Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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"Never waste a good crisis": Opportunities and constraints from the COVID-19 pandemic on pharmacists' scope of practice

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ABSTRACT

Background: In response to the COVID-19 pandemic, many pharmacy-based or pharmacist-delivered services were introduced or amended to mitigate the pandemic's health and social impact. This happened within the context of pharmacists seeking more opportunities to increase their clinical responsibilities and play a larger role in primary care.
Objective(s): To analyse the policymaking context and pharmacy responses to COVID-19 that enable or constrain the expansion of pharmacists' scope of practice.
Methods: This study is a policy analysis of documentary data detailing changes in pharmacy policy in Australia, drawing on a "policy space analysis" framework to identify opportunities and constraints to policy reform. Data were collected from news for health professionals; federal/jurisdictional legislation and media releases; and guidelines and directives from government health departments and agencies. Changes to pharmacy practice were identified and classified according to type. For each change, potential opportunities and constraints for expanding pharmacists' scope of practice were identified.
Results: Four categories of changes were identified: medicines limits/restrictions; alternatives to paper prescriptions; public health measures; and community pharmacist-delivered services. Opportunities from the pandemic response that could expand scope of practice include the potential permanence of temporary measures that increase pharmacists' responsibilities; remuneration to legitimise services; political acknowledgement of medicines safety and access as a priority; and government need to quickly address crises. Constraints include the potential permanence of temporary measures that restrict pharmacists' practice; negative perceptions of pharmacists from other clinicians; intra-professional disagreements regarding pharmacy-based services; and lack of pharmacist representation in institutional structures.
Conclusions: This analysis demonstrates that the pandemic responses and policy context may facilitate expansion of pharmacists' scope of practice, and identifies possible avenues to do so; it also highlights constraints that need to be further addressed to achieve this goal.

1. Introduction

The COVID-19 pandemic has highlighted the integral role that pharmacists play as healthcare professionals to mitigate the health impact of the pandemic on individuals and the community. In response to the pandemic, many policy strategies have been introduced or amended to ensure that patients continue to access their medicines reliably and safely. Additionally, services provided by pharmacists, particularly community pharmacists, have increased or been modified to adapt to the pandemic.

For example, across the United States, Canada, and various European Union countries, responses have included: introduction of e-prescriptions and telehealth/remote consultations; permission to compound antiseptics, disinfectants, or hydroalcoholic gels; home delivery services; eased restrictions to allow pharmacists to adjust, extend, or substitute medicines without prior prescriber approval; eased restrictions to allow pharmacists to supply controlled substances; and establishing community pharmacies as testing sites for COVID-19.[1,2]

These changes have followed a decade during which pharmacy practice globally has been undergoing a paradigm shift regarding their

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scope of practice, moving beyond the traditional roles of medication dispensing and supply.[3–7] Pharmacists are playing a larger role in primary care, with newer responsibilities in prescribing and/or therapeutic substitution; providing pharmaceutical care in non-pharmacy settings, such as aged care facilities or patients' homes; disease screening; and providing immediate care or first aid.[8] In pushing for these expansions, pharmacy practice advocates will first focus on the legal possibility of providing these services, before (or in parallel) pursuing remuneration.

The reconsiderations of pharmacy policy and practice in response to COVID-19 potentially offer a window for broader reform. As the pharmacy policymaking community and stakeholders have been considering and re-imagining the role of the pharmacist, there may be opportunities for these policy actors to take advantage of decisions made during the pandemic in order to advance the profession.

The situation in Australia is similar to that in many countries experiencing changes to their pharmacy workforce in their efforts to address the health and social crises arising from the pandemic. In this policy analysis, Australia is used as a case study to examine how responses to the pandemic may affect pharmacy policy in the future. In Australia, pharmacy peak bodies have put forward their professional roadmaps for the future, and they include envisioning pharmacists providing more vaccinations; prescribing for minor ailments; working within general practices and in residential aged care facilities; and being recognised and remunerated for their work.[9–11] These activities have also been listed in 2020–2022 budget submissions to jurisdictional governments,[12] highlighting the urgency felt by pharmacy practice advocates to implement them, particularly in light of the pandemic.

This research uses a policy space analysis approach[13,14] to 1) describe the changes to pharmacy practice in Australia in response to the COVID-19 pandemic, and 2) analyse the policymaking context and pharmacy-related COVID-19 responses that enable or constrain the expansion of policies affecting pharmacy practice.

2. Methods

2.1. Study design

This study is a policy analysis of documentary data regarding changes in pharmacy policy in Australia. It draws on a "policy space analysis" framework, which was developed from the political science field to identify opportunities and constraints to policy reform.[13,14]

2.2. Data sources and data collection

In order to identify changes to policy and the policy context, the authors systematically collected media data and government statements and reports. These were appropriate data sources for this analysis in the current context as the media provided a useful commentary given the rapidity of policy changes, and it was more appropriate to use existing sources rather than make demands on clinicians and policymakers for informant interviews.

Every few days starting from April 1, 2020, the lead author checked the Pharmaceutical Society of Australia's (PSA) microsite[15] for COVID-19 pharmacy practice updates and regulatory changes, and also received daily newsletters from the Australian Journal of Pharmacy and Australian Doctor, and weekly newsletters from the PSA and Australian Pharmacist — these provide news and updates for practising clinicians. Additionally, they would provide further links to media releases and announcements by the federal and/or state/territory governments and health departments; the national drug regulator, the Therapeutic Goods Administration (TGA); other government entities, such as the Australian Digital Health Agency (ADHA) and the Pharmaceutical Benefits Scheme (PBS); and health professional peak bodies, such as the Pharmacy Guild of Australia (the Guild) and the PSA. News for the general public was also purposively collected on specific policy changes as it would also contain details and public comments from key policy actors. Data were collected until July 28, 2021. To ensure the authors had captured all relevant changes, this list was verified by an external advisory group comprised of community pharmacists, and against the PSA microsite (which by design captured all relevant changes for clinicians).

2.3. Classification of changes to pharmacy practice

From these sources, the lead author made a list of all changes to pharmacy practice (a selection is described in Table 1), and documented a chronology for each change (overview in Fig. 1).

The lead author then inductively classified into four broad categories, according to similar aims and types of strategies: 1) limits and restrictions to medicines supply and access; 2) alternative methods to obtaining medicines without physical paper prescriptions; 3) public health measures; and 4) provision of services by community pharmacists.

2.4. Analysis framework and data analysis

To analyse how the pandemic response could influence policymaking for pharmacy practice in Australia, a policy space analysis was conducted. This framework is a useful way of mapping the opportunities and constraints for future policy reforms, and has been used in other areas of public health policy analysis such as family planning[16] and food policy.[17] By using this framework, opportunities and barriers from the COVID-19 pandemic response that would affect the expansion of pharmacy policies and scope of practice can be identified.

In this framework, a policy space represents the wider policy and political context for a given policy issue. Actors working within this policy space interact with factors relating to the policy's content and its acceptability (*policy characteristics*); international and national context (*policy context*); and the dynamic circumstances during the policy process (*policy circumstances*). All of these have the potential to provide opportunities and constraints that grow or shrink the scope of the policy space.

Firstly, the *policy characteristics* dimension discusses the features of policies, and its subsequent acceptability. This includes elements such as the resources required for implementation, level of incentives for stakeholders, and thus, their buy-in, participation, and policy sustainability. The next dimension is the *policy context*, which describes the pre-existing circumstances and context within which policymaking occurs. These include the historical, social, cultural, institutional, and political factors pertaining to the policy issue. The characteristics of policy actors are also considered in this dimension. Finally, *policy circumstances* involves policy actors' perceptions and understanding about the policy issue, and how these influence the changing reality of decision making. These factors differ from policy context in that these are dynamic and ongoing circumstances; they include actor power and influence, political dynamics, and policy issue framing. Fig. 2 presents a visual representation of this analytical framework.

For this analysis, the designated the policy space was pharmacists' scope of practice, which has been defined in the National Competency Standards Framework as "a time sensitive, dynamic aspect of practice which indicates those professional activities that a pharmacist is educated, competent and authorised to perform and for which they are accountable."[18] Expansions to this policy space would entail the addition of professional activities; conversely, contractions to the policy space would involve reducing the range of activities that pharmacists can perform.

This framework was chosen due to its ability to portray the active nature of policy change occurring in pharmacy practice and in the COVID-19 pandemic responses (particularly in a fast-moving environment), while accounting for the interaction between the underlying contextual factors, political framing and ongoing shifting circumstances, and the resultant policies.

The lead author coded each collected media release, legislation,

Table 1
Summary of select policy changes.

Policy	Description of current policy	Changes due to/since the COVID-19 pandemic
Continued Dispensing	• Allows patients to access a standard PBS pack of medicine required for continued therapy • There is no requirement for a prescription to be obtained to cover the supply or PBS supply of the medicine • Can only be accessed if the same medicine has not been supplied under this provision in the last 12 months • Temporary measure	• This was introduced in January 2020 before the pandemic, in response to the summer bushfire crisis • Now applies to most PBS prescription medicines; previously, it only applied to oral contraceptives and statins
Digital image prescriptions	• The prescriber writes a paper prescription as usual, which can be directly sent to a pharmacy via email, fax, or text (permissible transfer methods vary by jurisdiction) • The pharmacist prints a hardcopy of the image, and can dispense and claim any PBS medicines on the prescription • Covers most prescription medicines • Any repeats must be held at the pharmacy • Temporary measure	• The original paper prescription no longer needs to be sent to the dispensing pharmacy; previously, it needed to be sent within seven days of supply
Electronic prescriptions	• Replaces paper prescriptions • Two models o Token model – a unique QR code is sent to the patient, which the pharmacist unlocks to access and dispense the legal prescription o Active Script List model – pharmacists will be able to access the patient's prescription from a centralised database	• Implementation fast-tracked • The first stage (Token model) was available from May 2020; the second stage (Active Script List model) will be available from 2021
Therapeutic substitution	• Allows the pharmacist to supply an alternate strength, quantity, or formulation of specific products that are experiencing a national shortage, without requiring prior approval from a prescriber • The TGA must publish a Serious Scarcity Substitution Instrument (SSSI) for each product, which outlines the products that can be used as an alternative • As of July 28, 2021, there have been seven products for which the TGA have issued a SSSI, with all notices having expired by Jun 30, 2021	• This is a new scheme; previously (and for any other products or medicines without a SSSI), pharmacists are required to contact the prescriber to make any substitutions
Pharmacist-administered vaccinations	• Some vaccines may be administered to certain population groups by a trained pharmacist in a community pharmacy • Jurisdictions vary regarding which vaccines, minimum age, access to federal/State-funded doses, and where pharmacists can administer vaccines external to a pharmacy	• Five remaining jurisdictions lowered the minimum age for influenza vaccinations in pharmacies to 10 • Some jurisdictions lowered the minimum age for meningococcal ACWY, measles-mumps-rubella, and diphtheria-tetanus-pertussis vaccines • Some jurisdictions allowed pharmacists to provide vaccinations outside of the community pharmacy • Queensland legislated that trained pharmacists could administer cholera, diphtheria-tetanus-pertussis-inactivated poliovirus, *Haemophilus influenzae* type B, hepatitis A, poliomyelitis, pneumococcal, and COVID-19 vaccines • Regulatory changes made in all jurisdictions to allow pharmacists to administer COVID-19 vaccines, although the brand, minimum age, and locations where pharmacists can administer vary
COVID-19 testing in pharmacies	• Short independent pilots in South Australia and Queensland • Opportunistic testing for symptomatic individuals presenting to participating pharmacies and requesting symptom relief products	• Introduced due to COVID-19 pandemic

guideline, directive, and new article for factors under the three dimensions of the policy space analytical framework, then classified these as having the potential to enable or constrain the expansion of pharmacists' scope of practice.

2.5. Reflexivity and research rigour

KC is a doctoral candidate undertaking training in quantitative and qualitative research methods, particularly in policy analysis. KC is also a registered pharmacist and has been practising in a community pharmacy for the last four years, including during the COVID-19 pandemic. LB and AMT have used mixed methods approaches to study health policy development globally.

Research rigour was maintained through the use of a reflexive journal by the first author, to enable reflection on personal biases and experiences during data collection and coding, as well as through regular consultation with co-authors and a qualitative research analysis group to ensure validity in the research approach and findings.

3. Results

3.1. Timeline and classification of changes

Fig. 1 shows a timeline of the development of major policy changes affecting community pharmacy practice in Australia, from January 2020 to July 2021. The first category of *limits and restrictions to medicines supply and access* includes limits on the supply of hydroxychloroquine and salbutamol specifically, and general limits on all medicines. Next, *alternative methods to obtaining medicines without physical paper*

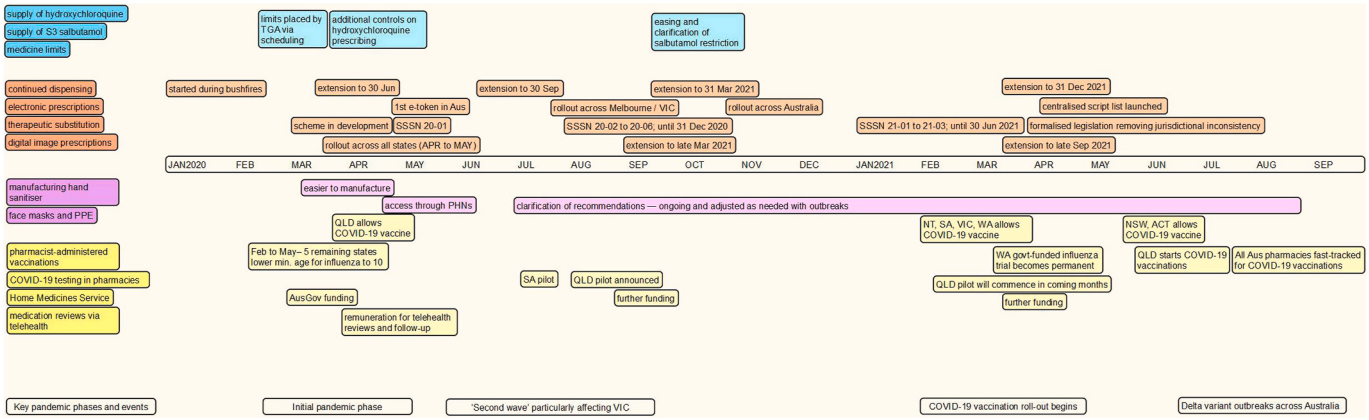

Fig. 1. Timeline of changes affecting pharmacy practice.

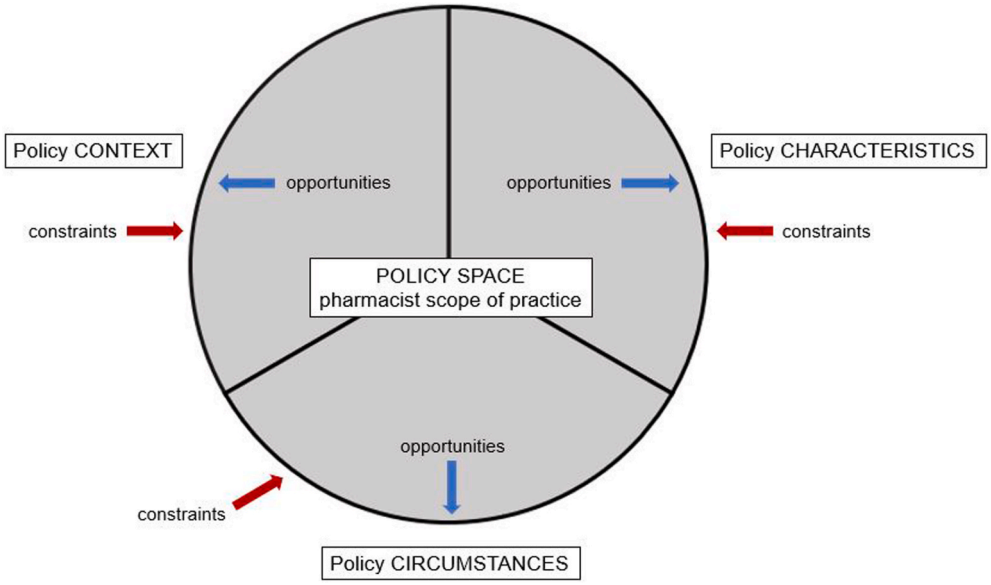

Fig. 2. Policy space analysis framework.

prescriptions encompasses strategies to assist patients in receiving their medicines without needing a physical prescription or repeat/refill, whether because of an inability to physically see their doctor, or due to medicine shortages. These include Continued Dispensing (no requirement for a prescription to cover a month's supply of the medicine), electronic prescriptions, therapeutic substitution, and digital image prescriptions. The next group covers changes that contribute to broader *public health measures*, and includes guidelines to manufacturing hand sanitiser, and on the distribution and use of personal protective equipment (including face masks) for pharmacists and the public. Finally, *provision of services by community pharmacists* comprises activities such as pharmacist-administered vaccinations (including, but not limited to the COVID-19 vaccine), COVID-19 testing in pharmacies, Home Medicines Service (medicine delivery), and medication reviews via telehealth. Some of these were existing programs that were expanded upon, and some were new and introduced in response to the pandemic.

In constructing a chronology for key changes to pharmacy practice in Australia, it is also useful to identify the key pandemic phases and events. This allows for identification of the evident 'policy problem' at different times, and demonstrates the fluidity of circumstances that can influence the overall policy space.

For example, in the initial phase of the pandemic, the responses affecting pharmacy practice mainly centred on addressing panic-buying and stockpiling of medicines, ensuring patients could access their medicines without physical prescriptions, and establishing or accelerating telehealth and digital health infrastructure. As Australia progressed into additional 'waves' and increased levels of community transmission, responses pivoted to improving testing capacity, use of face masks, and widespread implementation of electronic prescriptions. With the approval of COVID-19 vaccines and emergence of more transmissible COVID-19 variants, the urgency turned to the delivery of vaccinations and activation of pharmacists as vaccination providers.

Table 1 provides a summary of some of the key policy changes referred to in the following analysis.

3.2. Policy space analysis

In this analysis, a number of opportunities and constraints on expanding pharmacists' scope of practice were identified; these were posed by the pharmacy responses to the pandemic and the existing and dynamic policymaking context. They concerned the various legislation and policies that affect pharmacy practice, the dynamics between stakeholders in this policy space, and the institutional structures involved in these decisions (see Table 2).

Table 2
Analysis of the policy space for the expansion of pharmacy policies and scope of practice.

	Constraints (that shrink the policy space)	Opportunities (to expand policy space)
Policy CHARACTERISTICS	• Some new policies constrain scope of practice, so their permanence could adversely affect pharmacists' scope expansion • Some existing and COVID-19 policies can cause friction with other health professionals, as they're perceived to be clinically unsuitable for pharmacists, or encroach into other professional spaces — this decreases trust and opportunities for pharmacists to increase responsibilities	• Some temporary measures expand scope of practice, and their potential to become permanent is an opportunity for sustained expansion of scope of practice • Policy infrastructure already exists for some of the new policies, so it is relatively easy to build upon and further expand • Policies that remunerate pharmacists provide formal recognition of their role and legitimises pharmacist-delivered services • Evaluation component built-in to program to allow for future development and expansion
Policy CONTEXT	• Pharmacist actor characteristics o Lack of training for additional services — the skills to perform these services are not necessarily an inherent part of a pharmacist's training o Pharmacists are generally more risk-averse; there may be within-profession hesitation for providing additional pharmacy services • The Guild's political power could constrain expansion of scope of practice if they argue against services or policy approaches • A federated health system can constrain scope of practice if programs require national consistency in order for them to function properly • Differences between pharmacy professional bodies can pose constraints if unity is necessary for expansion of scope • Lack of understanding or appreciation of pharmacists' role from other HCPs can constrain the development of more opportunities for pharmacists • Lack of a federal Chief Pharmacist role may contribute to a lack of national leadership and representation of pharmacists in the federal Department of Health — there is a limited voice in that environment to develop policies that can expand scope of practice	• Pharmacist actor characteristics — pharmacists are perceived by the public and by policymakers as appropriate people to provide healthcare because they are: o Medicines experts o Very accessible, especially community pharmacists o Trusted o Starting to be involved in other areas of service provision • The Guild's political power could expand scope of practice if there are policy options that align with pharmacy owners' interests • A federated system can provide opportunities for expanding programs as jurisdictions constantly push each other along and can learn from each other (state-level innovation) • National health priorities of QUM & medicine safety and aged care present opportunities for pharmacists as medicines experts to play a more significant role in improving health outcomes • Currently (and over the last few decades), there has been a push towards expanded scope of practice across many countries; pharmacy groups worldwide are advocating for this, not just Australia • Government investments in telehealth and digital health provide a new and bigger environment in which pharmacists can clinically practice
Policy CIRCUMSTANCES	• No pharmacy representation on the three ATAGI subgroups for the vaccine rollout (prioritisation, implementation, monitoring [but particularly implementation]) • There has been public disagreement *within the profession* over a specific COVID measure (COVID testing in community pharmacies), which has cast doubt on expanded services • To some pharmacists, COVID-19 testing in pharmacies was seen as a steppingstone to further service delivery (pathology), but the perception that pharmacists only have profits in mind could constrain scope of practice	• Due to the pandemic, there has been increased recognition of pharmacists and perception of their accessibility (by the public and policymakers) • The need for all levels of governments to address COVID-19 quickly provides an opportunity for pharmacists to contribute more to healthcare in ways they previously have not • Involving pharmacies in COVID-19 testing increases the prominence of pharmacies as a health hub, maximising community value and opportunities for community pharmacists to deliver services within their principal workplace

3.2.1. *Policy characteristics*

3.2.1.1. Nature of policies in Australia. In Australia, there is no one policy that governs pharmacy practice; rather, there are a range of legislation, policies, standards, and guidelines involved, at both federal and state/territory level.

Firstly, each jurisdiction has their own poisons regulation, in addition to a federal poisons regulation. The federal legislative instrument is known as the Poisons Standard, and consists of medicines classification decisions that are adopted into state/territory poisons legislation.[19] These legislative instruments determine the level of access the public has to medicines (Schedules), legal requirements for a valid prescription, and the level of 'control' that pharmacists have to supply these (with or without prescriber intervention). As legislation, this dictates how pharmacists should legally practice and supply medicines. Schedule changes fall under the remit of the national drug regulator, the Therapeutic Goods Administration (TGA).

The Pharmacy Board of Australia is the professional regulator, and establishes the standards, codes, and guidelines that pharmacists need to adhere to in order to maintain their registration.[20]

In addition to legal responsibilities, pharmacists also have ethical responsibilities; for example, the Pharmaceutical Society of Australia (PSA) and Society of Hospital Pharmacists of Australia (SHPA) have Codes of Ethics that state the principles by which pharmacists communicate and interact with other healthcare providers, patients, and the community in their practice.[21,22]

Next, there are professional competencies and standards that describe the skills, attitudes, and attributes gained through study and experience that pharmacists need in order to practice to a required level. The National Competency Standards Framework for Pharmacists in Australia is published by the PSA[18] and applies nationally to pharmacists across the country. These competency standards evolve to ensure that the skills and values required reflect the dynamic nature of practice.

Practice guidelines have been developed by the PSA to guide pharmacy practice in the implementation and delivery of professional services. These are specific to individual services or activities (for example, administering medicines by injection,[23] conducting medication reviews,[24] providing dose administration aids,[25] and delivering immunisation services[26]) and give information on how to practically deliver these services in line with professional standards.

While the above policies detail how pharmacists should practice, there are other policy agreements that outline *what* pharmacists can do and be remunerated for. The Community Pharmacy Agreement is a 5-yearly funding agreement between the federal government and the Pharmacy Guild of Australia (and PSA in the most recent agreement).[27] This a commitment from the federal government and an indicative roadmap for funding priorities for the sector. The terms of the agreement specify the amount of funding that pharmacies receive for dispensing medicines subsidised under the Pharmaceutical Benefits Scheme and for providing medication reviews in the pharmacy (MedsChecks, Diabetes MedsChecks).

The National Medicines Policy is a framework that aims to provide better health outcomes for Australians "through their access to and wise use of medicines." It has four main objectives: 1) timely access to medicines; 2) medicines meeting appropriate standards of quality, safety, and efficacy; 3) quality use of medicines; and 4) maintaining a

responsible and viable medicines industry.[28] While the policy might not have any direct or tangible effect on pharmacists' everyday clinical practice, it forms the context within which other policies that affect pharmacy practice are developed.

The COVID-19 pandemic necessitated changes to some of these policies, mainly regarding the supply of medicines and increasing the services that could be delivered by pharmacists. Some of these changes include or affect:

- Continued Dispensing
- Therapeutic substitution
- Digital image prescriptions
- Pharmacist-administered vaccination programs
- Medication reviews via telehealth (and remuneration for these services)
- COVID-19 testing in community pharmacies
- Electronic prescriptions

Table 1 summarises and describes the main changes affecting pharmacy practice in Australia.

Measures that were designed to be temporary included Continued Dispensing, digital image prescriptions, and individual therapeutic substitution shortage notices, where federal and jurisdictional governments included end dates on legislative instruments, some of which have since been extended multiple times. COVID-19 testing in community pharmacies was also implemented as a limited pilot. Some changes are expansions on existing measures, such as Continued Dispensing, digital image prescriptions, and pharmacist-administered vaccinations. Medication reviews have been performed by pharmacists prior to the pandemic, but expanded opportunities arose from its delivery via telehealth and the remuneration of telehealth-delivered reviews. New policies included the therapeutic substitution scheme, COVID-19 testing in community pharmacies, and electronic prescriptions.

3.2.1.2. Opportunities to expand scope of practice. Some of the introduced temporary measures expand scope of practice, and their potential to become permanent is an opportunity for sustained expansion of scope of practice. Examples of this include Continued Dispensing (the expansion of which was a result of the 2019/2020 Australian bushfire crisis, predating the COVID-19 pandemic) and remunerated telehealth medication reviews. Pharmacy advocates have considered these to be 'good' policies because they are feasibly implemented and taken up, improve health outcomes, and recognise the skills and worth of pharmacists. As some of the new policies are expansions of existing measures, the policy infrastructure is already present, so is therefore relatively easy to continue to build upon. Additionally, this facilitates the further expansion of some of these programs, for example, in the case of pharmacist-administered vaccinations. Demonstrating that pharmacists already provide advice and services lends legitimacy to future programs and their expansion.

Pharmacists receive remuneration for some programs, including those introduced in response to the pandemic. This is an opportunity to grow the policy space as pharmacists are seeking remuneration and direct funding for providing services and have been lobbying to keep them. This could form the basis for remuneration of other services, which provides formal recognition of their roles and legitimises pharmacist-delivered services.

An evaluation component built-in to a program also allows for potential further development, and development of similar programs. For the COVID-19 testing pilot in South Australia, it was reported that outcomes would be evaluated after two weeks, to inform the potential for a further roll-out in regional and rural areas. Although it has not been clear what these outcomes were, nor has there been any publicly available evaluation report, the inclusion of an evaluation component can support the decision-making process for allowing pharmacists to increase their responsibilities in providing health care. Feedback is important for improving existing or new programs, and can also assist in identifying areas where pharmacists are appropriately trained and competent, or not.

3.2.1.3. Constraints on expanding scope of practice. However, some new policies may constrain scope of practice, so their potential permanence could adversely affect pharmacists' scope expansion. For example, digital image prescriptions and therapeutic substitution aimed to enable patients to gain easier access to necessary medicines, in the event they could not go to their GP for a physical prescription, or if there was a shortage of their original medication. However, in reality, these measures were impractical for pharmacists, and specifically for therapeutic substitution, pharmacists did not have the actual autonomy to ensure that patients had access to their medicines when there was a shortage. In order for a pharmacist to be able to substitute without prescriber intervention, the TGA has to issue a substitution notice for each individual product that is experiencing a shortage; this notice dictates which products can be used in replacement. Instead of allowing pharmacists to use their clinical judgement and expertise (e.g. substituting formulations or different medication strengths), pharmacists could only legally be allowed to autonomously substitute specific products in a piecemeal manner, and in a way that did not adequately address the issue of medicine shortages. Furthermore, while the TGA issued a notice on a federal level, some states required an additional legislative order for pharmacists in that jurisdiction to use the measure, providing another hurdle. While it could be a positive outcome for temporary COVID-19 responses to become permanent, having impractical policies become permanent reduces pharmacist opportunities to practice independently.

Some existing and COVID-19 policies can cause friction with other health professionals, as they are perceived to be clinically unsuitable for pharmacists (e.g. Continued Dispensing), or because the activities encroach into other professional spaces and scopes of practice (e.g. COVID-19 testing as pathology collection). As a result, there is a potential for a decrease in trust between professions (if not necessarily at the level of individual providers, then at the level of professional peak bodies), which may hinder opportunities for pharmacists to increase their clinical responsibilities.

3.2.2. Policy context

3.2.2.1. Pharmacy policy context in Australia. Similar to the *policy characteristics*, in which there are a range of policies that govern and affect pharmacy practice, currently in Australia, the policy actors involved in the development of these diverse types of policies include multiple sectors. For policies to be developed and implemented, governments, government bodies/agencies/advisory committees, and health departments are also engaged — as Australia is a federation, both federal and jurisdictional branches are involved, albeit to different extents. Depending on the policy, the mandate may fall on either the federal or jurisdictional government to resource and enact.

Notably, pharmacy professional peak bodies are invested in ensuring policies are developed that benefit the pharmacists they represent, and the patients and consumers they serve. Key stakeholder groups in the area of pharmacy policy include the PSA, the peak national professional organisation representing all pharmacists; the Guild, representing community pharmacy owners; and the SHPA, representing hospital pharmacists. Given their different constituencies, there are sometimes disparate within-profession views on the pharmacy profession and industry, and subsequently, different policy approaches to health issues. As pharmacists work within a healthcare system alongside other health professionals, other key actors involve medical practitioners (including general practitioners and specialists) and nurses, and their representative groups are often consulted or have strong opinions.

In terms of community pharmacy policy, the Guild plays a highly

prominent and influential role in shaping its direction, and has been recognised as being one of the most powerful lobby groups in Australia.[29–31] The community pharmacy sector exists in a public-private relationship, where pharmacies are small businesses that must be owned by registered pharmacists, and receive funding from the federal government to supply and dispense PBS medicines.[27] The Guild's lobbying activities have resulted in protecting pharmacy owners from competition, most notably through their successful opposition to relaxing ownership laws to allow non-pharmacist owners, and location rules preventing new pharmacies from opening within a certain distance from an existing pharmacy. Their influence can be due to the deep relationships formed between the organisation's leadership and members, and politicians; donations to both political parties; and the presence of pharmacies in every community and electorate across the country.[32] While they will often work with the PSA to improve opportunities and services that affect all pharmacists and pharmacy patients, ultimately, their work is in the interest of community pharmacy owners. This demonstrates the importance and centrality of the Guild in any policy development or changes affecting community pharmacy in Australia.

3.2.2.2. Opportunities to expand scope of practice. Pharmacists in Australia are perceived by the public and by policymakers as appropriate people to provide healthcare because they are: trained as experts in medicines; very accessible to the public, especially community pharmacists; and trusted health professionals. Additionally, they have started to be involved in other areas of health services provision, such as vaccinations, pharmacist prescribing, and chronic disease screening and monitoring (including blood pressure checks, blood glucose and cholesterol monitoring, and provision of sleep apnoea services).

Currently (and over the last few decades), there has been a push towards expanded scope of practice across many countries, for which many pharmacy groups worldwide are advocating.[3–5,8] This is the current discourse highlighting the direction that pharmacists should be moving towards, affecting the current culture in pharmacy practice. International evidence of effectiveness and good health outcomes from pharmacist-delivered services are incentives for Australia to follow with increased opportunities. Additionally, this places pressure on policymakers and stakeholders in Australia to avoid being 'left behind'. The International Pharmaceutical Federation (FIP) provides resources for countries that want to implement specific services, and facilitates learning between countries — in the COVID-19 pandemic context, this included prescribing and administering vaccinations (routine and COVID-19 vaccines); offering COVID-19 testing at pharmacies point-of-care; manufacturing hand sanitiser; renewing prescriptions and pharmacist prescribing; and telehealth services.

As mentioned previously, Australia has a federated governance system which affects how healthcare is delivered. This often results in the state/territory jurisdictions implementing pharmacy programs or expanding pharmacist opportunities in an independent and uncoordinated manner. However, this system also enables jurisdictions to push each other along to 'keep up', and to learn from each other. For example, pharmacist-administered vaccination programs are developed and implemented at the jurisdictional level, and as one jurisdiction expands their program (e.g. through the addition of vaccines, addition of government-funded vaccines, lowering minimum age, vaccinating in locations outside of community pharmacies), other states/territories are incentivised to follow suit. Another example where a minority of jurisdictions are piloting a new service is COVID-19 testing in community pharmacies, offered opportunistically to individuals requesting cold/flu symptom relief products. These demonstrate how state-level innovation can potentially encourage expansion of pharmacists' scope of practice.

In 2019, the Council of Australian Governments made the Quality Use of Medicines and Medicines Safety the 10th National Health Priority Area. Coupled with the federal Royal Commission into the Safety and Quality of Aged Care, it is evident that there are significant medicines-related harms that individuals experience. The underlying principle relevant to pharmacists is that individuals need good and appropriate access to medicines. This applies in the pandemic context, as a core role for pharmacists was to ensure their patients could continue to access their medicines despite not being able to physically see a medical practitioner, or if they were affected by medicine shortages. Measures like digital image prescriptions, Continued Dispensing, therapeutic substitution, and the Home Medicines Service were implemented or expanded to allow pharmacists more freedom to perform this core role. Thus, the continued framing of pharmacists' vital role in ensuring appropriate medicines access presents opportunities for pharmacists to use their skills as medicines experts to improve patient outcomes, and play a more significant role alongside other healthcare professionals in promoting health.

Government investments in telehealth and digital health also provide an additional and bigger environment for pharmacists in which to clinically practice. These include medication management services via telehealth and electronic prescriptions, both of which were significantly escalated during the pandemic. Thus, this newer digital space allows expansion of scope, by presenting more opportunities for pharmacists to help patients who are less accessible.

Finally, the Guild's political and lobbying power could assist with expanding scope of practice. The Guild has an interest in expanded opportunities that will benefit community pharmacies as businesses, and they may use their political influence to push for expansion of pharmacy services in the interests of community pharmacy owners. If there are appropriate policy options that intersect with the interests of the Guild, then this could be a synergistic opportunity for programs to be developed and implemented.

3.2.2.3. Constraints on expanding scope of practice. While pharmacists in Australia are considered medicines experts and can conduct activities beyond medication dispensing and counselling, the skills to perform some of these expanded services are not necessarily a part of a pharmacist's initial training; these are supplementary skills that need to be learned, which requires time, resources, and will from individual pharmacists, the pharmacy profession, the general public, and politicians and decision makers. Additionally, although there may be a few pioneers and leading advocates for additional pharmacy services, potential within-profession hesitation and risk-aversion may constrain the policy space.

In terms of institutional structures, jurisdictions may have their own legislative and regulatory approaches, and a federated health system can limit scope of practice if programs require national consistency for implementation and operation. This was also important considering most of the policy changes affecting pharmacy practice listed in Table 1 have been made at a national level, but enacted at the jurisdictional level. The structure may also result in legal uncertainties and loopholes, where a pharmacists may be allowed to use an emergency measure at a national level, but not on a jurisdictional level. This was seen during the pandemic with the TGA's therapeutic substitution scheme, which was designed to enable pharmacists to independently substitute a medicine in shortage situations; however, some jurisdictions required an additional public health order to be issued. In the future, this could hamper the development and implementation of national programs that have the potential to expand scope of practice.

Another institutional factor is an absence of national leadership and representation of pharmacists in the federal Department of Health due to the lack of a federal Chief Pharmacist role. As a result, there is a limited voice in that environment to develop policies that can expand scope of practice. While some jurisdictions have a Chief Pharmacist, the PSA believes that if there were a federal Chief Pharmacist, they would "fight for the role of pharmacists in this pandemic" as well as enable a "consistent and rapid implementation of relevant measures during public health emergencies and … strategic national leadership in

improving an overall medicine safety and quality use of medicines agenda for Australia."

As mentioned previously, there are a range of pharmacy professional bodies in Australia who represent different interests, and these differences can pose constraints if unity is necessary for expansion of scope. Even if interactions between peak bodies are generally productive, it is likely that there will be different visions and goals, and means of achieving them.

Another key component of policymaking for community pharmacy in Australia involves the Guild. While their political influence has the potential to expand scope of practice, it could also act as a constraint if the Guild argue *against* certain services, or *for* services that may be detrimental for the pharmacy profession as a whole. The group represents community pharmacy owners — a minority of the profession — and there are certain policy directions for community pharmacy of which the Guild is not in favour. An example of this is the embedding of pharmacists in residential aged care facilities (RACFs) and general practice, where the Guild believes it will weaken the connection between community pharmacies and these facilities, even though it presents increased opportunities for pharmacists as health professionals to use more of their skills as medicines experts, and as part of a larger multidisciplinary clinical team.

Finally, a lack of understanding or appreciation of pharmacists' roles from other healthcare professionals can constrain the development of more opportunities for pharmacists. Public interactions with other healthcare professional peak bodies (e.g. medical and nursing groups) have sometimes been tense, or there has been a lack of understanding as to what pharmacists actually do, or could do. Having other health professionals undermine pharmacists is not conducive to allowing pharmacists more opportunities, and it would be better to have the support of other health professionals and a working collaborative approach. Other professional groups could potentially have influence on the policymaking process and constrain the services that pharmacists can deliver; additionally, the 'turf wars' that play out in the media could affect public confidence in pharmacists and negatively shape their perceptions of them. Although it is unclear the extent to which this hinders expansion of pharmacy practice, it could still affect the general perceptions of pharmacists and the collaborative relationships in practice.

3.2.3. Policy circumstances

3.2.3.1. Current agenda-setting circumstances. The quote "never let a good crisis go to waste" has been used ubiquitously in the media throughout the COVID-19 pandemic to describe situations in which individuals or organisations have capitalised (or should capitalise) on the current crisis and its rapidly changing nature to advance their goals (not only for pharmacy policy, but also other policy issues). The pandemic has afforded opportunities for decisions to be made more quickly and with fewer bureaucratic hurdles, and for new or stronger collaborations between stakeholders. As the pharmacy profession has already been in an active state of policy reform over the past decade, these opportunities may facilitate pharmacy advocates to promote their agenda of expanding scope of practice to improve individual and public health, as well as increase their professional capacity.

Additionally, governments have a political need to address the health and social impacts of the pandemic; for example, several Australian jurisdictions underwent scheduled elections, and elected officials needed to demonstrate that their handling of the pandemic and future policy directions were favourable enough to justify re-election.

3.2.3.2. Opportunities to expand scope of practice. Federal and jurisdictional governments have a political imperative to address COVID-19 urgently, to contain any current and future outbreaks, and to effectively rollout a COVID-19 vaccination program, in order to mitigate health and economic impacts on the public. Therefore, governments need to rely on the expertise and work of healthcare professionals, and this is a recognised opportunity for pharmacists to draw from their existing skills to assist in addressing those needs — this includes ensuring continued medicines access, providing vaccinations in community pharmacies, educating the public about masks and hygiene, referring individuals presenting with cold/flu symptoms to get tested, and organising essential deliveries under lockdown situations. Successful delivery from the pharmacy sector could demonstrate to policymakers and elected officials the necessity of pharmacists in health crises and further establish an expanded role.

Additionally, there has been increased recognition of pharmacists and perception of their accessibility, by the public and policymakers. Community pharmacies remained physically open during the pandemic (particularly in the early months), compared to some general practice clinics that closed, or only accepted existing patients or telehealth appointments. Pharmacies became busier with new and existing patients consulting pharmacists as their first point of call. This led to an increasing recognition of pharmacists as primary care clinicians who could provide advice and/or treatment for minor ailments, while still referring to general practitioners when necessary, as well as an increased trust in pharmacists to manage medicines requirements. The pharmacy response to the pandemic has illustrated that pharmacists can potentially have an increased role in primary care, including remuneration for the management of non-urgent conditions through community pharmacies instead of through hospital emergency departments.

Another example that highlighted the accessibility of community pharmacies was their involvement in COVID-19 testing in South Australia and Queensland. Pathology collection (especially for infectious diseases) is not typically a usual activity of pharmacists and within community pharmacies; this pilot strategy would enable pharmacists to opportunistically identify symptomatic individuals for point-of-care testing at the pharmacy. Involving pharmacists in this manner could increase the prominence of pharmacies as a health hub, thus maximising community value; and enable pharmacists to become involved in other pathology collection services, providing an avenue to expand scope of practice in this direction.

3.2.3.3. Constraints on expanding scope of practice. The pandemic and health response has also shown instances where constantly shifting political and policy dynamics may constrain the expansion of pharmacists' scope of practice. An example of this was the lack of pharmacy representation on the Australian Technical Advisory Group on Immunisation (ATAGI) COVID-19 Working Group, which was established to provide advice to the federal government concerning the use of COVID-19 vaccines. This working group contained three sub-groups on: 1) vaccine utilisation and prioritisation; 2) vaccine distribution and program implementation; and 3) vaccine safety, evaluation, monitoring and confidence.[33] As pharmacists were not 'in the room', their perspectives were not heard nor represented, and this could constrain the extent of pharmacists' role in the COVID-19 vaccination rollout, and other future vaccination delivery.

In opportunities under the *policy circumstances*, COVID-19 testing in community pharmacies was presented as a potential pathway for pharmacists to play a larger role in healthcare delivery; however, the debate that occurred over this particular pandemic response may have constrained the broader discussion around expanded scope of practice. There was disagreement *within* the profession over COVID-19 testing in pharmacies: the Guild (particularly in Queensland) were in favour of the intervention, citing it as "another asset to protect Queenslanders" and that "community pharmacy has a proud history of playing our part in the evolution of Queensland's primary health care network."[34] However, other pharmacy groups, such as the Pharmaceutical Society of Australia and Professional Pharmacists Australia, were against the proposal, as it could be seen to encourage symptomatic individuals to leave their home, thus endangering pharmacy staff and the community, and undermining

public health messages. This disagreement was *publicly* expressed, which could affect policymakers' and the public perception of pharmacists, potentially casting doubt on expanded services.

Additionally, to some pharmacy advocates, COVID-19 testing in pharmacies was seen as a steppingstone to further service delivery (pathology), but the perception that pharmacists only have profits in mind could constrain scope of practice. The push from the Queensland branch of the Guild, especially compared against the response from other pharmacy groups, could be seen as placing politics and member interests over public health and safety, particularly as the pandemic is ongoing and outbreaks are likely to occur. This example supports the argument made by those generally opposing further pharmacy scope expansion — pharmacists prioritise financial or professional interests over individual and public health interests, when discussing more opportunities for service delivery. For example, this argument has been used by Australian medical peak bodies to oppose pilot programs for expanded pharmacist prescribing for urinary tract infections[35] and other chronic diseases.[36,37] The appropriateness for pharmacists to test individuals for COVID-19 and for pharmacies to be testing locations, calls into question the judgement of community pharmacy advocates on providing other services. Overall, this could adversely affect the discussion of expanding pharmacists' scope of practice.

4. Discussion

This analysis builds on other research that categorises changes and new programs introduced in the pharmacy space in response to COVID-19[1,38–40] by considering how each of these pandemic responses – combined with the current political, institutional, and health policy context – may support or constrain the future expansion of pharmacists' scope of practice. This kind of analysis is useful in pharmacy practice research as it recognises that decision makers' commitment to growing the policy space may fluctuate over time, but also offers insight into ways pharmacy policy actors can advocate for overlooked or unconsidered policies.

In Australia, some of the key opportunities afforded by the pandemic include the potential for temporary measures to become permanent; critical health crisis moments that necessitated a larger health workforce capacity (e.g. to administer vaccinations in an outbreak of a more transmissible COVID strain); and new responsibilities provided to pharmacists. As community pharmacists are medicines specialists in primary care, there has been a push for pharmacists to be able to prescribe, whether according to a protocol, in collaboration with other prescribers, or independently.[41,42] Continued Dispensing requires pharmacists to make a clinical decision as to the suitability of patients continuing with their medicine, which is effectively a form of prescribing. Pharmacy advocates have considered Continued Dispensing as a pathway to more opportunities for pharmacists to prescribe, and its permanence after the pandemic is a desirable outcome.

However, there were some key constraints demonstrated through the pandemic response. Structural factors such as minimal institutional representation through a federal Chief Pharmacist position in the Department of Health, as well as on the COVID-19 vaccination working groups may also limit the extent to which pharmacists can advocate for expanded roles in the health system. A lack of understanding or definition of pharmacists' role from both outside and within the profession may also pose barriers. Policies that constrain scope of practice, like the TGA Therapeutic Substitution Scheme, reflected a perception from bureaucrats that pharmacists must be instructed on how to substitute each product in the case of a medication shortage, instead of allowing them to use their existing clinical knowledge and judgement. Compared with the expanded Continued Dispensing initiative, this scheme has a negative effect on the pharmacist prescribing agenda as it undermines pharmacists' clinical ability. A lack of definition of pharmacists' role was also seen from within the profession, evident in the debate around COVID-19 testing within pharmacies. Although proponents may have thought community pharmacies were suitable access points for COVID-19 testing, it was unclear whether the act of pathology collection would have been performed by pharmacists, and whether this should be an additional responsibility for pharmacists during the pandemic. It also suggests that clarification is needed in defining the role of the pharmacist as a clinician versus the community pharmacy as a setting for healthcare delivery.

Internationally, similar priorities for dealing with the pandemic have seen pharmacists' responsibilities increase to ensure that patients' access to medicines were maintained, as well as capitalising on the accessibility of community pharmacies and pharmacists as the public's first point of contact in the health system.[1,38,39] Many countries in Europe developed pharmacy pandemic responses similar to those in Australia, such as allowing pharmacists to manufacture alcohol-based hand disinfectants/sanitisers, involving pharmacists in medicines delivery to patients' homes, introducing electronic prescriptions, renewal of medicines for chronic treatment, and substitution or replacement of medicines experiencing shortages.[1,39,40]

However, there were other countries that implemented additional measures, particularly making us of pharmacies as local community settings with accessible health professionals. For example, given the heightened risk for individuals experiencing domestic violence under COVID-19 lockdowns, in France, the Netherlands, and the United Kingdom (UK), pharmacists could be alerted via a codeword and assist individuals at risk of domestic violence.[1,43] These codeword schemes have been operating in countries such as Spain, Italy, and Argentina,[44] and their increasing use and legitimisation could be an opportunity for community pharmacists to deliver psychological interventions, and expand scope of practice in this direction.

Other examples are found in Canada and the UK, where pharmacists already deliver a wider range of services compared to Australia, such as formalised minor ailment schemes[39,45] (where community pharmacists provide advice, prescribe treatment, and/or refer for minor ailments) and pharmacist prescribing (which involves different models with different levels of pharmacist autonomy and responsibility). Both of these services are examples of activities that expand pharmacists' scope of practice, particularly the pharmacist prescribing agenda. In Canada and the UK, decision makers responded to the COVID-19 pandemic by allowing pharmacists to prescribe and/or supply controlled drugs in certain circumstances,[1] indicating further trust in pharmacist prescribing. In conjunction with other European countries also implementing pandemic responses such as emergency supply or continued dispensing of patients' regular medicines, this highlights a general trajectory towards increased pharmacist prescribing, with the COVID-19 pandemic providing many opportunities and avenues to facilitate this.

In Australia, scope of practice comprises activities in which a pharmacist has the required level of competence, professional accountability, and legislative authority to perform a specified activity.[18,23] There does not appear to be a definitive list of services that pharmacists are aiming to provide; rather the aim is for pharmacists to be able to practice to their "full scope", which includes activities under the categories of prescribing, reviewing medications, chronic disease management, triage and referral of patient symptoms; administering medicines, and ordering and interpreting laboratory tests.[46,47] As long as other countries also seek to expand pharmacists' scope of practice, this provides the basis and models for countries like Australia to follow suit and consider how 'new' services could be implemented within their context and practice framework.

Clarifying the scope of practice and the rationale behind each new activity will be necessary to ensure that patient and public needs are met. The example of COVID-19 testing in pharmacies – while a potential gateway to pathology collection performed by pharmacists – highlighted the lack of consideration for the value that pharmacists would add, compared to the risks to pharmacy staff and to the public. This is not to suggest that expansion of scope in this manner should not occur, but that the *purpose* of additional services should be considered beyond simply

enhancing professional interests.

4.1. Limitations

This study relied on data collected by only one author during the COVID-19 pandemic while policies were constantly changing, and directives and guidelines were being updated. In some situations, new sources did not include all details about program changes, and a lot of specific details were not publicly available through documents (e.g. regarding the COVID-19 testing pilots in community pharmacies). Additionally, the search for documents involved purposive and snowball strategies meant that this was not a fully exhaustive policy review; however, it was decided that this would be one of the more systematic and suitable approaches available. Finally, opportunities to interview key policy actors would have strengthened the analysis; however, it is unlikely they would have responded to requests for interviews given their role and preoccupation with the pandemic response.

Despite these limitations, sufficient data were obtained to undertake this exploratory policy space analysis. Further research in the future involving key informant interviews may yield a richer understanding of how the pandemic shaped policies affecting pharmacy practice. As the COVID-19 pandemic still continues (including the rise of more transmissible variants), and the healthcare responses needed are continually changing, this analysis should not be considered the end of the story, but rather as a piece to help inform pharmacy practice policy as it is evolving.

5. Conclusion

The COVID-19 pandemic has highlighted the integral role that pharmacists play in the healthcare system. This policy space analysis demonstrated that the various pharmacy responses to the pandemic as well as the surrounding policy context have provided opportunities and constraints for the pharmacy sector currently seeking to expand pharmacists' scope of practice. In order to successfully and appropriately expand scope, policy advocates and decision makers should consider how pharmacists can best use their clinical expertise and accessibility to improve patient health.

Author statement

Kellia Chiu: Conceptualization, methodology, investigation, formal analysis, writing – original draft, funding acquisition (scholarship obtained).

Anne Marie Thow: Conceptualization, methodology, formal analysis, writing – review & editing, supervision.

Lisa Bero: Conceptualization, methodology, formal analysis, writing – review & editing, supervision.

Declaration of competing interest

None.

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