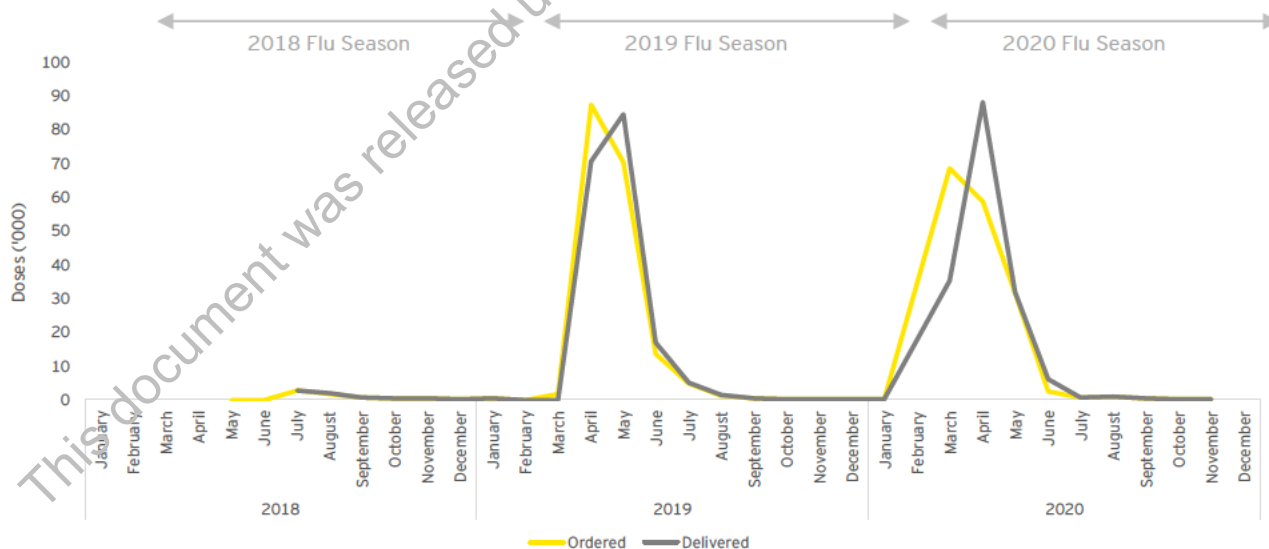
Source: Queensland order and delivery data

South Australia

Orders and deliveries over time

Data available on South Australia orders and deliveries of seasonal flu vaccines lacks information on 2018 volumes for orders and deliveries during the months of January to June (as illustrated in Figure 12). Therefore, only 2019 data can be used for a meaningful comparison against 2020. Given that in Australia, a normal flu season starts in the final months of the previous year, the data recorded for the second and third quarters of 2018 as shown on the graph below could instead be considered as the volume part of the beginning of the 2019 flu season.

Figure 12: Monthly flu vaccine orders and deliveries in South Australia (2018 to 2020)



Source: South Australia order and delivery data

Overall, the total number of units ordered and delivered in South Australia in 2020 was less than in 2019. South Australia brought orders forward by three weeks which resulted in an earlier delivery peak in 2020 in comparison to 2019 as shown in in Figure 12. That decision led to what the state described as the best NIP flu vaccine rollout in 9 years.

Peaks in deliveries were observed spanning across both April and May in 2019, whilst in 2020, the majority of the vaccines were only delivered in April. May, June and July 2020 saw significantly less delivery volumes than the previous year, following a similar trend to the delivery curves observed for Queensland, albeit at much lower volumes. This early peak of deliveries in April could be contributed to the higher volumes of orders placed across South Australia in the previous month. It could also be indicative of a more proactive approach driven by the State towards vaccine uptake in 2020.



Top providers

Across South Australia there appeared to have been a widespread increase in quantities of vaccines ordered by, and delivered to, service providers during 2020 in comparison to the previous two years of data (Table 10). Six of the top ten service providers ordering flu vaccines experienced increases in their supply quantities of vaccines. The largest total purchase volume was ordered by Victor Medical Clinic, whose order of 2,980 units was almost triple their 2019 volume (1,070 units), and was more than double the volume of the second largest purchaser, Trinity Medical Centre (1,835 units).

Table 10: Top 10 South Australia service providers by flu vaccine supply quantity (2018 to 2020)

Provider	2020 supply quantity	2019 supply quantity	2018 supply quantity
Victor Medical Clinic	2,980	1,070	
Trinity Medical Centre	1,835	1,555	30
Mawson Lakes Medical Centre	1,350	900	100
Clinical Worker Health Service	1,200		
Playford Family Medical	1,200	1,130	143
Bridge Clinic	1,200	1,170	
Lyell McEwin Hospital	1,090	650	
Martins Rd Family Medical Practice	1,075	1,355	50
Flinders Medical Centre	1,050	1,960	480
Hampstead Health Family	1,020	1,555	40

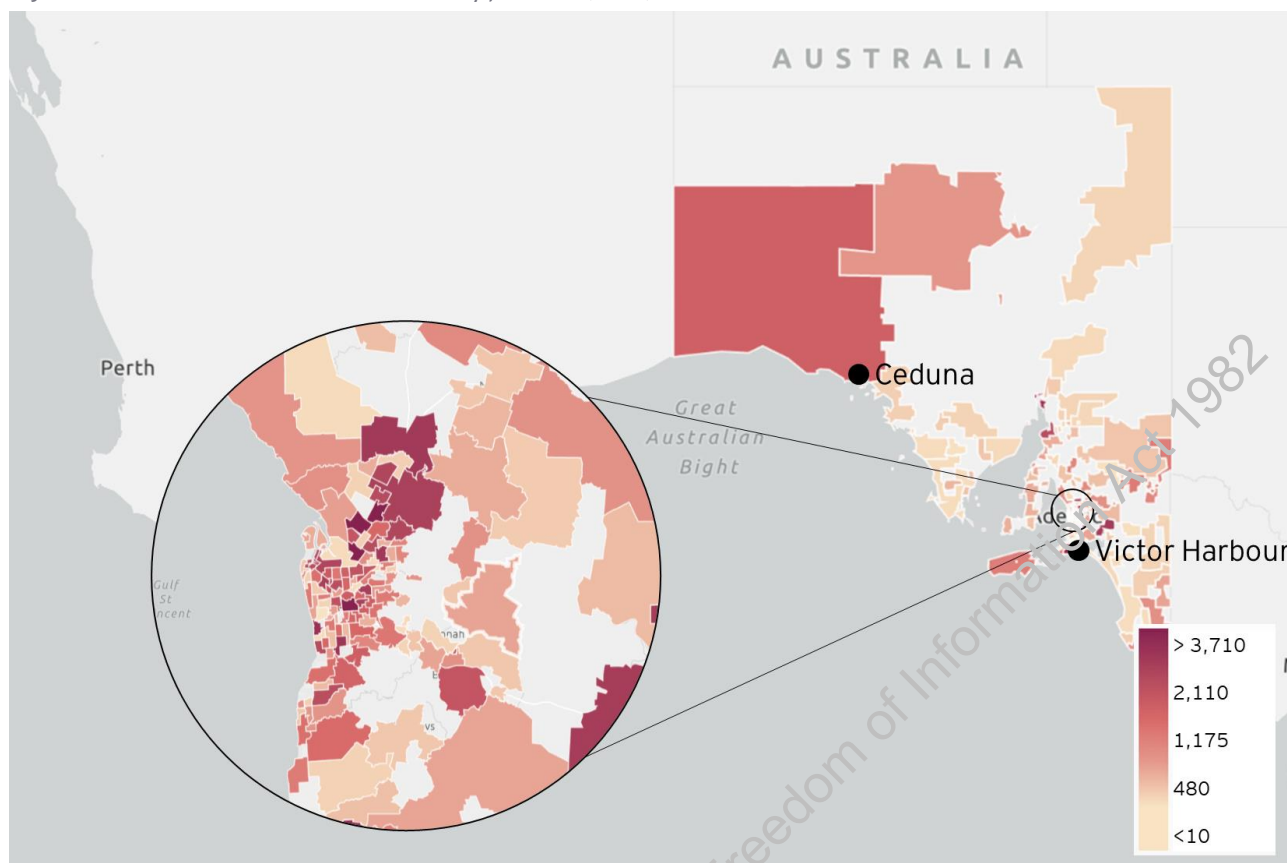
Source: South Australia order and delivery data

Eight of the top ten service providers in South Australia's 2020 data were general practice medical centres and clinics, while one was an Department for Health and Wellbeing South Australia (SA Health) public hospital, Lyell McEwin Hospital. The remaining service provider, ranked as having the fourth largest supply quantity in the State, was the Clinical Worker Health Service, a healthcare worker vaccination program in South Australia, similar to those observed in the Queensland data. It is evident that in this SA Health program, seasonal flu vaccination is also not mandatory but recommended. Further, in similarity to the Queensland volumes, there appears to be no records for purchasing volumes of these vaccinations for the Clinical Worker Health Service vaccination program in the previous two years of data collection, which could either represent a genuine uptake in healthcare worker vaccinations, or gaps and inconsistencies in the data.

Location of orders

South Australia's capital city of Adelaide accounted for the largest allocation of orders in 2020 of 5,597 or 3.4%. This is consistent with 2019 order distribution across the State, as the Adelaide region also accounted for 3.5% of orders placed. Orders placed in the northern and western regions of the state were relatively small, with the majority of orders located on the south eastern coast closer to the State's metropolitan centre. The exception to this observation is the regional area of Ceduna, comprising a large medium-red area on the State's western border. Relatively high order volumes in this area are driven by a 59% increase from Tullawon Health Service.

Figure 13: South Australia flu vaccine orders by postcode (2020)



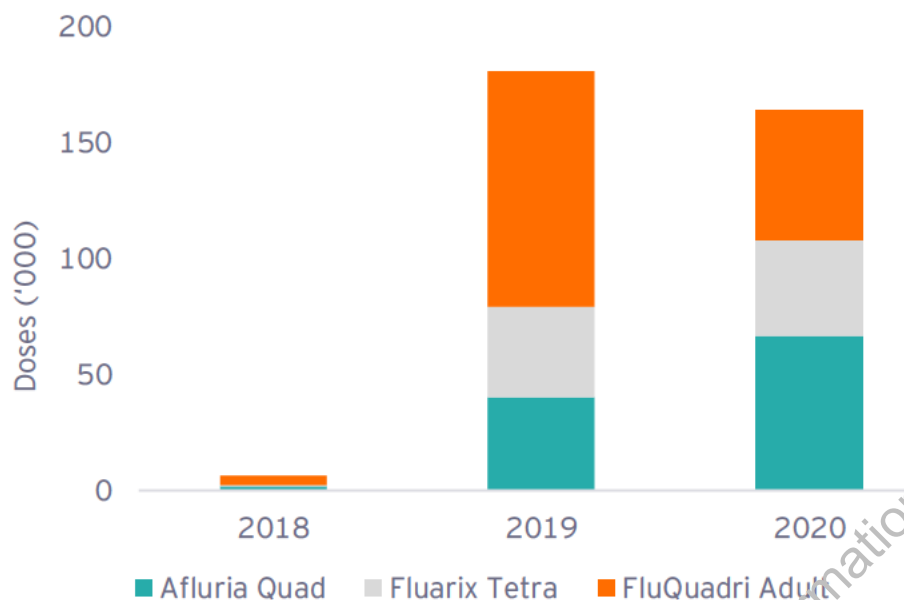
Source: SA order and delivery data

The region with the second-largest volume of orders was Victor Harbour, with 3,325 units comprising 2% of the yearly total. The number of flu vaccine units ordered in Victor Harbour increased significantly between 2019 and 2020, from 1,370 to 3,235 (136% increase). Upon further analysis, it was revealed that the majority of this volume was driven by Victor Medical. As described in the previous section and illustrated in Table 10, Victor Medical's 2020 order was almost triple their volume in 2019. Victor Medical's large order comprised 92% of the total units ordered in Victor Harbour, and made up for over 100% of the 1,865 unit increase in the region, as the only other service provider in Victor Harbour decreased their order volume between 2019 and 2020.

Products ordered

Only three types of seasonal flu vaccines were ordered in South Australia across the three years examined; these being the Afluria Quad, Fluarix Tetra and FluQuadri Adult. 2019 order volumes saw the FluQuadri Adult as the dominant virus ordered (55%), the split between the three in 2020 was more even. During this year, the FluQuadri Adult accounted for only 34%, while the Afluria Quad and Fluarix Tetra comprised 41% and 25% respectively. All three vaccines are quadrivalent and are licensed for those of 65 years old and above, however, according to Australian health authorities they are not a preferred vaccine of choice for this age group. Order volumes of Fluarix Tetra remained relatively stable between the two years, however some of the FluQuadri Adult volume was replaced by the Afluria Quad between 2019 and 2020.

Figure 14: Annual flu vaccine orders in South Australia by product name (2018 to 2020)



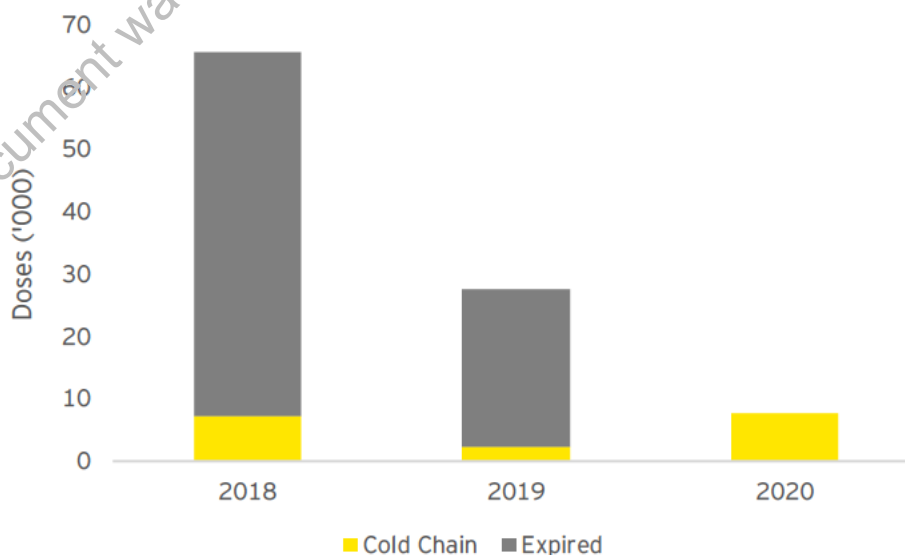
Source: SA Order and Delivery Data

2018 data that was recorded in the volume received from the State has been included in the graph for completeness purposes, however as discussed previously, this data lacks records from January to June, and therefore does not cover the peak flu season in Australia and cannot be used as a valid comparator in this analysis. As described above, the 2018 data could instead be considered part of the 2019 flu season, as the season in Australia typically starts in the final months of the previous year.

Wastage

Across 2018 to 2020, the largest provider type driving flu vaccine wastage are GP practices, consistently attributing to around 90% of wastage. However, they are also the largest vaccination provider. Generally, the wastage experienced for the over and under 65 vaccines are even across all years and the wastage caused by expired stock attributes to around 90% of total wastage whereas cold chain incidents only around 10%. In comparison to 2018 and 2019, 2020 wastage to date is low as the 2020 season is only partly complete. Of note is that wastage from cold chain incidents reached a high in 2020, just exceeding 2018 with 7,739 vaccines wasted.

Figure 15: Annual flu vaccine wastage in South Australia (2018 to 2020)



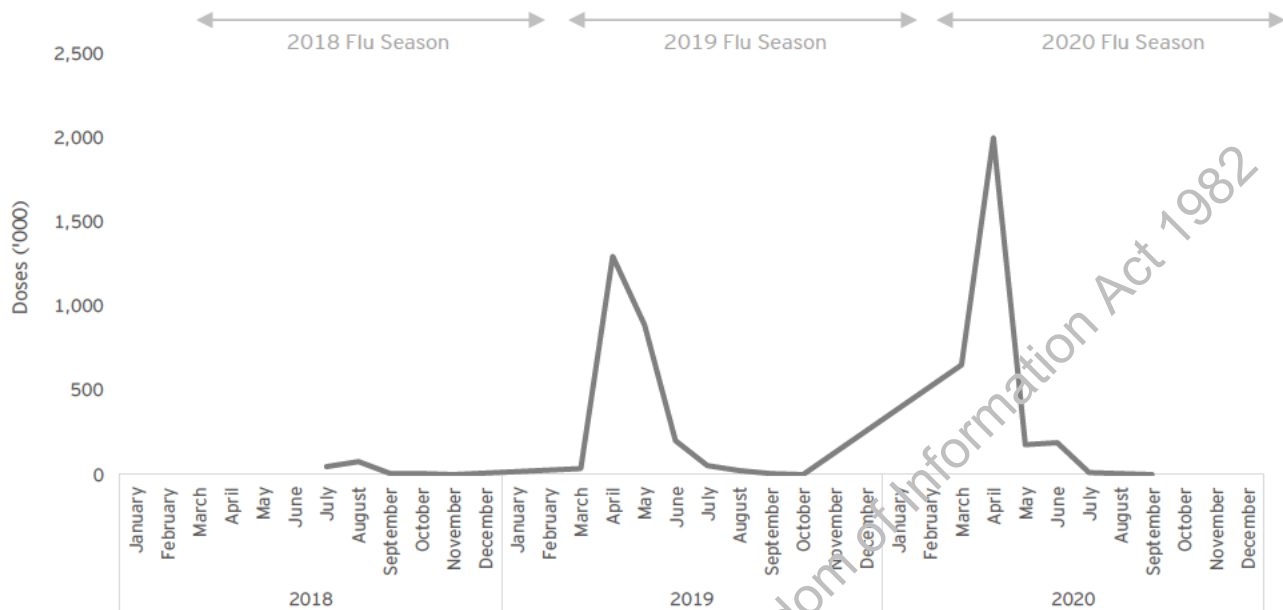
Source: SA Wastage Data

Note: 2020 expired data is not shown as these vaccine expirations have not occurred yet

New South Wales

Deliveries over time

Figure 16: Monthly flu vaccine deliveries in New South Wales (2018 to 2020)



Source: New South Wales order and delivery data

New South Wales does not currently record orders, with only deliveries data recorded in their supply chain system. As such, only the volumes and timing of vaccine deliveries have been considered. In addition, delivery data provided for 2018 only covers the months of July to November, and the minimal number of units delivered over this period refutes the appropriateness of this data to represent a valid comparison to 2019 and 2020, for which data covers the most part of the calendar year. The tail-end data from the end of 2018 could instead be considered as the beginning of the 2019 flu season, as the Australian season typically starts in the last few months of the previous year. The months of June onwards follow an almost identical trend to the volumes that were seen in 2019 and 2018.

The 2020 delivery volumes show an extremely high peak in volumes of 2,001,020, representing a 54% increase from the volumes observed in the same month of the previous year. In addition, deliveries appeared to have been rolled out earlier in 2020 than in 2018, as volumes also reached a high total of 652,975 in March, when in 2019 there was only 35,971 units delivered in this month, representing less than 6% of the 2020 volume. The volumes observed in March and April 2020 may be indicative of a proactive and fast-moving approach to distribution in the State, however given the extreme differences between 2019 and 2020 volumes, it could also be indicative of an over-ordering issue that could potentially lead to higher cost and wastage for the State.

However, a drastic drop in volumes can be observed for the month of May 2020, as the number of units delivered (180,118) are less than one tenth of what they were in the previous month, and only one fifth of the volumes recorded in May of the previous year. As such, there was an 80% decrease in the number of units delivered in this month compared to May 2019. There are several potential explanations for this drop in May 2020; one being that the high volumes ordered in the previous two months created a shortage in available units for distribution in the state. Alternatively, it could indicate that demand in the State had already been met early and the volumes observed in May of the previous year were not required in 2020.

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Top providers

Six of the top ten service providers by flu vaccine supply quantity are large public hospitals in the State of New South Wales, as show in the table below (Table 11). This is somewhat dissimilar to what is observed in other jurisdictions analysed, whose list of top providers typically comprised of general practice medical centres. In comparison, only four providers on the top ten list for New South Wales are medical centres. Regarding the hospitals, the six on this list represent metropolitan and large city centre areas, including Sydney, Parramatta, Wollongong and Newcastle. Five of the six hospitals experienced a large increase in supply volumes, ranging from 20% (Westmead Hospital) to 190% (Sutherland Hospital). On the other hand, John Hunter Hospital experienced a 22% reduction in supply quantities in comparison to 2019.

Table 11: Top 10 New South Wales service providers by flu vaccine supply quantity (2018 to 2020)

Provider	2020 supply quantity	2019 supply quantity	2018 supply quantity
Westmead Hospital	10,050	8,390	
Family Medical Practice	9,610	10,097	195
Plumpton Marketplace Medical	9,200	4,665	330
Royal Prince Alfred Hospital	8,710	6,950	5
The Gardens Medical Group	8,500	9,800	100
Prince of Wales Hospital	8,000	6,085	
Wollongong Hospital	7,700	5,760	
Castle Hill Medical Centre	7,410	5,258	205
Sutherland Hospital	7,010	2,415	
John Hunter Hospital	6,850	8,750	

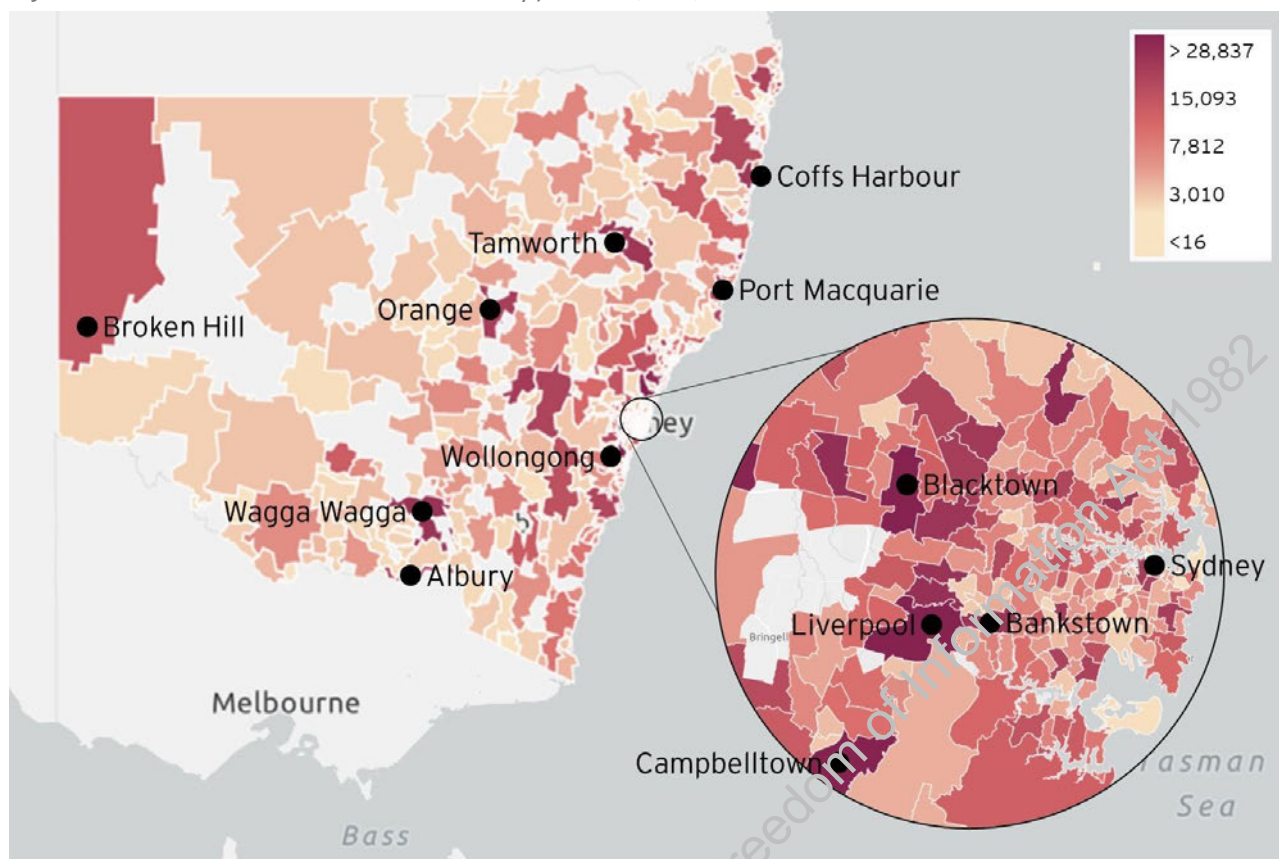
Source: New South Wales order and delivery data

It is unknown whether the quantities of vaccines ordered by these hospitals are for use on public patients or as part of a vaccination program for healthcare workers, as observed in other jurisdictions. However, the significant variance in volumes in comparison to the previous year must be scrutinised to ensure that it did not represent an over-ordering or over-allocation issue that may have led to wastage of vaccines.

Location of orders

2020 vaccine distribution in New South Wales, as illustrated in the below figure (Figure 17), appears to be concentrated within major metropolitan centre of Sydney, along the eastern coast of the State, and in certain regional and rural town centres. Most notably, Sydney's Western Suburbs including Blacktown, Campbelltown, Bankstown and Liverpool were found to have some of the highest volume of flu vaccine deliveries in the State, with these four suburbs accounting for 4% of the total volume alone. Volume in these regions is assumed to be driven by the increasing population in Greater Western Sydney, and the existence of large public hospitals in each of these regions. Sydney city itself was distributed 21,910 flu vaccines in 2020, and was the 15th highest region in terms of volume.

Figure 17: New South Wales flu vaccine deliveries by postcode (2020)



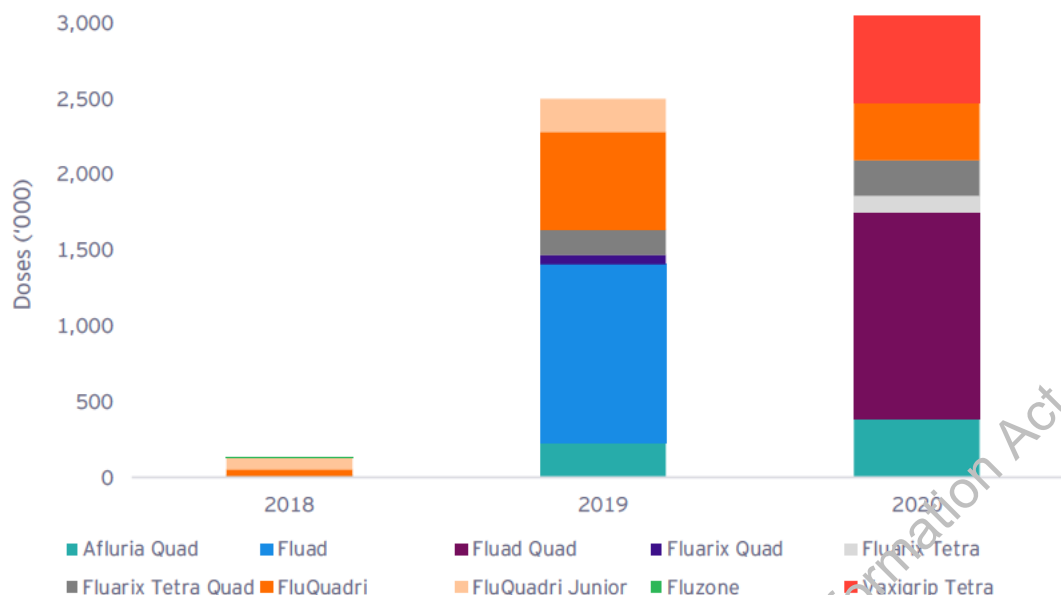
Source: New South Wales order and delivery data

The consistency of medium to dark red spread of volume across the State's heat map is indicative of New South Wales' dense and broadly distributed population. Large deliver volumes were observed in rural and remote areas located more than 400 kilometres away from the city centre. These regions are illustrated in dark red on the above map, and include Wagga Wagga (13th populated region within the New South Wales), Orange, Tamworth, Port Macquarie, Coffs Harbour, Wollongong and Albury. A large dark region in the far left corner of the state is also observed to have a high number of vaccine deliveries. The number of units delivered in this region, Broken Hill (59th populated region within the New South Wales), was 13,365 in 2020, representing a 20% increase from their 2019 volume of 11,123.

Products ordered

As illustrated in the graph below (Figure 18), New South Wales' flu vaccine portfolio of products in 2020 comprised several different vaccines. Similar to what was observe in Queensland orders, a significant portion of the units delivered in 2019 were provided by the Fluad vaccine; the usage of which appears to have been replaced by Seqirus' new Fluad Quad vaccine in 2020. The Fluad Quad accounts for almost half of the total vaccines delivered in the state, with its usage recommended for older populations of 65 years and above.

Figure 18: Annual flu vaccine deliveries in New South Wales by product name (2018 to 2020)



Source: New South Wales order and delivery data

Volumes of the various Fluarix vaccines (Quad, Tetra and Tetra Quad) remains relatively stable between 2019 and 2020, while FluQuadri volumes are significantly reduced from 654,995 in 2019 to only 376,020 in 2020, and delivery volumes of the FluQuadri Junior Paediatric Vaccine that were seen in the previous year have been removed entirely from the state in 2020. It is understood that the reduced volume of these two products have been replaced by the Vaxigrip Tetra, a quadrivalent vaccine newly developed in 2020 for the use of adults and infants from 6 months of age. The market share distribution between New South Wales' flu vaccine portfolio is indicates that coverage has been provided for all age groups , with the majority of vaccinations provided to adults of 65 years of age and above.

Tasmania

Orders and deliveries over time

The curves of order and delivery volumes over time in Tasmania between 2018 and 2019 appear to be fairly similar, as illustrated on the graph below (Figure 19). However, the volumes ordered and delivered during 2020 stand out as remarkably different from the pattern of orders and deliveries typically seen in the previous years. For instance, the peak in delivery volume during the month of April, at 157,017 units, is nearly twice that of the volume of that recorded during the same peak month in 2019, at 86,275. The month of May 2020 saw a sharp decrease, with only 450 total units delivered in this Month, whereas previous years had still seen significant volumes over this time, of 59,360 and 67,259 in 2019 and 2018 respectively. Delivery volumes in June 2020 in Tasmania saw another small peak of 23,781, while the month of June typically had minimal delivery volumes in previous years.

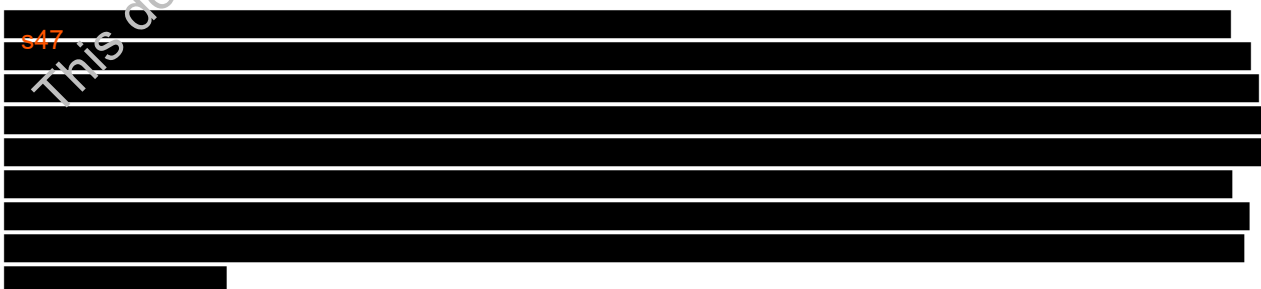
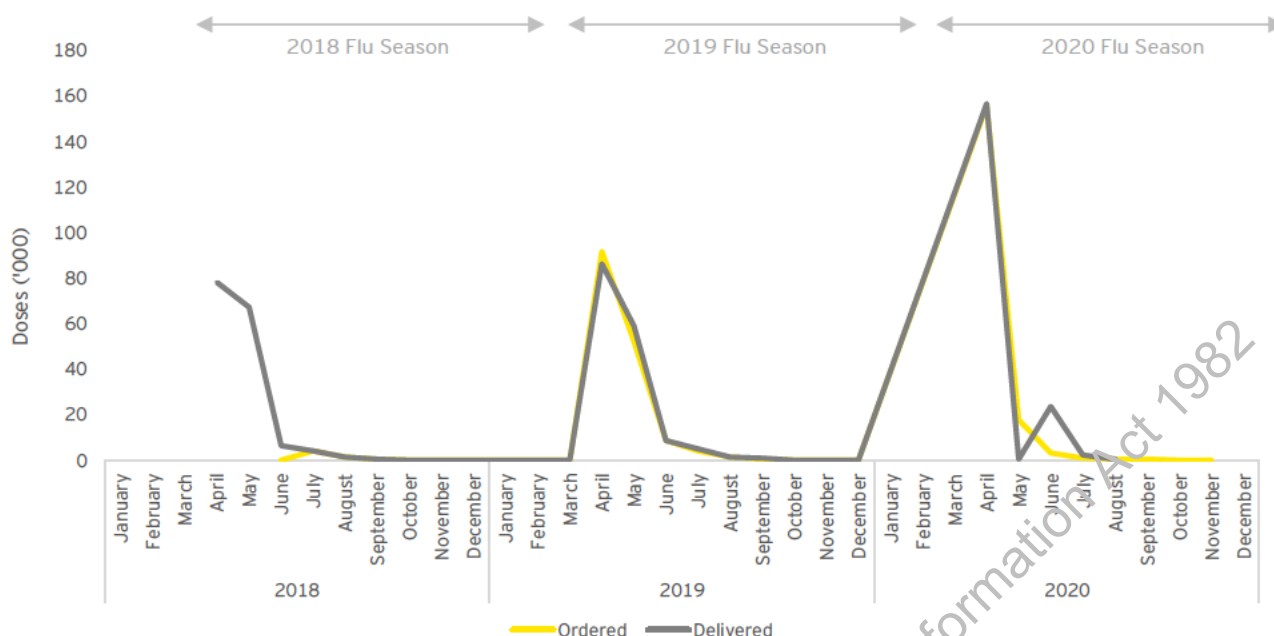


Figure 19: Monthly flu vaccine orders and deliveries in Tasmania (2018 to 2020)



Source: TAS order and delivery data

Top providers

All of Tasmania's top ten service providers by flu vaccine supply quantity in 2020 are general practice medical centres, as shown in the table below (Table 12). Six of the top ten experienced growth in volumes in 2020 when compared to the 2019 records. In particular, Launceston Medical Centre, the second highest ranked provider in terms of 2020 volume, increased their volume from only 350 units in 2019 to 4,305 in 2020. Similarly, SmartClinics Devonport also recorded an increase from 90 units to 2,810 units in 2020. Of the four clinics whose order volumes decreased between 2019 and 2020, three experienced small decreases between three and six per cents, while Kingsborough Medical Centre's order volumes were reduced by 33%.

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Table 12: Top 10 Tasmania service providers by flu vaccine supply quantity (2018 to 2020)

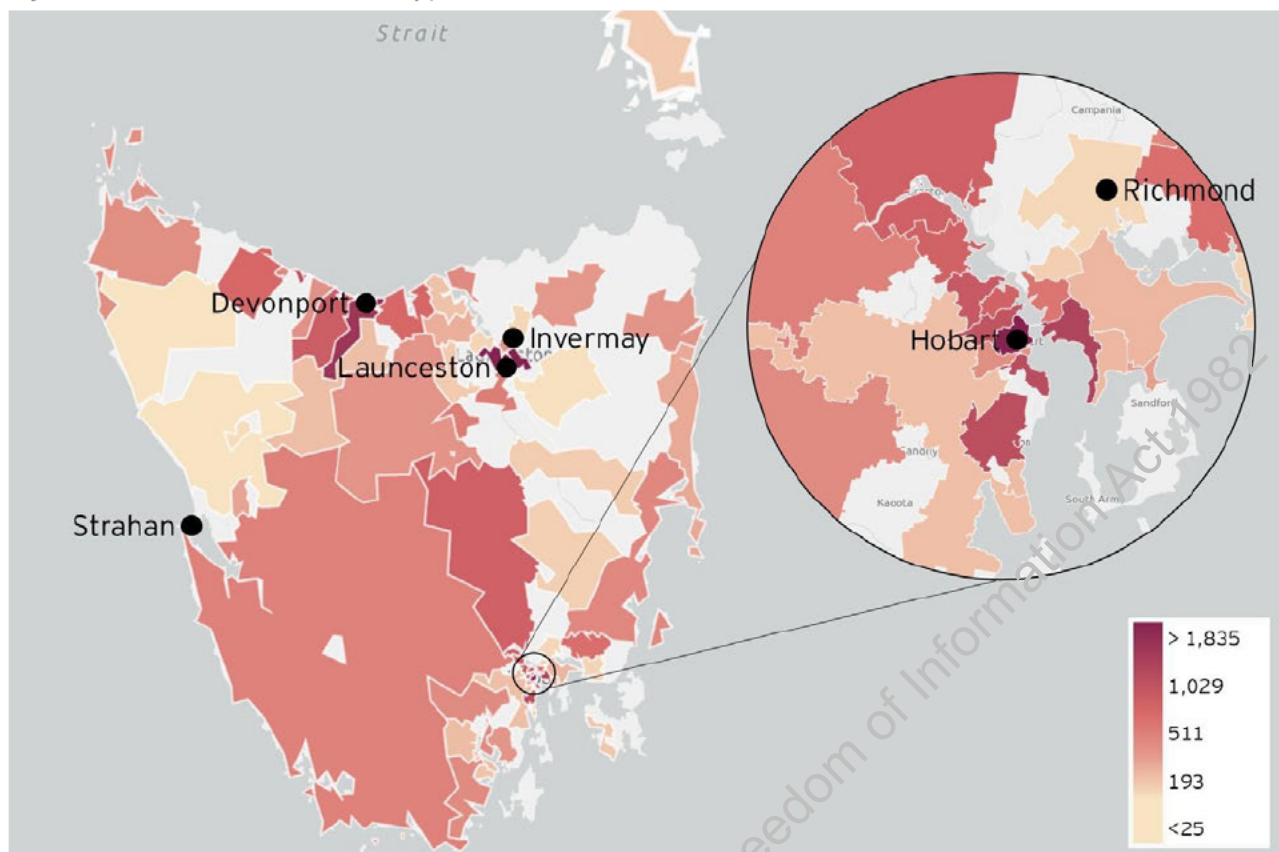
Provider	2020 supply quantity	2019 supply quantity	2018 supply quantity
Glenorchy Medical Centre	5,140	4,360	40
Launceston Medical Centre	4,305	350	70
Newstead Medical Centre	4,040	3,760	120
West Tamar Health	3,745	3,760	85
Kingsborough Medical Centre	3,320	4,930	255
Victoria St Clinic	3,115	3,320	60
Summerdale Medical Centre	3,075	3,185	270
Northern Midlands Medical Services	3,020	2,300	
East Devonport Med Practice	2,950	2,380	30
SmartClinics Devonport - CBD	2,810	90	

Source: TAS order and delivery data

Location of orders

The majority of the orders for flu vaccines placed in Tasmania were concentrated in the three highest populated cities, Hobart, Launceston and Devonport. Together, the 2020 vaccine volumes in these cities accounted for nearly 20% of the State's total number of units ordered. Additional regions with high volumes of orders appear to surround the North-West and South-East coastal areas of the state, where higher population densities can be found.

Figure 20: Tasmania flu vaccine orders by postcode (2020)

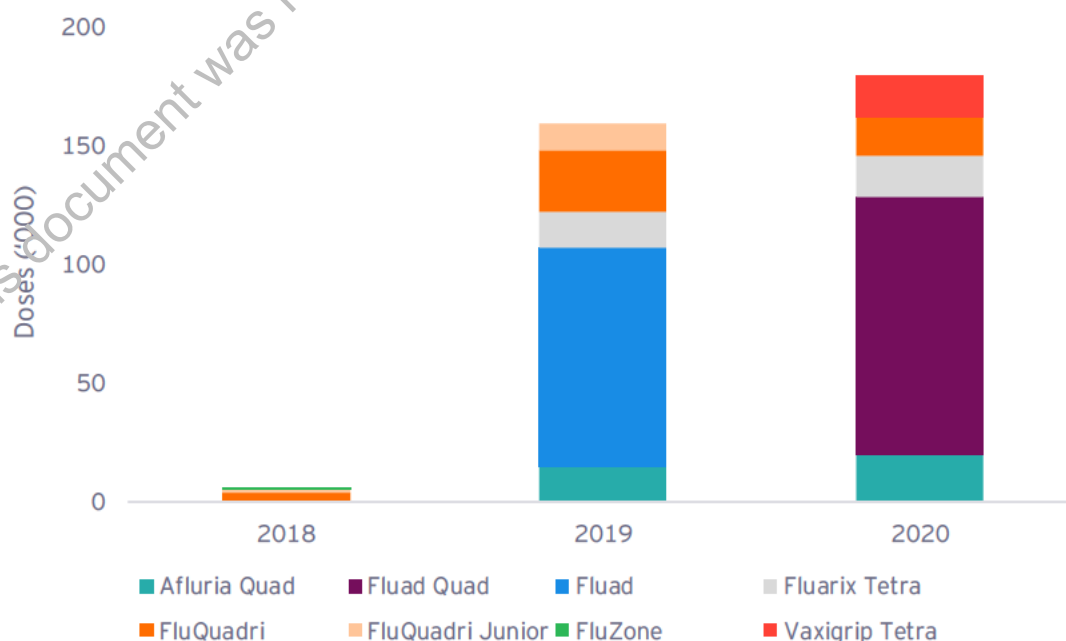


Source: TAS order and delivery data

Questionably, no volumes of orders were recorded for the regions of Richmond, Invermay or Strahan, when in previous year they had been delivered 763, 500 and 265 units respectively. This could potentially indicate that the populations in these areas were being directed elsewhere to receive their seasonal flu vaccines in 2020. Alternatively, it could also mean that there are gaps in the data set or the records are incorrectly attributed to different postcodes or localities.

Products ordered

Figure 21: Annual flu vaccine orders in Tasmania by product name (2018 to 2020)



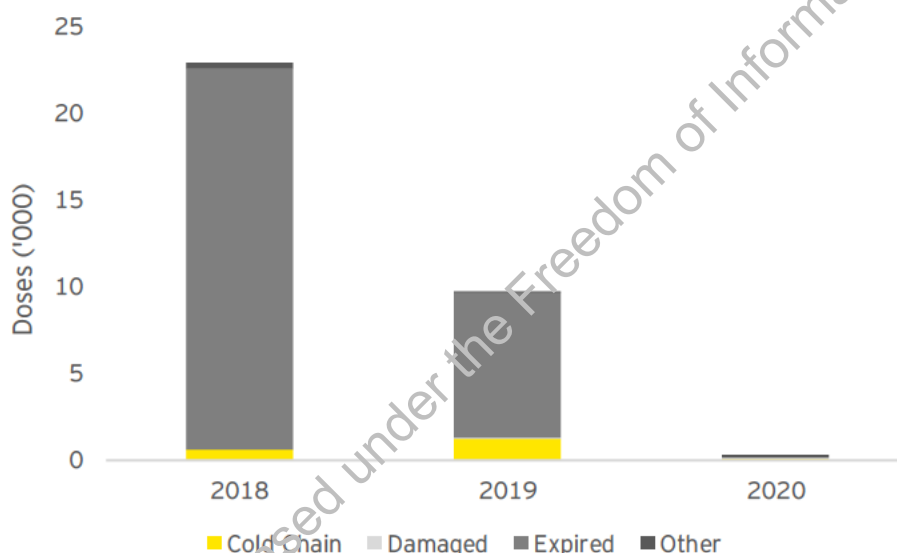
Source: TAS order and delivery data

As observed in several other jurisdictions, the large portion of the total flu vaccine volumes ordered in Tasmania that was previously fulfilled by the Fluad trivalent vaccine has been replaced in 2020 by Seqirus' new Fluad Quadrivalent vaccine (as illustrated in Figure 21). The Fluad Quad comprises roughly 60% of the total volume of orders in the State. The remainder of the vaccine volume ordered was evenly split between The Afluria Quad, Fluorix Tetra, FluQuadri, and the newly introduced Vaxigrip Tetra. However, in comparison to Queensland and New South Wales, Vaxigrip Tetra was only ordered in small amounts.

Wastage

The volumes of discarded vaccines in Tasmania has decreased since 2018, although 2020 cannot be accurately compared as the full year's expiry data is not yet available. Expired vaccines consistently make up around 90% of total vaccine wastage. Both cold chain and damages increased from 2018 to 2019, however due to the 62% decrease in wastages caused by vaccine expiration 2019 had a much lower overall wastage compared to 2018. Whilst the data for 2020 only includes months up to September 2020, at this stage the cold chain wastages are much lower than past years. The total number of wastages could still change drastically for 2020 as expiration is the key driver of vaccine wastage. As the season's vaccines expire in the latter months this is not shown in the graph below.

Figure 22: Annual flu vaccine wastage in Tasmania (2018 to 2020)



Source: Tasmania Wastage Data

Note: 2020 expired data is not shown as these vaccine expirations have not occurred yet

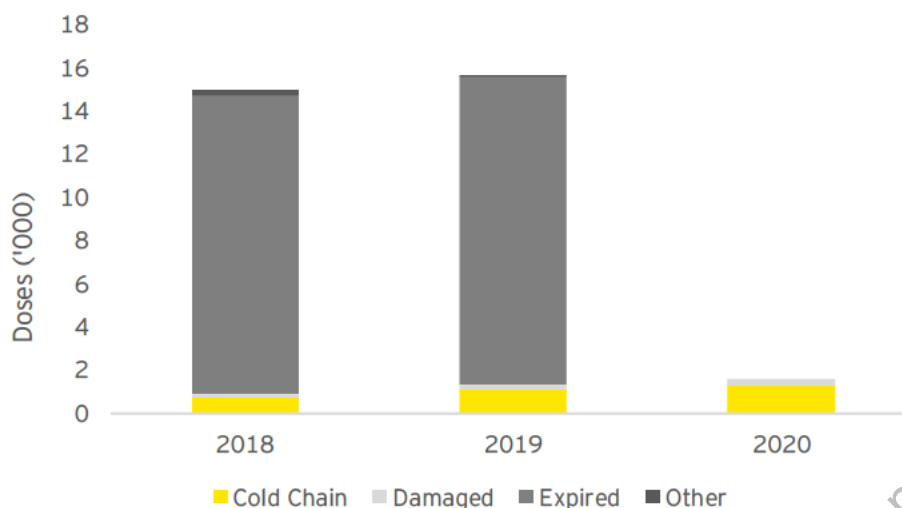
Note: Seasons are defined as April to March

Australian Capital Territory

Wastage

Wastage has increased slightly between 2018 and 2019. Comparing 2018 and 2019, as data for 2020 is not yet complete with vaccine expirations still being recorded, expiration was the primary reason for wastage, consistently attributing to just over 90% of total wastage. Cold chain breaches were the second largest, although significantly smaller overall, contributing around 5% to total wastage. The numbers of cold chain breaches have been steadily climbing from 744 to 1,125 to 1,293 for 2018, 2019 and 2020 respectively. Damaged vaccines contributed very little, around 1%, to vaccine wastage, although the total numbers have again climbed from 2018 to 2020.

Figure 23: Annual influenza vaccine wastage in Australian Capital Territory (2018 to 2020)



Source: Australian Capital Territory Wastage Data

Note: 2020 expired data is not shown as these vaccine expirations have not occurred yet

Note: Orders and deliveries data was not available for the territory.

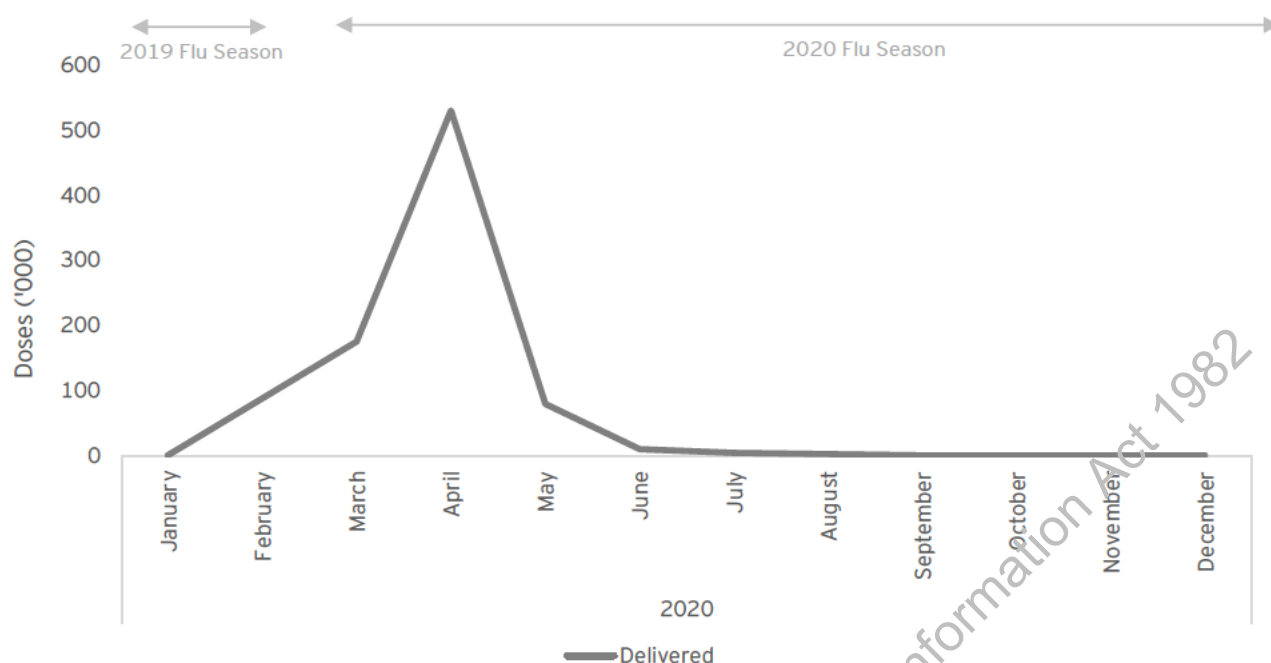
Western Australia

Deliveries over time

With regards to the data collected for Western Australia, only flu vaccine deliveries for the 2020 calendar year was provided, therefore in the figure and observations described below only the volumes and timing of vaccine deliveries have been considered.

The total number of vaccine doses delivered throughout the 2020 calendar year amounted to ~807,000, reaching its peak in April where deliveries totaled 530,920. The preceding month, March, had the second largest number of deliveries at 176,170, which was over three times less than April. Following April a drastic drop in volumes was observed for the month of May 2020, as the number of doses delivered (80,188) was over six times less than what they were in the previous month. As such, there was an 85% decrease in the number of units delivered in April 2020 compared to May 2020. The deliveries throughout the remainder of the year decreased exponentially to only 155 doses in December 2020.

Figure 24: Monthly flu vaccine orders and deliveries in Western Australia (2020)



Source: Western Australia delivery data

Note: There was no data reported for February and hence the graph has been adjusted for its continuation

Top providers by provider type

Vaccines supplied by provider type is shown in the table below (Table 13). GPs ranked the highest out of 2020 service providers, having been delivered over 674,000 flu vaccine doses from January to December 2020 and attributing to 84% of the total supply. The second largest provider were community health clinics and shire councils, although they made up a much smaller 6% of the total provision. Pharmacies closely followed at 5% of total supply, then Aboriginal (3%), hospitals (2%) and aged care providers (1%).

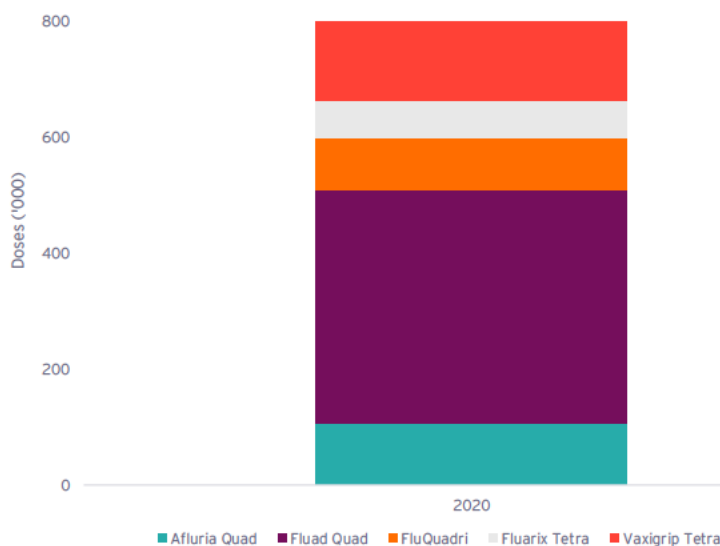
Table 13: Top 10 Western Australia service providers by flu vaccine supply quantity (2020)

Provider	2020 supply quantity
GPs	674,295
Community Health / Shire	49,958
Pharmacy Distributors	41,000
Aboriginal	22,885
Hospitals	13,807
Aged Care	5,080

Source: Western Australia delivery data

Products ordered

Figure 25: Annual flu vaccine orders in Western Australia by product name (2020)



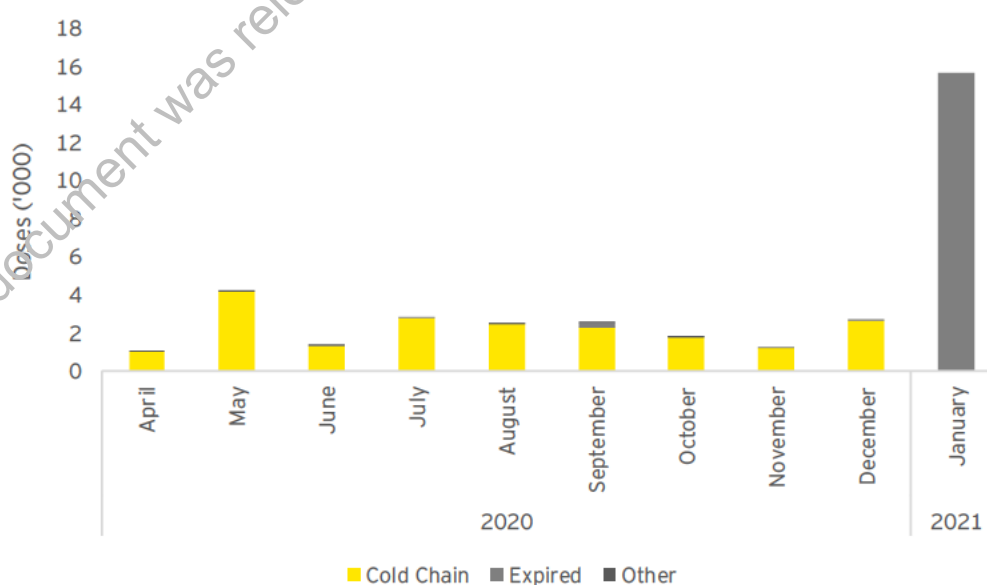
Source: Western Australia delivery data

As observed in several other jurisdictions, a large portion of the total flu vaccine volumes ordered in 2020 was the Flud Quadrivalent vaccine (as illustrated in Figure 25). The Flud Quad comprises 50% of the total volume of orders in the State for the year, which indicates that the 65+ cohort was the main group that accessed NIP vaccines. The remainder of the vaccine volume ordered was distributed fairly evenly between the Vaxigrip Tetra (18%), Afluria Quad (13%), FluQuadri (11%) and Fluarix Tetra (8%) vaccines.

Wastage

Western Australia only reported wastage data for the 2020 season, whilst noting that February and March 2021 are yet to be reported. It is observed that within the periods displayed in the graph below for the 2020 season, 36,180 vaccines were reported as wasted. While the wastage was fairly consistent across the months, it was slightly higher in May due to a larger number of cold chain breaches and in January due to stock reaching expiry.

Figure 26: Annual flu vaccine wastage in Western Australia (2020)



Source: Western Australia Wastage Data

Note: 2020 expired data is not shown as these vaccine expirations have not occurred yet

Victoria

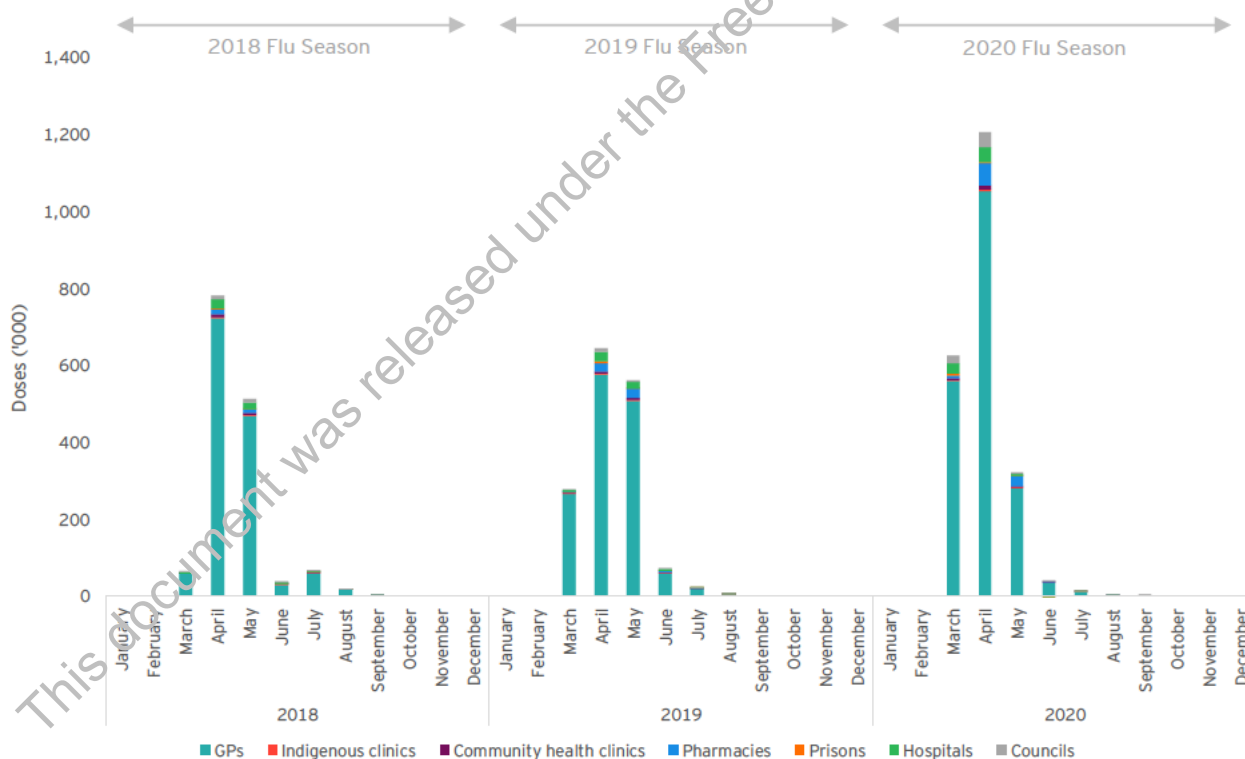
Deliveries over time

With regards to the data collected for Victoria, only flu vaccine deliveries by type of provider was provided, therefore in the figure and observations described below only the volumes and timing of vaccine deliveries have been considered. In addition, some months within the delivery data provided for 2018 to 2020 were omitted, so it was assumed that these were equal to zero.

Firstly from the graph, it can be seen that GPs deliver the largest proportion of flu vaccines across Victoria, followed by hospitals and pharmacies. While total delivery numbers have increased from 2018 to 2020, the proportion of deliveries by provider type has remained relatively consistent with the exception of pharmacies which have seen their contribution grow significantly. This is because of the increasingly significant role pharmacies are playing in the rollout of the flu vaccine.

The 2020 delivery volumes depicted in Figure 27 observed a distinct peak in April totalling 1,208,189, an 87% increase from the volumes seen in the same month of the previous year. Deliveries also appeared to have been rolled out earlier in 2020 than in previous years, displaying 880% and 126% higher delivery volumes in March 2020 compared to March 2018 and 2019 respectively. Unlike previous years, in particular 2019, May 2020 did not experience similar delivery levels but instead saw a dramatic decrease of 73% compared to the previous month. In addition, the volumes in May 2020 (322,551) were below that of both 2018 (513,645) and 2019 (562,642). Potential explanations for this significant drop observed in 2020 include social distancing restrictions that made accessing the vaccine more difficult, more people becoming vaccinated earlier in the year leaving demand in May to fall, or logistical issues with the provision of stock to immunisation providers.

Figure 27: Monthly flu vaccine deliveries in Victoria by provider (2018 to 2020)



Source: Victoria delivery data

Northern Territory

Supply chain data was not available for analysis for the Northern Territory as the territory uses a hospital inventory management system to manage its vaccine stock. The system uses generic vaccine codes and cannot break vaccines down into unique vaccine codes. It also cannot track vaccine deliveries.

Appendix D Social media analysis

A social media analysis was conducted with the aim of understanding the extent to which the flu vaccine was discussed on public platforms. The analysis sought to unpack the timing around key peaks of social media posts relating to the vaccine, and key influencers mentioning and sharing posts about the flu vaccine.

Filters

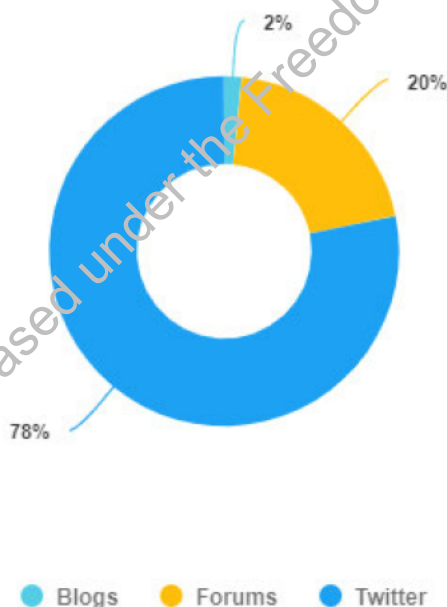
Keywords

A multi-word filter was been used in order to ensure that all references shown relate to the flu vaccination and immunisation season, rather than the COVID-19 vaccine. That is, the terms "seasonal flu" or "influenza" must have been also mentioned alongside any references to "vaccination", "vaccine" or "immunisation".

Sources

Three key sources of online content, Blogs, Forums (including Reddit) and Twitter, were analysed. These were chosen as it was deemed these sources were most relevant given the topics being explored. As a result of the analysis, the large majority of results tended to be from Twitter. Figure 28 highlights the content source breakdown for the 2020 period in Australia.

Figure 28: 2020 Australia content source breakdown



Influencers

The ten top influencers were all from Twitter, as, with posts on the flu conversation reaching up to almost 400,000 people. Reach is an estimation on how many users they would likely see a post on average, on the basis of the likes, retweets and shares that content tends to receive on Twitter per amount of followers. The top ten influencers is dominated by accounts run by members of the public. Only one new account, @abcnews, is included in the top ten, and no official government accounts are featured. There is an opportunity for the Department to create a more influential presence on Twitter.

Table 14: Top ten influencers who mentioned keywords in their posts

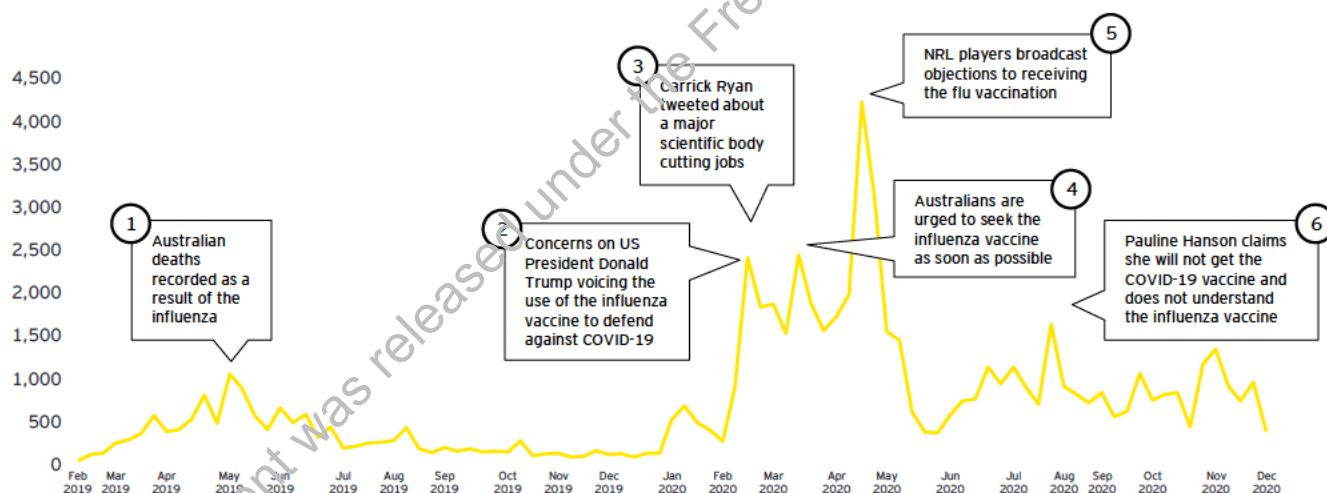
Author	Source	Reach
realCarrickRyan	twitter.com	383,035

Author	Source	Reach
ALBrusey	twitter.com	346,137
keir_scarlett	twitter.com	238,293
PatsKarvelas	twitter.com	193,619
abcnews	twitter.com	152,281
JMacGreens	twitter.com	149,576
askegg	twitter.com	140,831
SaveEarthFromUs	twitter.com	140,433
elisabeth_pal	twitter.com	133,873
Charrisa11	twitter.com	133,789

Volume

When looking at the 2020 volume of mentions on social media platforms related to the flu vaccine, public discussions began spiking in February, much earlier than previous years. This appears to have been driven by discussion around the effectiveness of the flu vaccine in protecting the public against the COVID-19 vaccine. In 2019, volumes were nowhere near 2020 volumes, even with a high number of flu deaths being a focal topic of discussion. Discussions in 2019 also did not start picking up until later in the season, towards the end of March / start of April, and trended down after the singular peak. The lower volume in 2019 when compared to 2020 can likely be attributed to an increased focus on the flu vaccine as a result of the COVID-19 pandemic.

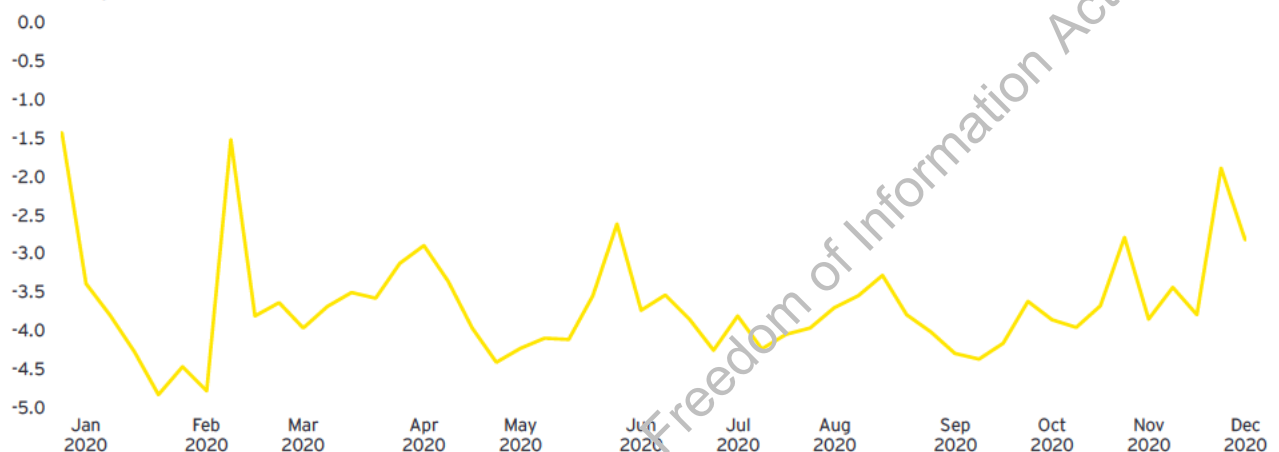
Figure 29: Volume of mentions



1. The main peak of conversation in early May 2019 was driven by flu deaths recorded in Australia. This was shared mainly by news sites which have a large reach across Australia hence having the ability to create a highly discussed point of conversation
2. Early in 2020 in the onset of the pandemic, the conversation spotlighted The American President's claims that the flu vaccine would be beneficial during the COVID-19 pandemic. As conversations peaked at this time it can be inferred that politicians have a strong effect on the discussion
3. Also occurring early in 2020 was a tweet posted by Australian public figure Carrick Ryan, who is a former Federal Agent with the Australian Federal Police come political commentator and blogger. His celebrity standing was the cause behind having a significant effect on social media discourse
4. In March 2020, messaging of 'Australians are urged to seek the influenza vaccine as soon as possible' circulated social media urging Australians to receive the flu vaccine as soon as possible

5. The highest peak of 2020 coincided with NRL players objecting to receiving the flu vaccination. The large volume of discussion generated at this time demonstrates the ability of public figures to have a large impact on influencing the conversation
6. Towards the middle of 2020 a smaller peak in volumes of social media activity was observed. A prominent post by Australian politician Pauline Hanson expressing negative views on the COVID-19 and flu vaccinations was a likely drive behind this peak. Again, it can be inferred that well know figures are able to strongly influence discussions
7. Conversations on social media platforms were predominately negative in 2020, as seen in Figure 30, including topics such as refusals to receive the flu vaccine and US strategies. Whilst public attitudes were not necessarily targeted at the distribution or supply of the flu vaccine, the net sentiment has been negative for the entirety of the year

Figure 30: Net public sentiment



One of the most popular social media platforms for discussions surrounding the flu season was Twitter, followed by News sites and Forums. Twitter generally held a majority of the public conversation, with News sites also contributing to a major proportion of the volumes. This was consistent for both 2019 and 2020.

Figure 31: Content sources

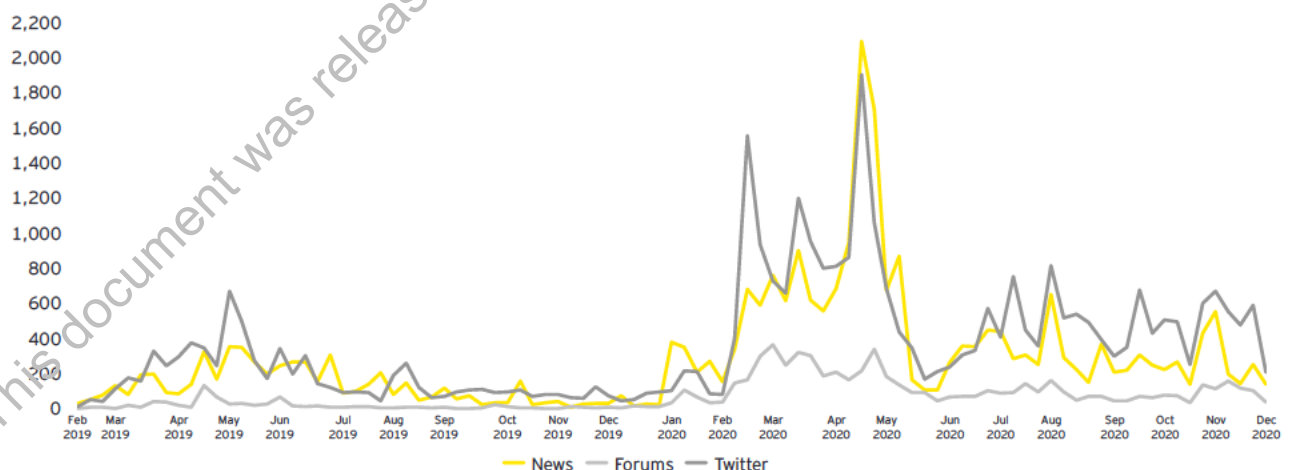
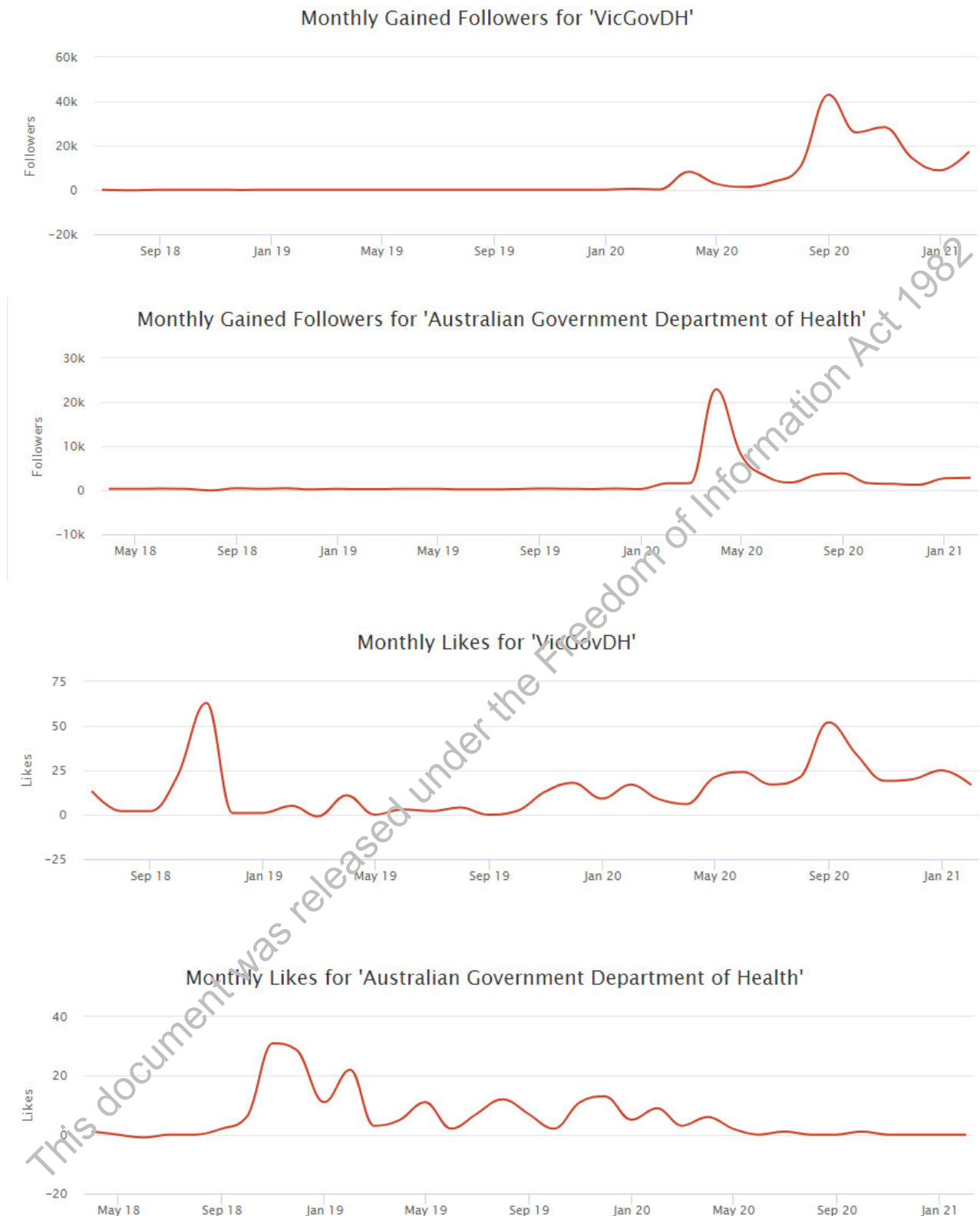


Figure 32: Case Study - Comparison between Victorian and Federal department of health Twitter Followers and Engagement



Source: Social Blade LLC.⁷⁸

⁷⁸ Social Blade LLC. Twitter analytical history for VicGovDH. <<https://socialblade.com/twitter/user/vicgovdh>> [Accessed 2 February 2021]

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