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The tension between national consistency and jurisdictional professional expansion: The case of pharmacist-administered vaccinations

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ABSTRACT

Background: The COVID-19 pandemic has highlighted the importance of coordinating policies on vaccinations at the national level. In Australia, the regulation and management of pharmacist-administered vaccination programs are the responsibility of each of the eight jurisdictions (six states and two territories), and have been developed independently of each other, leading to substantial variation. Consequently, there are variations regarding which vaccines pharmacists can administer, the minimum age, and whether these vaccines are publicly funded.

Objective(s): To identify opportunities for a nationally consistent approach to pharmacist-administered vaccinations in Australia.

Methods: This policy analysis used the Multiple Streams Framework to identify barriers and enablers within the three “streams” of problem, policy, and politics, and how they affected the development of a national approach. Data were drawn from semi-structured interviews with 13 key policy actors and documents (pre-budget submissions and parliamentary inquiry reports). Themes were generated around actor interests, current and proposed pharmacist vaccination programs, and policymaking processes.

Results: From the pharmacy sector, there was little clarity around the need for a nationally consistent approach. This issue was linked to their ultimate goal of expanding pharmacist vaccination programs; it was seen as a means for states/territories with smaller programs to ‘catch up’ to other jurisdictions. There was also no unified policy approach from this sector; additionally, decision-makers within jurisdictional health departments faced different service delivery models, policy priorities, agendas, and policy actor relationships. Lastly, there was no federal body that had the capacity to coordinate a national approach. Possible enablers include refining the problem definition and re-framing it to a patient-centric model.

Conclusions: Coordination of vaccination policies is an ongoing policy issue with implications for pharmacist vaccination programs and other health policy areas in which a national approach is being considered. This analysis provides insight into how this may be developed in the future.

1. Introduction

Vaccination is regarded as one of the most effective measures on a population level for reducing, controlling, and preventing certain diseases; it is a critical element of public health strategy.¹ However, the successful delivery and uptake of vaccination services requires extensive logistical consideration and support; therefore, coordinated policy is necessary for their effective provision.^{2,3} Scaling up vaccine coverage (the necessity of which has been particularly relevant given the context of the COVID-19 pandemic) will require the public to access vaccination

services, and community pharmacies are an avenue to achieving this.^{4,5}

There has been much discussion globally about the role of pharmacists in vaccination services. In 1996, the American Pharmacists Association highlighted three ways in which pharmacists have a role: 1) as educators, advocating for vaccines and encouraging patients; 2) as facilitators, hosting other immunising practitioners in a pharmacy, such as nurse immunisers; and 3) as immunisers, directly administering vaccines to patients.⁶ Vaccination policies vary worldwide, including the degree to which pharmacists are involved, but the integration of pharmacists and pharmacies into national health and vaccination policies is

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becoming increasingly recognised.⁷ Globally, 36 countries have legislation and programs that support pharmacy-based vaccination services, and 26 of these countries allow pharmacists to administer vaccinations.⁸ These include Argentina, the United States (US), the United Kingdom (UK), Portugal, Canada, and Switzerland.⁹

In Australia, pharmacists have been facilitating vaccinations in community pharmacies by hosting nurse immunisers in their highly accessible retail setting.¹⁰ As other countries worldwide developed pharmacist-administered vaccination programs, key pharmacy representative bodies in Australia sought to have pharmacists trained to administer vaccines. The Pharmacy Guild of Australia (the peak body representing community pharmacy owners, hereafter, the Guild) released a position statement in 2011 on immunisation within community pharmacy, raising the possibility of vaccination administration by appropriately trained pharmacists. The Pharmaceutical Society of Australia (PSA), representing all pharmacists, released guidelines in early 2013 on the provision of immunisation services in community pharmacy using a nurse immuniser model.¹¹

Australia has eight states/territories (in this paper, ‘states/territories’ will be used interchangeably with ‘jurisdiction’). The first pilot program began in 2014 in one of the jurisdictions (Queensland), where pharmacists were able to administer influenza vaccines to individuals aged 18 and over.¹¹ In 2015, the first *Standards for the Accreditation of Programs to Support Pharmacist Administration of Vaccines* was published by the Australian Pharmacy Council, providing the framework for the development and delivery of pharmacist immunisation training.¹⁰ Within 2014 to 2016, all jurisdictions amended or introduced legislation that would enable pharmacists to administer vaccines, commencing with influenza vaccines, with most jurisdictions setting the minimum age of the recipient at 18 years.

Over the subsequent years, all jurisdictions have independently added other vaccines, such as the diphtheria-tetanus-pertussis (dTpa) and measles-mumps-rubella (MMR) vaccines, and lowered the minimum age to 10 years for influenza. However, currently in Australia, these pharmacist-administered vaccination programs are developed independently, resulting in jurisdictional differences in terms of which additional vaccines can be administered by trained pharmacists, the minimum age, and the availability of vaccines at community pharmacies that are funded under the federal or state/territory programs.¹² This lack of national consistency has been identified as a problem for patients, healthcare professionals, and health officials managing these programs, due to a potential inequity of consumer access, and the possible confusion caused.

There have been calls from peak pharmacy representative bodies to develop a nationally consistent approach for the delivery of vaccinations through community pharmacies.^{13,14} The Council of Australian Governments (COAG) was the nation’s primary intergovernmental forum, and in October 2018, its Health Council embarked on developing options for a nationally consistent approach.¹⁵ As of September 2021, there have been no clear, public developments aside from a clause in the 7th Community Pharmacy Agreement (June 2020) — the five-yearly funding agreement between the Australian Government and the Guild — stating that “the Australian Government intends to support ... the adoption of a nationally consistent approach in respect of the vaccines that may be administered by appropriately trained registered pharmacists.”¹⁶ Globally, this discussion remains current as the role of pharmacists in delivering COVID-19 vaccines is being debated, and in Australia, with similar variations between states/territories.

This study drew on policy theory to identify opportunities for a more consistent approach to pharmacist-administered vaccinations, in order to enhance Australia’s approach to population vaccination. By using Kingdon’s Multiple Streams Framework, this policy analysis sought to understand the factors that could be leveraged to open a “policy window” for the development and implementation of a national approach in Australia. These findings could also inform development of pharmacy or health policies in other federated countries, in which there are

jurisdictional differences, and a national approach is proposed.

1.1. Research question

How have current pharmacist-administered vaccination policies in Australia been developed, and what are the opportunities and barriers to developing a nationally consistent approach?

2. Methods

2.1. Study design

This study is a policy analysis using qualitative research methodology and methods; specifically, it is a case study approach, which allows for the in-depth examination of how and why a phenomenon occurs (in this situation, the development of a nationally consistent approach to pharmacist-administered vaccinations). This research was underpinned by the philosophical paradigm of pragmatism, where reality or ‘truth’ is viewed as what is useful and practical, and can be known through using research tools that reflect deductive and inductive evidence.^{17,18} This aligns with our methodological approach of using a hybrid process of deductive and inductive analysis¹⁹ guided by a policy analysis framework,²⁰ and of using case study research methods such as document analysis and semi-structured interviews.

2.1.1. Multiple Streams Framework

Kingdon’s Multiple Streams Framework (MSF)²⁰ is used in policy analysis to understand why certain ideas and policies reach the policy-making agenda, and others do not. It was used to guide the data analysis for this study, due to the study focus on current policy options for pharmacist-administered vaccinations, and the potential for active policy change towards a nationally consistent approach. This framework was first described by Kingdon in 1984 and has been used extensively in policy research to analyse health areas such as drug and alcohol policy^{21,22} and obesity prevention policy.^{23,24}

The MSF portrays successful policy agenda-setting and change as the result of the three streams coming together to form an opportunity or policy window.²⁰ The **problem** stream involves the definition of a problem that warrants attention; whether and how the problem is defined is shaped by actor interests, indicators that act as ‘evidence’ of a problem, focusing events, or feedback of existing policies. Problems are constructed in a way that attracts policymakers’ attention and are therefore important to the framing of policy solutions. Although related, the **policy** stream is independent of the problem stream and includes the ideas and solutions suggested by policy actors. These policies and their development are affected by the structures of policymaking, and the viability of policies is dependent on their technical feasibility and political acceptability. Lastly, the **politics** stream explores the political context of an issue, characterised by policy actors’ relationships and interests, the national mood, and the nature of governments and bureaucracies.

The MSF was identified as relevant for this case study on pharmacist-administered vaccinations as it enables understanding a ‘non-decision’ in terms of a nationally consistent approach, as well as considerations relevant to opening a policy window. In line with the research aim to understand the current development process, barriers, and enablers, these three aspects were integrated into the three streams. [Table 1](#) presents the coding and analytical scheme structured around the MSF.

2.2. Data sources and collection

2.2.1. Semi-structured interviews

The lead author conducted semi-structured interviews with 13 key informants between February 2020 and March 2021. Initial participants were identified from pharmacy peak bodies (who publicly listed the individuals on branch committees and in leadership positions), news

Table 1
Coding scheme structured on the Multiple Streams Framework.

Stream	Nature of the stream	Barriers	Enablers
Problem stream	What is the problem such that a nationally consistent approach is the ‘solution’? What do the different policy actors understand the problem to be? How much of a problem is it, and does it require a solution?	What is wrong with how the problem is defined? What are the problems as to why there is a struggle to have a nationally consistent approach?	How can the problem be re-defined or re-framed?
Policy stream	What are the proposed solutions, with regards to a nationally consistent approach?	What are the difficulties with the proposed solutions?	What are alternative solutions? How can the proposed solutions be improved? Is there evidence to support any of the solutions?
Politics stream	What are the institutional processes and mechanisms? Who are the stakeholders and what are their interests?	What are the institutional and political barriers? How do any conflicting interests create barriers to developing a nationally consistent approach?	How can these political and institutional mechanisms be leveraged for a nationally consistent approach?

articles detailing changes to pharmacist vaccination programs, and technical advisory groups supporting vaccination policy (who also publicly list their members). Further participants were identified through snowball sampling and through documentary data until saturation was reached. This occurred when the data collected both contributed no new information and sufficiently illustrated the application of the MSF to this policy.

Interviews lasted 40–77 min (average 53 min). [Table 2](#) provides a summary of participants’ roles and whether they worked at a national or subnational level. Six participants identified as having multiple roles, and one participant identified as having worked at both national and subnational levels. All participants were policy actors and knowledgeable about policy and processes related to pharmacist-administered vaccinations. Interview requests were also sent to 13 other individuals; however, no response was received from them. Quoted participants in this text will be referred to by a pseudonym.

An interview guide ([Appendix I](#)) was developed based on the research question, with topics covering the informants’ perspectives and insights on pharmacist-administered vaccinations in general; the appropriateness of a nationally consistent approach; their experiences with the policy development; and their view on what constitutes evidence and its role in the process. The interview guide was piloted in a qualitative analysis research group prior to the commencement of interviews. This was done to identify any missing questions or topics and

Table 2
Summary of participant characteristics.

Participant characteristic	N = 13
Role	
Healthcare professional representative body	6
Practising clinician	5
Immunisation expert in government health department	5
Researcher	3
Consumer representative	1
Manufacturing/wholesaler representative	1
Level of operation	
National	6
Subnational state/territory	8

to ensure that questions would address the research aims.

Ethics approval was obtained from the relevant institution’s review committee.

2.2.2. Documentary data

During the course of interviews, participants mentioned various policy documents that include relevant information regarding pharmacist-administered vaccinations. These documents included seven PSA jurisdictional pre-budget submissions from 2020 to 2021 and 2021–2022, as well as a State Parliamentary Inquiry report which discussed the extension of scope of practice for pharmacists (including pharmacist-administered vaccinations). These were collected to retrieve information relating to the pharmacy sector’s goals and stated objectives related to expanding pharmacist-administered vaccination programs, as well as their problem definition, and justification and details of policy proposals. Documentary data were collected between February 2020 and July 2021.

2.3. Data analysis

Interviews were audio-recorded (as permitted for all but one participant, where detailed notes were taken instead) and transcribed. All interview transcripts, documents, and field notes were imported into the qualitative data analysis software, NVivo 12 Plus (QSR International).

Data analysis in this study integrated *a priori* theory-driven categories, based on the MSF and understanding of policy processes, with inductively data-driven codes. This approach allowed for the MSF to be central to the analysis while also allowing for themes to be generated using inductive coding.¹⁹ Interview transcripts were inductively coded into broad categories (determined *a priori*) around actor interests, the current state of pharmacist vaccinations, proposed policies, and policymaking structures and processes. Relevant documentary data were extracted and similarly coded. An integrated analysis was then conducted by re-coding these key findings from both interview and documentary sources to the coding scheme outlined in [Table 1](#). For each stream of the MSF, its nature was described to provide context, and the barriers and enablers specific to the development of a nationally consistent approach to pharmacist-administered vaccinations were analysed.

2.4. Research rigour and reflexivity

To ensure research rigour and trustworthiness of findings, the lead author wrote memos during data collection and took fieldnotes after each interview; these were re-visited throughout data collection and analysis in a self-reflection process. Documentary and interview data were also triangulated to confirm the validity of inferences drawn. Data were coded by the lead author, in discussion with co-authors and a qualitative research analysis group (not directly involved in the research project) to ensure validity in approach and findings. To improve transparency of this qualitative research study, the Standards for Reporting Qualitative Research checklist²⁵ was completed and is attached here as [Appendix II](#).

The authors have experience with qualitative and quantitative research methods and have previously used these research approaches to examine health policy development globally. Additionally, the lead author is also an early career pharmacist practising in community pharmacy and, thus, was able to understand contextual nuances and build rapport with interviewees.

3. Results

In this analysis using the MSF, the nature and current context within each stream is first described, then the barriers and enablers to developing a nationally consistent approach ([Table 3](#)). Overall, these centred

Table 3
Summary of the barriers and enablers to implementation of a nationally consistent approach for pharmacist-administered vaccinations in Australia.

Stream	Nature of the stream	Barriers	Enablers
Problem stream	<p>Inconsistency between jurisdictions regarding practice of pharmacist-administered vaccinations</p> <ul style="list-style-type: none"> Logistically confusing and difficult for pharmacists and consumers Confusing message about what pharmacists can do if there are different ‘rules’ There is ‘inequality’ of consumer access; consumers should be able to choose between providers for the same service Variation in pharmacists’ training and education, practice audits, recording requirements <p>Pharmacy sector felt they were not currently delivering vaccination services to their full capacity</p> <ul style="list-style-type: none"> In comparison to other countries and states/territories, pharmacists “should and could be doing more” 	<ul style="list-style-type: none"> Lack of clarity from the pharmacy sector in defining the problem that would warrant a nationally consistent approach as a policy solution <ul style="list-style-type: none"> –Possible competing goals of 1) expanding pharmacist-administered vaccination programs; 2) national consistency The discourse and understanding of vaccines remove them from their clinical and public health context; at times, it does not adequately or explicitly consider the value that pharmacists add to delivering each vaccine 	<ul style="list-style-type: none"> Pharmacy advocates should re-frame the problem to a patient-centric approach, considering how pharmacist-administered vaccinations can be a “thoughtful value add to the community”
Policy stream	<p>Current nature and context</p> <ul style="list-style-type: none"> Jurisdictional differences in which vaccines can be administered; minimum age; whether vaccine doses are publicly funded; and where pharmacists can administer vaccines in addition to community pharmacies Differences also in which vaccines the pharmacy sector wanted to ‘pursue’ next and why In late 2018, there was a federal effort made to consider options for developing a national approach <p>Agenda and proposed policies</p> <ul style="list-style-type: none"> Keeping the status quo, where jurisdictions continue to expand 	<p>Pharmacy sector</p> <ul style="list-style-type: none"> Lack of unified policy proposals within the pharmacy sector <ul style="list-style-type: none"> –Between Guild and PSA –Within Guild –Within PSA Unclear how decisions are made as to which vaccines to ‘pursue’ next or why Immunisation managers <ul style="list-style-type: none"> •To ‘catch up’ to other states/territories, there were logistical difficulties with how to include pharmacists as additional NIP providers •Time-consuming, long consultation processes may be needed to expand programs 	<ul style="list-style-type: none"> It may not be “100% essential” to have an exact list that every jurisdiction permits pharmacists to administer; rather, national consistency could refer to decision-making based on the same evidence Another conceptualisation could refer to an agreed-upon minimum set of vaccines, with additional vaccines at the discretion of jurisdictions; if national consistency means catching up to other jurisdictions, there may be helpful opportunities to learn how programs are managed

Table 3 (continued)

Stream	Nature of the stream	Barriers	Enablers
		<p>programs independently, which may eventually lead to national consistency</p> <ul style="list-style-type: none"> Active and substantive policy reform <ul style="list-style-type: none"> –Directive to bring all jurisdictions to the level of the state/territory with the largest program (‘catching up’) – ‘Exclusionary list’ where pharmacists could administer all vaccines, <i>except</i> for those deemed unsuitable <ul style="list-style-type: none"> –Risk assessment matrix for the suitability of vaccines for pharmacist administration, to guide decision-making 	
Politics stream	<p>Pharmacy sector</p> <ul style="list-style-type: none"> Guild and PSA represent different pharmacy interests (and sometimes seem to compete) Guild and PSA routinely lobby jurisdictional health ministers and departments of health Jurisdictional governments Differences in: <ul style="list-style-type: none"> –Health needs and health service delivery models –Legislative requirements and policy processes Local political interests may influence development and expansion of pharmacist vaccination programs <ul style="list-style-type: none"> –Elections – Parliamentary inquiries 	<ul style="list-style-type: none"> Decision-makers’ differences in perceptions of pharmacists’ ability and role as immunisers may impede pharmacists in some jurisdictions from administering ‘more’ vaccines The varying strength of relationships and influences between policy advocates and decision-makers may also negatively affect progress for consistency Absence of a federal body with the capacity or mandate to coordinate a nationally consistent approach Minimal pharmacy representation on working groups discussing harmonisation 	<ul style="list-style-type: none"> Better collaboration between the Guild and the PSA on both jurisdictional and national levels could lead to unified plans to present to decision-makers

around how the pharmacy sector defined the policy problem, the policies proposed by the sector in each jurisdiction, and the institutional and political processes that characterise Australia's federated structure.

3.1. Nature of policymaking — problem stream

Two main policy problems were identified relating to the consistency of pharmacist-administered vaccinations. Firstly, the inconsistency between jurisdictions regarding the practice of pharmacist-administered vaccinations was identified as a significant policy problem by the majority of interview participants. From the pharmacy sector perspective, it was logistically confusing and difficult to have pharmacies operate differently depending on jurisdictions. Despite the universality of vaccines themselves, as jurisdictions have different 'rules' about pharmacist-administered vaccinations, it could send the public a confusing message about what pharmacists are capable of administering.

"Is it safe for us to immunise a 13-year-old, or not? ... Because it certainly isn't different, yet one state says it is and one state says it isn't." [William, manufacturing/wholesaler representative]

These inconsistencies also extended beyond the vaccines that pharmacists could administer and the population groups receiving vaccine doses; there were also differences in training and education, practice audits, reporting requirements, and decision-making processes. This was observed to be a problem by the participants who were immunisation technical experts and those working within jurisdictional health departments to manage immunisation programs.

Secondly, participants in the pharmacy sector indicated that pharmacists were not currently delivering pharmacist-administered vaccination services to their full capacity, that in comparison to other jurisdictions and other countries, pharmacists "should and could be doing more" than they are currently:

"Queensland is fantastic, Tasmania is fantastic, it just seems to be that New South Wales is last. And we have the biggest population. We have the largest number of pharmacists. We have the hugest rural areas that need to have better resources ... Community pharmacy is dying to be able to provide these services, and ready at the get-go to do it, investing resources to do it." [Daniela, pharmacy representative]

It was clear that frustration was particularly felt from participants in states/territories where pharmacists did not have as many 'permissions', in terms of the range of vaccines they could administer and the population groups eligible to receive them.

3.2. Nature of policymaking — policy stream

In the policy stream relevant to a nationally consistent approach, two main policy solutions were identified: 1) keeping the status quo; and 2) active and substantive policy reform towards a nationally consistent approach.

Currently, states/territories have their own regulations and policies relevant to pharmacist-administered vaccinations. Each jurisdiction has been independently developing and expanding the scope of pharmacist-administered vaccinations, and without any policy reform towards national consistency, this would continue where individual jurisdictions might eventually reach consistency by matching other states/territories.

Participants indicated that policy stakeholders representing the community pharmacy sector have been actively lobbying to expand the scope of these programs (through increasing the range of vaccines and population groups reached), primarily on a jurisdictional level via representative bodies such as the PSA and the Guild. Over the last two years, PSA state/territory branches have outlined their proposals regarding pharmacist vaccinations in pre-budget submissions to their respective governments and treasurers. All wanted pharmacist access to

the vaccines on the federally funded National Immunisation Program (NIP); however, their proposals differed regarding requests for other vaccines and the rationale/why for the request.

A few interviewees from within a peak pharmacy body acknowledged that the current situation could be confusing and that national consistency would be less complicated for consumers and healthcare professionals. However, they also noted that an advantage is that current differences between jurisdictions could compel those with a smaller program to keep chasing the states/territories with a larger range, which would be productive for overall expansion of pharmacist vaccination programs.

"Were Australia to get to a stage where everyone was completely consistent, that consistency may become a barrier to further removing those other barriers to vaccines, once you get to that period of stasis ... you really want to keep growing and trying to pass each other to maintain momentum, to continually remove barriers." [Cal, pharmacy representative]

In contrast, the other policy option in this stream was substantive policy reform towards a nationally consistent approach, which seemed to refer to an active imposition of a 'national consistency' policy. The specific nature of this proposed reform was not clearly nor uniformly defined, and multiple potential options to achieve national consistency were identified; however, none appeared to be tangible proposals or to have been publicly announced or endorsed.

Firstly, some participants suggested that national consistency could refer to a directive initially bringing all jurisdictions up to the level of the jurisdiction(s) with the largest program, or with the most permissions. This would address the jurisdictional inconsistencies with pharmacist vaccinations, as well as expand these programs (a current priority at the state/territory level). In addition to affecting pharmacy practice, inconsistencies were also thought to result in an 'inequality' of consumer access. Thus, this national approach would enable individuals to "experience consistency wherever they go" [Cal, pharmacy representative], and this was highlighted to be particularly important for those receiving care in communities situated near geographical borders. Additionally, as community pharmacies are very accessible, this would expand avenues through which to access vaccinations.

Next, from the pharmacy sector, a few participants hinted at (without a concrete proposal) the possibility of an "exclusionary list", where instead of allowing pharmacists to administer certain vaccines, the approach would assume pharmacists could administer all, *except* for those deemed unsuitable.

Finally, in several interviews, immunisation technical experts and staff working within jurisdictional health departments alluded to a risk assessment matrix for the suitability of vaccines for pharmacist administration, which would classify them as low, medium, or high risk — this was hinted to be related to the policy options sought by the COAG Health Council, although it was not officially confirmed. It was led by one state with involvement of the National Centre for Immunisation Research and Surveillance (NCIRS) and aimed to guide future decision-making on the vaccines and population groups to which pharmacists can administer vaccinations. This document is not publicly available; however, some informants were able to broadly describe the factors that are considered: the vaccine characteristics (e.g., live vaccine, novelty, administration needs); indicated population (and associated comorbidities, medical history); screening process; counselling, follow-up care, and monitoring required; and the dosage and vaccination schedule. Policy reform could constitute the formalisation of this list as a reference point for state/territory-level policy.

3.3. Nature of policymaking — politics stream

Decision-making for this health issue occurred in the political sphere, where there were strong political interests, engagement, and influential policy actors. Increased public access to pharmacist-administered

vaccinations was campaigned upon in numerous states/territories leading up to elections. As election promises and parliamentary inquiries were subject to the political priorities of jurisdictional governments, this may have contributed to the inconsistencies. In another example, the introduction of pharmacist-administered vaccines for travel purposes in Queensland arose from a parliamentary inquiry into community pharmacists' scope of practice, and was perceived by an interview participant to be a political promise at the jurisdictional level.

In Australia, the two groups most invested in the advancement of pharmacist-administered vaccinations through community pharmacies are the Guild and the PSA. However, they represent different pharmacy sector interests — the Guild represents community pharmacy owners, and the PSA is the national pharmacist representative group — and sometimes appear to be competing against each other. One participant familiar with the pharmacy sector observed that:

“some of it still comes down to point scoring. Somebody wants to be the one that gets the win, but the win should be about the patients and the system and the outcome ... they're trying in essence to get the same outcome, which is pharmacists in the game, but they're not working together.” [Natalia, pharmacy academic]

Despite these differences, both groups advocated for pharmacists to be able to provide more vaccinations through lobbying jurisdictional health ministers and health departments for program expansion.

Australia's federated system of government means that while there is a division of responsibility between the federal and jurisdictional authorities, many decisions are made at the state/territory level. In healthcare, and specifically in relation to vaccines, the federal government is responsible for the regulation of medicines, the funding of pharmaceuticals through the national Pharmaceutical Benefits Scheme (PBS), which requires evidence of cost-effectiveness, and the implementation of the NIP, in which vaccines must also be assessed for cost-effectiveness before inclusion in the program. However, the delivery of immunisation services is the responsibility of the states/territories, and thus, subject to each individual jurisdiction's health needs, legislative requirements, and policy processes. This shapes the development of a nationally consistent approach as the culture of changing legislation to allow pharmacists to administer vaccines is different between jurisdictions. One participant explained that one state might make larger changes at once, compared to another that will make “a series of smaller incremental changes to their regulations.” [Cal, pharmacy representative].

3.4. Integrated analysis of the barriers and enablers to a nationally consistent approach

While the current policy context for each of the problem, policy, and politics streams has been described, it is also important to examine why a nationally consistent approach had not been developed yet. This section provides an analysis of the barriers and enablers posed in the three streams, drawn from the collected data.

One of the most important barriers was the lack of clarity around defining a nationally consistent approach and defining the problem, such that a nationally consistent approach is warranted as a policy solution. After analysis of the PSA jurisdictional pre-budget submissions and informant interviews, it appeared that there were two possibly competing goals from the pharmacy sector: 1) to expand each jurisdiction's pharmacist-administered vaccination program; and 2) to achieve a nationally consistent approach. However, national consistency often referred to a “they have it, so why don't we?” approach, which essentially encapsulated the sentiment expressed in the first goal, and was practically seen when jurisdictions ‘caught up’ to those with a larger scope. Furthermore, states/territories with a larger program would want to continue their trajectory and add more vaccines and more population groups for pharmacist administration. It was not clear if or how an endpoint would be reached where all jurisdictions had exactly the same

programs, or if this was indeed a desired outcome.

Given that much of the conceptualization of a nationally consistent approach is predicated on expanding individual jurisdictional pharmacist vaccination programs, there was sometimes also a lack of clarity and purpose to justify the addition of certain vaccines or population groups to these programs. At times, the current discourse and approach from the pharmacy sector removed vaccines from their clinical and public health context, with a lack of clarity, understanding, and/or justification presented as to the use of vaccines or the addition of pharmacists as immunisation providers.

This was seen through a seeming lack of consideration of the purpose of vaccines on an individual and population level, and of the value of adding *pharmacist-administered* vaccines. For example, ‘herd immunity’ or ‘herd protection’ refers to the protection of a population from a disease, when a large proportion of the population has gained sufficient immunity (whether through vaccination or natural infection), thus reducing the likelihood of disease transmission. In advocating for expanded vaccination programs, the argument that pharmacists should be able to administer vaccines in order to “increase herd immunity” or “achieve herd immunity” had been ubiquitously employed. However, as noted by immunisation experts, not all vaccines given on an individual or population level are designed to provide herd protection. This was in contrast to the broad statements made by the pharmacy sector, without further elaboration on the purpose or value of adding pharmacists as providers of a particular vaccine, for the vaccine-preventable disease, in a targeted population group.

“Removing barriers to vaccination is essential to achieving herd immunity and protecting Queenslanders against vaccine-preventable diseases.” [PSA Queensland pre-budget submission]

Overall, it appeared that the approach and problem definition from the pharmacy sector advocating for the expansion of pharmacist-administered vaccination programs (regardless of whether this was to achieve national consistency) was pharmacist-centric, rather than public health or patient-centric. This posed a barrier as arguments did not sufficiently consider how pharmacist-administered vaccinations could be a “thoughtful value add to the community” [Natalia, pharmacy academic], thus presenting a less persuasive and consistent case to decision-makers regarding any additions to state/territory pharmacist vaccination programs.

The differences between jurisdictions in terms of the range of vaccines, minimum age, and where pharmacists could administer vaccines were seen by the pharmacy sector as somewhat arbitrary barriers to pharmacists being able to deliver more vaccinations. This was further reinforced through the assumption and perception that pharmacists have the same skill set and ‘clinical rights’ as doctors and nurses when it comes to vaccination, that “in terms of the qualification, pharmacists must complete the same standards as nurse immunisers. So, in fact if nurses can do it, why can't pharmacists?” [Virginia, pharmacy representative] One pharmacist participant observed that:

“If you want [a vaccine] ... you have to come and vaccinate in my pharmacy. That's a ridiculous thing. A nurse or a doctor can pick up their doctors' bag and their little esky and they can go and vaccinate everywhere else.” [Daniela, pharmacy representative]

By conceptualising the expansion of pharmacist vaccination programs as a ‘removal of barriers’, the underlying assumption is that pharmacists are entitled to administer *all vaccines*, but are just presently unable to do so. This again appeared to be framed around ‘pharmacists' rights’ and did not adequately or explicitly consider what pharmacists add to delivering each vaccine.

From analysis of documents and interviews, another prominent barrier to a nationally consistent approach that was identified was the lack of unified policy proposals within the pharmacy sector — between the Guild and the PSA, between the PSA branches, and between the Guild branches. In terms of the two bodies at a national level, there had

been no unified plan presented by the pharmacy sector as a whole. One key informant working within the Guild noted that in their experience,

“[Guild] state branches do what they do. Where they could collaborate with the PSA at [the] local level, they do. Where they don’t, they don’t. PSA may do their own advocacy, I don’t know.” [Virginia, pharmacy representative]

When asked about the collaboration between the PSA and the Guild in terms of vaccinations, a pharmacy participant external to both organisations believed that “it’s quite poor” nationally and “[didn’t] think there’s a consistent message that’s being sent.” [Natalia, pharmacy academic].

Further external observations about the lack of unity from within the profession were noted by Patrick, a jurisdictional immunisation manager: “You’ve also not just got eight different jurisdictions; you’ve got eight different Guilds. They’re pushing for different things, they’re not even on the same page.” It also appeared that there was a disconnect between the Guild’s National Council and its state/territory branches, where their national policy on harmonisation might be sent to the jurisdictional branches and left for them to “do what they do.” Likewise, there did not appear to be a unified plan with the PSA. This was evident from each jurisdiction’s pre-budget submissions where different items were requested and with different rationales. However, a few participants explained that the differences accounted for the need for jurisdictions to have a level of autonomy and flexibility.

“[It’s] partly decided on looking at what the local needs in an area will be. And having a recognition for how that health system is structured ... it’s about really looking at, within that state’s current system, what’s the next logical change that we think has a deep, reasonable chance of success.” [Cal, pharmacy representative]

Given the many differences in interests between the range of decision-makers and policy advocates, it may not be possible to reconcile them all for a unified approach. However, an opportunity to address this was raised by several interviewees. A more cohesive strategy representing the interests of the pharmacy sector could be achieved if there was better collaboration between the two main representative bodies. While this may be more likely to occur between the state/territory branches of the two groups, it would be especially important at the federal level for enabling a nationally consistent approach.

It was also unclear *how* decisions were made by the pharmacy sector as to which vaccines to ‘pursue’ next, if and what evidence was used to support proposals, and whether this was the same evidence that other jurisdictions were using. While requiring identical evidence for all jurisdictions might be impractical given their inherent differences, one participant hypothesised that the process was not evidence-based:

“I think people have just gone, ‘Oh, here’s a list. Let’s pick one.’ ... [Some people] went for a political thing. Other people have gone, ‘they’ve got one, so we should get one.’ I don’t necessarily think there’s been a thoughtful strategy for some of it.” [Natalia, pharmacy academic]

To address this, it was suggested that a nationally consistent approach could be re-framed as not simply one national policy stating what pharmacists can and cannot administer, but as a way of guiding decisions. This would affect the role of the risk assessment matrix, which might not explicitly dictate what jurisdictions should permit regarding pharmacist-administered vaccinations, and some participants from the immunisation sector indicated that “it might lead to the closest thing to consistency.” [Patrick, immunisation manager] This was further expanded upon by a participant who suggested that national consistency might not be “100% essential”; rather that

“working from the same evidence base is essential ... even if a jurisdiction wants to have slightly different legislation to another jurisdiction that maybe takes account of other factors that are

necessary for that individual state or territory to consider ... ensuring that there is consistency of decision-making around a consistent and robust evidence base is important.” [Laurie, immunisation expert]

Similarly, another participant raised the possibility that consistency could refer to an agreed-upon minimum set of vaccines and minimum age for these vaccines, with any additional vaccines at the discretion of individual jurisdictions.

Given that a proposed solution to achieve national consistency involved individual jurisdictions ‘catching up’ and expanding to a larger range of vaccines or including publicly funded vaccines, another barrier was faced by the immunisation branches within the jurisdictional health departments. This concerned the logistical and service delivery considerations of adding pharmacists as vaccination providers, especially in the resourcing of NIP or state/territory-funded doses. While some jurisdictions have existing systems that include pharmacists as NIP providers, immunisation staff in jurisdictions without such systems claimed it was difficult to operationalise — given the finite number of NIP doses provided by the federal government, adding more providers to the mix would “dilute” the stock and effectively make it “more scarce.”

Despite these operational differences, immunisation branches also recognised that they could learn from other jurisdictions that had larger programs, particularly those that already delivered pharmacist-administered NIP vaccines. Although they acknowledged that the social and geographical context is different, they saw this as an opportunity to learn how they managed their programs and any logistical challenges.

In addition to these operational and implementation differences, some participants from the pharmacy sector felt that the jurisdictional differences also extended to the cultural differences between individuals working in the health departments, who may be more or less resistant to pharmacist-administered vaccinations, and more broadly, further expansion of pharmacists’ scope of practice. A few of these participants believed that individuals with a background in nursing were more likely to object, or individuals who took more of a holistic “workforce development” approach (compared to a regulatory approach) were more likely to think about pharmacists’ role in the broader healthcare system and more open to expanding their role in providing vaccinations.

This was further reinforced by observations regarding the relationships between policy actors and how they affected policy development. A particular example that was raised several times was the role of the Guild’s (and to a lesser extent, the PSA’s) lobbying activities. This was widely known and involved forming working relationships with the various health ministers and staff in departments of health. Some participants reflected that the level of lobbying and the productivity of relationships could vary significantly between states/territories, with some jurisdictions reporting more constructive, upfront discussions with bureaucrats and health department staff (including Chief Pharmacists, Chief Health Officers, and the immunisation branches) or with health ministers, and others reporting more difficulty in these relationships. The involvement of medical representative groups and their branches (e.g., the Australian Medical Association or the Royal Australian College of General Practitioners) may have also affected policy development, given their public opposition to pharmacist-administered vaccinations.

Another noticeable barrier was the absence of a group that had the capacity or mandate to coordinate a nationally consistent approach, rendering an approach institutionally homeless at the federal level. While the federal government has been publicly supportive of a national approach, and of pharmacists providing more vaccinations, it has been fundamentally the jurisdictions’ responsibility to determine what pharmacists can do. COAG Health Council had a role with establishing a working group (which was referenced by several interview participants). This work was led and coordinated by one jurisdiction; however, participants working within immunisation branches acknowledged that it would be difficult if they themselves were one of the jurisdictions, suggesting instead that any solutions would be better coordinated from a

federal level. Additionally, due to the COVID-19 pandemic, COAG along with its councils was dissolved and replaced with a different intergovernmental forum, and many of the relevant individuals who were involved with the initial working group would have most likely been preoccupied with the COVID-19 pandemic responses.

When asked who at the national level could or should be responsible for coordinating a national policy (including its development), interviewees currently involved in vaccination policy raised different options, ranging from particular offices within the Commonwealth Department of Health, to the national research organisation providing technical advice to government (NCIRS), to a general “national group that had the capacity to be the arbiters.” [Natalia, pharmacy academic] This suggested that there is still a lack of progression in the development, and a lack of clarity for the rationale and remit, of a hypothetical national body. As immunisation programs are the responsibility of state/territory governments, and thus responsive to jurisdictional health and societal contexts, this would need to be accounted for when developing the mandate and scope of a national group.

4. Discussion

Pharmacist-administered vaccination policies in Australia have been independently developed and implemented in each state/territory, and there have been calls for a nationally consistent approach. In this analysis, the MSF was used to identify factors in each of the three streams that would be barriers or enablers to such a policy. It was observed that there was a lack of clarity around defining a nationally consistent approach, and a lack of agreement regarding whether the ‘problem’ warranted this as a ‘solution’. From the pharmacy sector’s perspective, the issue of a nationally consistent approach was inherently tied into their desire to expand pharmacist vaccination programs, using it as a means for jurisdictions with smaller programs to expand by ‘catching up’ to other jurisdictions — this potentially led to competing goals of national consistency *and* jurisdictional program expansion. In some situations, the pharmacy sector discourse also inadequately justified the addition of vaccines to these programs or provided different rationales, which may make it more difficult to achieve a cohesive approach. The lack of clear, unified policy proposals and collaboration within the pharmacy sector (between representative bodies, and between state/territory branches) also presented difficulties, as did the logistical and service delivery challenges faced by immunisation program policymakers. Each jurisdiction had their own policy priorities, agendas, and relationships between policy actors; politically, this could result in impediments to a national approach.

As many of the barriers identified in the *problem stream* by the pharmacy sector were related to a lack of clarity in policy problem definition, it may help to re-define and re-frame the value that pharmacists can add as vaccine providers. More attention could be paid to the individual and public health needs and policy context within which pharmacists are advocating, and the solutions that are being conceived to address this; a shift from a profession-centric approach to one focused on individual and public health. This is not to suggest that pharmacists

should not or cannot contribute as vaccine providers but addressing why and how pharmacists can add value for patients and the public related to each vaccine may facilitate its inclusion in individual jurisdictional pharmacist vaccination programs. Thus, uptake would be more likely on a national level. Additionally, as the current situation does not necessarily distinguish between pharmacists *initiating* or *prescribing* vaccinations and *administering* them, clarifying these distinctions for each vaccine may also be helpful, especially given concerns and opposition over pharmacists’ ability to clinically assess, prescribe, counsel, and monitor patients (Box 1). This could potentially allow pharmacists to *administer* more vaccines on their own authority (or a prescriber’s) through community pharmacy settings, bolstering their arguments that pharmacist-administered vaccinations are necessary for consumer access.

Given the nature of Australia’s federated system, it is understandable that these differences between jurisdictions pose challenges in developing a nationally consistent approach to pharmacist-administered vaccinations. State/territory governments and health departments have different approaches to policy change, and different priorities, budgets, and logistics. A federalist governance system offers jurisdictions autonomy in this respect; likewise, there may also be the desire for jurisdictions to ‘compete’ with each other to ensure they do not fall behind in terms of progressing their agenda. These differences and ‘competition’ can foster innovation where each state/territory functions as a ‘laboratory’ for new policies and approaches²⁶; this, in turn, may result in learning opportunities for other jurisdictions to further expand their programs.

This case study also revealed underlying questions about the role of pharmacists (particularly community pharmacists) in the healthcare system. Much of the argument from the pharmacy sector regarding pharmacist vaccinations was framed around the concept of community pharmacies as essential access points for primary health, and thus, community pharmacists should rightfully have the authority to administer vaccinations. There are definite situations in which community pharmacies provide valuable, accessible settings for healthcare, such as in regional or remote communities with limited primary health resources, or in culturally and linguistically diverse communities where pharmacists who understand the culture and language are trusted health professionals. However, the pharmacist- or profession-centric approach, as opposed to a more patient-centric framing (which was noted by several participants), appeared more prominently, where a lack of permissibility was perceived to be an indictment on pharmacists’ professional ability. This indicates that while pharmacist-administered vaccination is one health service in which pharmacists are eager to increase their roles and responsibilities, there are other policies and programs into which the profession may want to expand, raising deeper questions about pharmacists’ professional identity and capacity, and the appropriateness of their ongoing appeal to expand their scope of practice.

A comparable example is demonstrated in Canada, another federated country where health services delivery is a shared responsibility between federal and province/territory authorities, and where decisions

Box 1

Description of possible roles for pharmacists in vaccination

Facilitate through community pharmacies (host as an accessible setting): hosting other immunising practitioners (e.g. nurse immunisers) in a community pharmacy.

Administer: directly, physically administer a vaccine dose to an individual.

Initiate/prescribe: assess and make the clinical judgement that a vaccine is appropriate for an individual.

Initiate/prescribe and administer: assess and make the clinical judgement that a vaccine is appropriate for an individual, and administer the vaccine dose.

regarding immunisation programs are also made at the jurisdictional level.²⁷ There have been similar calls to harmonise pharmacist vaccination programs^{28,29} and similar rationales around consumer equity and expanding pharmacists' scope of practice. In a review of the jurisdictional differences in pharmacy-based or pharmacist-delivered services more broadly,³⁰ researchers argued that this 'patchwork' nature may stem from the absence of pharmacy advocates at the macro level of health policymaking and an inadequate integration of community pharmacy services into the primary healthcare system. They suggested that efforts for harmonisation should be led by national pharmacy representative groups, with a stronger and clearer declaration of the role and value of pharmacists in the wider healthcare system; this may offer learning opportunities for pharmacy policymaking in Australia.

Within the context of the COVID-19 pandemic, the issue of jurisdictional differences in pharmacist-administered vaccinations is important as it has implications for the uptake and coverage of COVID-19 vaccinations. Pharmacists may be an integral part of the COVID-19 immunising workforce as additional immunisers in mass vaccination facilities, or through accessible community pharmacies; their inclusion could assist in increasing vaccination rates, which may be critical in areas experiencing outbreaks. However, the current situation in Australia regarding pharmacist-administered COVID-19 vaccines involves state/territory differences in the range of vaccines, age groups, whether intern pharmacists can administer, and other brand-specific requirements.³¹ This was also similarly seen in Canada,³² with additional differences in whether pharmacists could administer first and/or second doses. National consistency in these situations may reduce confusion and enable individuals to access COVID-19 vaccines regardless of jurisdiction; however, as explored in our analysis, decision-makers in each jurisdiction may also have political, policy process, vaccine supply, or service delivery model considerations that result in differences.

The MSF has previously been used to explain the development of immunisation policies.^{27,33,34} For example, De Wals et al. analysed the decision-making processes involved in publicly funded immunisation programs in Canada. While these authors provided a broad overview of the factors in immunisation policy more generally, our analysis specifically investigated the policy of a nationally consistent approach to pharmacist-administered vaccinations. The use of the MSF allows for further analysis of the political dimension affecting policymaking, much of which has been neglected in previous studies of immunisation policy development.²⁷ Policy analyses have often drawn on the MSF to demonstrate how an issue arrives on policymakers' agendas; in contrast, in this study, the MSF was used as a structure for understanding why a policy had not been developed yet.

4.1. Limitations

Interviews for this study were conducted between February 2020 and March 2021, during the COVID-19 pandemic, and the pandemic may have affected the participant response rate, especially given how potential participants would be involved with the pandemic response. However, documentary data was also drawn upon, and the triangulation of documents and interview data provided us with a clearer picture of how the policy problems and solutions were conceptualised.

While some interview participants had experience working in regional or rural communities, most were primarily working within state/territory capital cities and metropolitan areas. This may have influenced how participants viewed the need and suitability of a nationally consistent approach to pharmacist vaccinations. However, some participants were involved in policymaking on a national level and understood the experiences and necessity of patients in non-metropolitan areas having good access to vaccines; additionally, this was expressed and captured in PSA pre-budget submissions to jurisdictional governments.

As this is an ongoing policy area, it was evident that interviewees

were not able to fully disclose information about the process, and it is possible they were only able to divulge already publicly available knowledge or adhered to the 'party line.' Although this may affect our understanding of the policy details, the ways in which the policy problems, solutions, and process were discussed could still be analysed, answering the research questions.

Finally, the MSF may present some limitations in that it does not theoretically address or emphasise certain elements of the policy process, such as the role of political institutions or mass media.^{35,36} However, some scholars have integrated institutionalism into their policy analyses using the MSF.³⁶ In our study, we considered the role of institutions as part of the politics stream (e.g., the institutional roles of healthcare representative bodies and national/subnational health agencies).

4.2. Future research

Pharmacist-administered vaccinations in Australia is one example of pharmacy policy impacted by federalism. Further research could investigate how federalism as an institutional and political factor influences pharmacy policy in other countries and on other policy areas. Ultimately, this could contribute to the small but growing literature on the development of policies affecting pharmacy practice.

5. Conclusion

The governance of pharmacist-administered vaccination is a pressing issue globally, in light of the COVID-19 pandemic. The regulation and management of pharmacist-administered vaccination programs in Australia are the responsibility of each of Australia's eight states/territories; this has resulted in jurisdictional differences, leading to calls for a nationally consistent approach. In this analysis, the MSF was used to identify how different understandings of the nature of the problem, diffuse policy proposals, and contextual politics has hampered the development of a nationally consistent approach. One opportunity identified is for jurisdictions with a smaller program of permissible vaccines 'catching up' to those with a larger program. Enablers of a national approach include re-framing the policy problem from a profession-centric to a patient-centric view and considering the value that pharmacists can add to existing vaccination services. These study findings are relevant for Australia as well as other federated countries that are seeking to strengthen and create consistency in pharmacist-administered vaccines. The findings on enablers will also assist advocates of pharmacist-administered vaccines to develop and communicate policy proposals more effectively.

CRedit author statement

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Declarations of competing interest

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Appendix A. Supplementary data

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