

Making policy in emergencies – insights for routine policy making. The case example of opioid pharmacotherapy maintenance

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# Making policy in emergencies – insights for routine policy-making

## The case example of opioid pharmacotherapy maintenance

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Richard Mellor, Matthew Kearnes, Kari Lancaster, Laura McLauchlan, Alison Ritter

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### MAKING POLICY IN EMERGENCIES – INSIGHTS FOR ROUTINE POLICY-MAKING THE CASE EXAMPLE OF OPIOID PHARMACOTHERAPY MAINTENANCE

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#### **Executive summary**

#### Introduction

COVID-19 has precipitated significant policy changes to many health and social welfare services. One area of policy change has been the opioid pharmacotherapy maintenance program. A treatment for opioid dependence, this pharmacotherapy treatment provides a prescribed, safe opioid medication of proven efficacy and cost-effectiveness in improving health and wellbeing, reducing mortality, and reducing illicit opioid consumption.

The opioid pharmacotherapy maintenance program serves some of society's most marginalised members, and is often characterised by lack of flexibility and limited choice, resulting in experiences of stigma, control, and surveillance rather than supportive care. People receiving treatment may experience insecure housing, poor health status, be in receipt of income or disability support, and many have experienced incarceration. Stigma and discrimination in the context of opioid pharmacotherapy are well-documented. It is a highly regulated treatment, for example despite research evidence that takeaway doses — collection and self-administration rather than supervised dosing — can enhance treatment outcomes, these have been limited to date. In Australia, the medications are Schedule 8 drugs, and as such have significant regulations concerned with their prescribing and dispensing.

In this report we consider the conditions that enabled changes to opioid pharmacotherapy policy in response to COVID-19 in three Australian jurisdictions. In response to the emerging conditions precipitated by public health measures to address the pandemic, changes to opioid pharmacotherapy policies in Victoria, NSW and the ACT entailed efforts to reduce face-to-face contact between clients and the people dispensing and prescribing the medications. The policy changes included changed guidance on takeaway dosing allowing increased numbers of unsupervised doses; regulations enabling the delivery of these medications to people in isolation or quarantine; rapid expansion of long-acting injectable treatment formulations; and the expansion of more flexible prescribing practices.

This work focussed on the processes that enabled and facilitated these new policy guidelines. We aimed to analyse:

- How the policy changes came about (e.g., what committees were organised, what discussions took place, and what other practices were carried out during the policy-making process);
- Who was (or was not) involved in the process, and what perspectives were accounted for;
- Whether this was business-as-usual, or a case of policy being done differently; and
- The lessons that can be learnt and key insights to inform future policy-making.

Semi-structured in-depth interviews (n=22) were conducted with policy stakeholders (including government, drug user representatives, senior clinicians and clinical advisors to government) who were involved in the policy changes for pharmacotherapy treatment in three different jurisdictions in Australia (the ACT, NSW, and Victoria).

#### **Findings**

Context matters for policy making

There were five contextual features for this case example of policy-making:

- 1. Opioid pharmacotherapy maintenance policy is characterised by stigma and discrimination: participants frequently characterised pharmacotherapy policies and treatment as "punitive", "prohibitive", "rigid", and "restrictive".<sup>1</sup>
- 2. A substantial evidence-base, built over many years of research, had demonstrated the importance of increasing the flexibility of pharmacotherapy treatment. This evidence-base included concrete policy proposals that have been part of wider policy conversations for some years.
- 3. There were widely acknowledged shortcomings with the treatment system before the pandemic "our current system was already not prepared for the current demand in the absence of a pandemic, let alone this current scenario" (# 13). Issues that posed a problem before the pandemic for instance unmet demand for opioid pharmacotherapy treatment, and the shortage of prescribers became more pressing issues in the context of the pandemic.
- 4. Past emergencies, for example the 2019-2020 Australian bushfires, provided a backdrop to understanding system failures. Like COVID-19, during the bushfires "people were trapped at home, couldn't go outside, the air quality was really bad, moving around [was limited]" (# 5). This meant that there were already elevated levels of concern driven by past experiences.
- 5. COVID-19 created and was seen as a public health emergency. At the time of this research, this came with a sense of urgency and a strong feeling of common purpose. Participants talked of a sense of all working together to achieve the same goals, and being driven and motivated by a shared commitment.

'Business as usual' policy-making processes

Before describing the features of policy-making under emergency conditions, we summarise the participants' perspectives on usual policy processes. These were characterised by:

- Slow formal decision-making processes;
- Committee processes (described as "byzantine") that create stability and also inertia. Policy
  making was reliant, for example, on "formal all-day meetings that are of dubious value" (# 1);
- Committee membership was characterised by "a seat at the table" (# 15 and 11) and the "usual suspects";
- There was unclear or diffuse responsibility, described as "cop out" practices where policy change is "everyone and no one's responsibility" (# 5);

<sup>&</sup>lt;sup>1</sup> All material in double quotation marks comes from interviews conducted as part of this study. For those quotes greater than a couple of words, the interview number is provided after the quote.

- Decision-making structures were described as fragmented and siloed;
- Perceptions of separateness in the sector a "battleground" like atmosphere with everyone having "their own kind of barrow that they're pushing" (# 13); and
- A lack of political will to change policy.

Policy-making processes under emergency conditions

With COVID-19, including the anticipation of it in late 2019-early 2020 and the reality of it in 2020/2021, the policy processes as described by participants were characterised by:

- A crisis mode, moving from "business as usual into crisis mode" (# 11), and a sense of urgency;
- A strong "authorising environment", where "normal processes of checks along the way became much less rigorous" (# 22);
- There was a shorter chain of command, with "quick unfiltered feedback";
- Timeframes were significantly condensed and those involved in the policy change processes were "making time for meetings.... working long hours to draft up new guidelines" (# 10);
- Given the large uncertainties around COVID-19, there was room to ask "what-if..." questions;
- In addition to formal committee structures for voicing concerns and decision-making (the ubiquitous "table") a new form emerged, that of a huddle: the huddles were seen as more responsive, flexible, problem-solving venues, where "solutions to tricky problems" (# 10) were developed;
- Huddles were characterised by "short punchy meetings" that "really quickly address the
  issues" (# 22). These features provided a "different structure". For people participating in the
  huddles it fostered a sense of togetherness they were described as "fun", "inspiring", and
  "amicable" experiences;
- Policy processes were described as collaborative, with reduced conflict and a strong sense of common purpose; for example: "we were all working together more beautifully than normal rather than people pointing fingers and being angry" (# 21); and
- Policy making was allowed to be "good enough" rather than perfect, and importantly there
  was a sense that decisions were supported: "we will back you to take the risk. What we won't
  do is throw you under the bus if it's not perfect" (# 5).

#### Insights to inform future policy making

The insights speak to the actions of three different types of policy actors (viz the bureaucrat, the drug user representative, and the clinician). Some insights may be more applicable to one set of actors than another, but we assume a model of policy-making where it is the network of mutually-dependent actors that achieves policy reform.

#### (1) Recognise that many ideas and solutions are already there

The problem(s) with opioid pharmacotherapy maintenance treatment and the restrictive nature of the guidelines and regulations were well-known. There were also well worked out and articulated solutions that were available. This reminds us that many ideas are already floating around, held in peoples' minds or listed as past agenda items in committees. Many new ideas have been subject to research and analysis (that may languish in old issues of journals, or in disciplinary siloes). A crisis precipitated the opportunity for existing ideas to be revisited. One insight therefore is the opportunity to mobilise existing ideas in the absence of a public health crisis. We suggest value in establishing mechanisms for old ideas to be re-surfaced (for example putting them on meeting agendas) such that they can be considered under routine policy-making conditions.

#### (2) Be receptive to new ideas which emerge through flexible problem framings

Whereas past attempts to change the regulations had been stymied by perceptions of the risks outweighing the benefits, in the circumstance of COVID-19 the imperative to act opened-up risk framings to instead focus on what might be possible, in an evolving situation of need. The pandemic also facilitated a wider conception of both risks and benefits and created the conditions where different forms of knowledge became relevant (for example, 'let's think about what transport people use to get to the pharmacy'). Multiple and diverse forms of evidence, and ways of thinking about the problems became available. Mobilising capacity for flexible problem framings allows for intervention pragmatism and policy responsiveness, even in the midst of uncertainties. The tendency for policy to be fixed (stultified) should be resisted, with regular, ongoing assessment of new possibilities and new ideas given flexible problem framings.

#### (3) Create flexible problem-solving venues (huddles)

Our research has shown that the pre-existing formal decision-making venues (the *tables* of participation) presaged new flexible forms of problem-solving and decision-making venues (the *huddles*). Bringing this new form to routine policy-making may have value. In practical terms this may involve meeting without set agenda items and employing strategies to facilitate and enable more innovative problem-solving. Making room for uncertainty and "what-ifs" might be one way to facilitate a problem-solving approach. Sometimes simply changing the physical environment for meetings can engender more flexible problem-solving.

#### (4) Review formalised systems (such as committees, and who has a seat at the table)

The existing policy-making structures enabled the *huddles* to emerge. It was often the case that the same network of actors who participated in the *tables* also participated in the *huddles*. This then suggests that it is vital to consider membership of committees in times of routine policy-making. Our findings suggest that we might forgo the usual 'representation' role of committee members, and ask 'do we have the right people in the room?'.

#### (5) Allow new lights to shine

While we observed in this research that the 'usual suspects' who participate in the formal preexisting decision-making processes were engaged in the new form of the *huddles* and were central actors to the policy changes, there were also new voices that emerged. Some of these voices played dynamic roles. This suggests that making the space for new voices, and providing encouragement and support for new natural leaders to emerge may improve routine policy-making.

#### (6) Build relationships

The research revealed that rather than seeing relationship-building and trust as peripheral, and a nice 'added extra' to good policy-making, these were essential to effective policy-making in times of crisis. This suggests that investment and resources put into building interpersonal knowledge, trust and relationships is a vital part of good policy infrastructure.

#### (7) Assign resources and labour

The distribution of resources and labour was uneven. In most cases, non-government and drug user representatives were not resourced to undertake the additional policy development work (though service provision was resourced). While some other actors could put existing projects on hold, the NGO and drug user groups could not. This meant significant labour and long working hours for these policy stakeholders. Ensuring that labour and resources are equitably spread amongst key policy actors and stakeholders is essential.

#### (8) Increase the sense of responsibility and empower participation in policy-making

An apparently powerful intervention early in the COVID-19 pandemic was to hold so-called "insider briefings" about COVID-19, for all policy stakeholders (including government and non-government and peer organisations). This appeared to create a strong sense of shared responsibility and empowerment. Using the idea of "insider briefings", open to anyone, is a potential strategy to increase participation, increase responsibility, facilitate new voices, and create an environment where no stakeholder is left behind.

#### (9) Back innovation, back people, and create systems capable of innovating

A strong message was the sense of support and being "backed" in decision-making. Acknowledging risk and uncertainty seemed inevitable under COVID-19: the key challenge is how to recognise risk and uncertainty in times of routine policy-making and not let that stymie innovation. Systems capable of innovating have components of all the insights here. When innovation is allowed to occur, backing people is essential. Processes which harness innovation (including being less risk averse, backing and funding proactive people, allowing uncertainty and "good enough" policy) will facilitate improved routine policy-making.

### (10) Ensure that the people in the system responsible for implementing the changes are part of the decision-making processes

One participant suggested that providers who were part of drafting of the policy reforms were more likely to provide more flexible treatment, whereas other practitioners were less likely to do so. This suggests that it is important to facilitate the presence of those responsible for implementation in the decision-making process. Whilst this is impractical in its entirety, there are key clinicians and service providers who should be involved in the decision-making in order to enhance implementation. Champions, opinion-leaders, those with the highest caseloads are all ways of identifying the most important clinicians to engage in policy design.

#### (11) Don't sacrifice good patient-centred clinical practice

In the haste to reduce face-to-face contact (or other risk factors) for COVID-19 or other future emergencies, an eye on patient-centred practice is required. One of the solutions available under COVID-19 involved the rapid scale-up of a relatively new medication option — depot buprenorphine. The research and clinical experience with this new medication (which involves weekly, fortnightly, or monthly injections administered subcutaneously by a healthcare provider, doing away with the need for daily dosing) was underway before COVID-19. Given the need to reduce face-to-face contact, depot buprenorphine was a perfectly situated solution. The positive aspect of this has been scale-up and increased access to new treatment options, especially to under-served populations such as people in prison; the risk is that patient choice is compromised. Maintaining patient choice is vital.

#### (12) Think systemically

COVID-19 forced consideration of people's daily lives – not just as patients, but as people in the context of the physical and social world. This broader context highlighted, for example, that treatment access relies on a range of infrastructure (such as public transport). Logistics questions became paramount (for example for those with disabilities). A different way of thinking about the lives of people receiving pharmacotherapy maintenance was enabled. It highlighted the multiple governmental worlds (of health services, employment services, transport services, housing services) that patients navigate and negotiate daily. Under routine conditions, taking a systemic perspective in policy-making not only forces a reframing, it enables proactive problem-solving.

#### (13) Reduce system fragmentation

Relatedly, system fragmentation stood in the way of new solutions. The bureaucratic structures and silos (for example the BBV and AOD silos) were able to be reduced (in some instances) to allow more effective problem-solving. One observation was the way Zoom enabled much greater participation in policy discussions from diverse (and geographically dispersed) stakeholders. Future policy work should continue to use video conference as a mode of engagement which could facilitate system defragmentation and the wider inclusion of diverse voices. Experts and peers also mobilised across state borders to share information and guidelines, which in turn gave purchase to advocacy efforts and facilitated shared learning. Reducing system fragmentation is much easier said than done (and has been a longstanding policy agenda). Strategies to reduce fragmentation at the macro (state), meso (community) and micro (client) level would all enhance routine policy-making.

#### (14) Organise as a community

One of the comparisons that has been made is between the policy response to HIV in the mid-1980s and the COVID-19 response today. Community mobilisation was key to the HIV response, where community action and expertise were relied on as central to the policy process. This involved community organising and new configurations of power, which have been maintained such that HIV policy continues to innovate. Alcohol and other drug communities are not (yet) as well mobilised, empowered or resourced, despite a strong history of drug user activism in Australia. The long-term goal is to have a powerful, resourced, and mobilised community that drives innovation.

#### **Conclusions**

This case study of opioid pharmacotherapy maintenance policy-making in a time of crisis, revealed that policy-making processes can adapt and change. In the context of a public health emergency, that emerged in the context of wider recognition of shortcomings in the policy settings regulating opioid pharmacotherapy treatment, seemingly intractable policy problems were addressed rapidly, in ways that were flexible and inclusive. A number of insights have emerged that can inform policy-making under routine conditions. There is little reason to think that these insights do not also apply to other aspects of alcohol and other drug policy, and also to health policy more generally, and indeed to all domains of policy work: education, transport, social welfare and so on.

At time of writing, some of the policy reforms in relation to opioid pharmacotherapy maintenance have been wound back; others are still in place. While the aim of this report was not to provide an evaluation of the effectiveness of the policy changes that have occurred over the last 18 months, evaluations being conducted in each of the jurisdictions studied here will clearly be crucial. Our research points to the need for policy evaluations to address the insights pertaining to decision making processes, and the collaboration between actors and organisations, that we detail in this report in addition to assessing the substance of policy changes.

There continue to be crises, whether they are triggered by a health crisis (pandemic), an economic crisis (a recession), or an environmental crisis (floods, bushfires). Indeed scholarly literature and analysis points to the fact that routine policy-making processes are unlikely to serve as effective structures for decision-making in times of multiple and overlapping crises. New forms, people and processes need to be mobilised to respond rapidly and effectively. Innovation is key. Yet what is also clear is that we need innovation (and better policy) every day. Waiting for the next crisis to mobilise better policy-making is not the solution. We are surrounded by enduring crises: people in receipt of opioid pharmacotherapy are marginalised and can experience crises in the everyday, for instance unstable housing and unemployment. Beyond individuals receiving treatment, the system itself is in chronic crisis; for instance the large unmet demand for opioid pharmacotherapy treatment, or the shortage of prescribers. There is a continuing urgency to improve policy responses, through better, more innovative processes that surface new and existing ideas, engage in collaborative problemsolving, have participation from varied existing and new stakeholders, take risks, and back people to implement them.

#### Introduction

There have been significant changes associated with the provision of health and social care services due to COVID-19. This has included the provision of drug treatment services, where reduced face-to-face contact has required transition to e-health and virtual care models, introduction of personal protective measures, reduced service delivery where social distancing and physical constraints on space have been required, alternatives to fixed site service provision found, and new harm reduction measures to reduce risks of COVID-19 introduced (Dunlop et al., 2020; European Monitoring Centre for Drugs and Drug Addiction, 2020; Marsden et al., 2020; van de Ven, Ritter, & Stirling, 2021). While all drug treatment services have been affected, we focus here on one particular drug treatment, opioid pharmacotherapy maintenance (Grebely, Cerdá, & Rhodes, 2020). Opioid pharmacotherapy maintenance<sup>2</sup> provides a safe, legal and prescribed supply of opioids to people who are opioid dependent. The treatment is available globally, and has very strong evidence of its efficacy and effectiveness in improving health and wellbeing, reducing mortality, and reducing illicit opioid consumption (Amato et al., 2005; Connock et al., 2007; Ling, Shoptaw, & Goodman-Meza, 2019; MacArthur et al., 2012; Mattick, Breen, Kimber, & Davoli, 2014; Nielsen et al., 2016; Platt et al., 2018).

The opioid pharmacotherapy maintenance program serves some of society's most marginalised members, and is often characterised by lack of flexibility and limited choice, resulting in experiences of stigma, control, and surveillance rather than supportive care (Crawford, 2013; Fraser & valentine, 2008; Radcliffe & Stevens, 2008; Treloar & valentine, 2013). Clients³ receiving treatment may experience insecure housing, poor health status, be in receipt of income or disability support, have experienced incarceration, and Aboriginal people are over-represented within the program (Australian Institue of Health and Welfare, 2020; Magwood et al., 2020; Peacock et al., 2021). Experiences of stigma and discrimination in the context of opioid pharmacotherapy are well-documented, and patients are not seen as trustworthy (Crawford, 2013; Fraser & valentine, 2008; Lancaster, Seear, & Ritter, 2018; Radcliffe & Stevens, 2008; Treloar & valentine, 2013). It is a highly regulated treatment, where medications are consumed under supervision, rather than given to be consumed later by patients – known as take-home or takeaway doses (Berends, Chalmers, & Lancaster, 2015; Harris & Rhodes, 2013; Lintzeris, Lenne, & Ritter, 1999; Ritter & Di Natale, 2005).

Across the globe, necessitated by COVID-19, changes have been made to the provision of opioid pharmacotherapy maintenance (British Columbia Centre on Substance Use, 2020; Farhoudian et al., 2020; Lintzeris, Hayes, & Arunogri, 2020; Substance Abuse and Mental Health Services Administration, 2020). These have been largely similar and have been characterised by reduced face-to-face contact, increases in the availability of unsupervised dosing, adoption of e-health

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<sup>&</sup>lt;sup>2</sup> There are many different terms and acronyms for opioid pharmacotherapy maintenance: Opioid Assisted Therapy (OAT), Opioid Substitution Treatment (OST), Medication Assisted Treatment for Opioid Dependence (MATOD), Opioid Maintenance Treatment (OMT) and Methadone/Buprenorphine Maintenance Treatment (MMT). In Australia, each jurisdiction uses its own term. Throughout here we use the term 'opioid pharmacotherapy maintenance'.

<sup>&</sup>lt;sup>3</sup> In pharmacotherapy treatment, people in receipt of care are either referred to as 'clients' (more common outside the medical system) or 'patients' (common in the medical system). As one form of treatment for drug dependence, pharmacotherapy maintenance sits more clearly within the medical system (requiring prescribers and pharmacists or nurses to dispense the drugs). In this report we use both terms interchangeably.

interventions, and expansion of long-acting injectable opioid medications, which reduce the frequency of face-to-face contact between clients and clinicians (Lintzeris et al., 2020). There is unsurprisingly significant interest in tracing the outcomes and impacts of these policy changes to the program (Lintzeris et al., 2021; Livingston, Ameral, Banducci, & Weisberg, 2021). Our interest here however is in the policy-making processes that facilitated such changes. Given the tight regulations that surround opioid pharmacotherapy maintenance programs, for example in Australia the medications are Schedule 8 drugs, we think it provides a very useful case study of policy-making under conditions of emergency. We sought to understand how the policy changes were made, who was involved in the processes, differences from policy-making under routine conditions, and insights that can improve policy-making in the future.

This work focussed on three Australian jurisdictions: New South Wales (NSW), Victoria, and the Australian Capital Territory (ACT).<sup>4</sup> Table 1 provides background information for each jurisdiction, in terms of population figures, pharmacotherapy treatment data, and the features of COVID-19 with reference to the year 2020.<sup>5</sup> The key differences to note are the population size differences (ACT 431,114 people, NSW 8.2 million people, and Victoria 6.7 million people). In terms of opioid pharmacotherapy treatment, prescribing and dosing is done almost exclusively through private practices in Victoria, whereas in NSW and the ACT, treatment provision is shared by public and private providers (see Table 1). Relative to NSW and the ACT, in 2020 the COVID-19 pandemic was more severe in Victoria, in terms of the cumulative case numbers and deaths associated with COVID-19 and the length of concurrent lockdown measures (see Table 1).

The main changes to pharmacotherapy actioned in response to COVID-19 in these jurisdictions were increased provision of takeaway unsupervised dosing, the delivery of medications to people in isolation or quarantine, increased use of telemedicine, increased expansion of long-acting injectables, and the expansion of more flexible prescribing practices..

In terms of takeaway dosing, the NSW Ministry of Health released a memorandum on the 18<sup>th</sup> of March 2020, indicating that prescribers and clinics were not expected to adhere to numerical limits on takeaway doses during the COVID-19 public health emergency (NSW Health, 2020). On the 11<sup>th</sup> of April 2020, similar guidance was released by the Victorian Department of Health and Human Services (DHHS), again allowing providers to step outside the standing takeaway dosing limits when considering patient risk during the COVID-19 pandemic (Department of Health of Human Services, 2020). On the 13<sup>th</sup> of July 2020, the ACT Health Directorate issued contingency guidelines, instructing that up to three additional takeaway doses are permitted during a declared public health emergency and where a person cannot access their usual dosing site (ACT Health Directorate, 2020). Further, should a client need to isolate or be placed in quarantine, up to and exceeding fourteen takeaway doses could be provided upon approval, under the ACT contingency guidelines (ACT Health Directorate, 2020). As a supplement to government guidance, on the 21<sup>st</sup> of April 2020, the national

 $<sup>^4</sup>$  Most of the changes to opioid pharmacotherapy were initiated at the state rather than national level in Australia.

<sup>&</sup>lt;sup>5</sup> The table references the calendar year 2020 (the first case in Australia was detected in January 2020) corresponding to our period of interest when the policy changes were made. Since then, the Delta variant has increased the number of cases and deaths and lockdown measures have also been reintroduced across all three jurisdictions.

interim guidance for the delivery of pharmacotherapy in response to COVID-19 was also issued by experts in the field (Lintzeris et al., 2020). In this national document it was recommended, among many other things, that the limits on takeaway doses should be increased – for instance, allowing up to six takeaway doses of methadone per week for "low risk" clients during COVID-19 (Lintzeris et al., 2020).

Other changes in healthcare provision brought further adaptations to pharmacotherapy treatment. In March 2020, the COVID-19 Home Medicines Service was developed as a temporary program which provided a "fee per delivery payable to Australian pharmacies for the home delivery of Pharmaceutical Benefits Scheme (PBS) and Repatriation Pharmaceutical Benefits Scheme (RPBS) medications thereby removing the need for a patient to visit a Pharmacy" (Pharmacy Programs Administrator, 2020). Governments from all three jurisdictions issued similar guidance around the delivery of opioid pharmacotherapy medications. It was recommended that in the event of a client isolating or being placed into quarantine, the medications could either be delivered to the client by a health provider in the first instance, or if that were not an option, an approved nominated agent – a family member, friend, or carer - could collect the medications on the client's behalf (ACT Health Directorate, 2020; Department of Health of Human Services, 2020; NSW Ministry of Health, 2020b). Additionally, in the ACT further steps were taken regarding the delivery of pharmacotherapy medications. On the 5<sup>th</sup> of June 2020, technical amendments were made to the legislation in the ACT to ensure the legal protection of any agent delivering the medications. In amendment 631 and 632 of part 15.1 of the Medicines, Poisons and Therapeutic Goods Regulation 2008, any person nominated as an agent of a pharmacotherapy client during the COVID-19 emergency, or under other contingency guidelines, would be exempt from prosecution under the Act in the ACT.

Other changes to pharmacotherapy included the increased expansion of telemedicine across Australia to reduce the need for in-person treatment visits, wherein it was recommended that telehealth be used for regular reviews and the monitoring of clients (Lintzeris et al., 2020). More flexible prescribing practices were also expanded, for instance in Victoria prescription durations were extended for up to 6 months, and medical practitioners allowed to prescribe buprenorphine/naloxone for up to 30 patients without prior training (an increase from 5 patients) (Department of Health of Human Services, 2020). Experts and governments, particularly from NSW, also encouraged the acceleration of implementation of long-acting injectable products in response to COVID-19, including transferring patients receiving sublingual buprenorphine to depot buprenorphine, and providing depot buprenorphine to new treatment entrants (Lintzeris et al., 2020; NSW Ministry of Health, 2020a).

This project examined the following questions:

- How did the policy changes come about (e.g., what committees were organised, what discussions took place, and what other practices were carried out during the policy-making process)?
- Who was (or was not) involved in the process, and what perspectives were accounted for?
- Was this business-as-usual, or was this a case of policy being done differently?
- What lessons have been learnt and what are the key insights to inform future policy making?

#### **Method**

#### Sample

Semi-structured interviews were conducted with policy stakeholders (from the government, peer and non-government sector) who were identified as being involved in the pharmacotherapy treatment policy changes in the ACT, NSW, and Victoria. Potential participants were initially identified based on the research team's existing knowledge of drug policy leaders and people referred to in publicly available reports and communications about the opioid pharmacotherapy maintenance program. In the interview encounter participants also mentioned the names of other people closely involved in the policy processes, and these individuals were then invited by the research team to participate in an interview.

Overall, 22 interviews were conducted with 21 people: one participant was interviewed twice because they were closely involved in the policy processes in two jurisdictions. Besides one interview which had a national focus, the remaining interviews focused on a single jurisdiction: 6 interviews focused on the ACT, 7 on NSW, and 8 on Victoria. The interviews were conducted with a range of policy stakeholders, including treatment providers and clinical directors (n = 7), government policymakers (n = 5), representatives of people who use drugs (n = 5), researchers (n = 3), and representatives from peak bodies of alcohol and other drug treatment services (n = 2). We have deidentified the interview data and do not report by jurisdiction to preserve the anonymity of the participants.

#### Data collection

All semi-structured interviews were conducted between August 2020 and March 2021 over videoconference. The interviews followed a range of domains related to the policy changes surrounding pharmacotherapy treatment, including what policies were changed, how the policies were changed, who was involved in meetings and discussions, the role of participation in drug policy more broadly and within the case study, the backdrop to the changes (what brought them about), and views about the permanence of the policy changes. The interviews lasted between 32 and 78 minutes (average length 60 minutes) and were audio-recorded and transcribed verbatim with informed consent. Ethics approval was received from the UNSW Ethics Committee (HC200510).

#### **Analysis**

Once transcribed and checked for accuracy, a complete read-through of all the interviews was followed by an iterative process of coding and mapping the data to identify key thematic categories and produce a descriptive analysis. The descriptive analysis was generated using both inductive codes through close reading of the interview accounts and deductive codes derived from the interview schedule, extant literature, and the research questions. Key thematic categories covered: processes of policy-making (for example formal meetings and out of session conversations), an analysis of who was involved in the policy-making process (including identifying those with long-standing engagement and new people); the role of consumer participation in policy processes; and the role of communication and knowledge sharing. Interview material was also reviewed to identify any historical and contextual features associated with the policy changes.

Once the descriptive analysis was completed, we prepared a document summarising this work, and engaged in team-based collaborative analysis, with the authors plus three experts (Dr Will

Tregoning, Unharm, Dr Mary Harrod, NUAA and Dr Marianne Jauncey, Uniting) all of whom have indepth expertise in drug policy. The aim of the collaborative analysis process was to distil key lessons and insights for policy making (for decision makers, for clinicians and for advocates). Through this iterative process (with drafts of key insights circulated, revised, and refined) we distilled 14 key insights for future policy making.

In the quotes given below, participants are identified by a unique interview number, and not which jurisdiction they are from or their position/role, given the risk of identification when conducting interviews with a relatively small group of key actors who potentially know each other and have a long history of working together (Lancaster, 2017).

We present the findings according to the following areas. First, we consider the backdrop against which these policy changes arose. It was clear that COVID-19 and the sense of urgency this afforded was the most saliant background feature, but a number of historical and contextual factors form part of understanding the policy change process. We also explore how the policy changes were made, including the various actors and organisations who triggered policy discussions, and the different types of formal meetings and out of session discussions convened to discuss and develop policy documents. Thirdly, we focus on who was involved in the policy discussions and who did the work. Fourthly, we focus on participation in the decision-making, with particular reference to consumer participation in the context of this case study. Finally, we also consider other aspects, including some features of implementation of the policies arising from the data, communication and information sharing, and reflections by participants on the future of the policy changes.

This report provides a largely descriptive analysis. Further in-depth analyses will be conducted and published in the form of journal articles<sup>6</sup>.

<sup>&</sup>lt;sup>6</sup> The first of these is currently under review at the *International Journal of Drug Policy* (see Mellor et al., {under review]).

Table 1. Key background information on Australian jurisdictions, COVID-19 case numbers and opioid pharmacotherapy treatment characteristics in 2020

	New South Wales (NSW)	Australian Capital Territory (ACT)	Victoria
Size of the total population <sup>1</sup>	8,164,128 persons	431,114 persons	6,694,884 persons
Pharmacotherapy treatment data <sup>2</sup>			
Number of clients (on a given day)	22,949 (281.1 per 100,000 persons)	1,120 (259.8 per 100,000 persons)	14,968 (223.6 per 100,000 persons)
Medication type	Methadone: 62.4% of clients	Methadone: 68.9% of clients	Methadone: 62.3% of clients
	Buprenorphine: 37.6% of clients	Buprenorphine: 1.0% of clients	Buprenorphine: 2.9% of clients
	Buprenorphine-naloxone: not available	Buprenorphine-naloxone: 19.8% of clients	Buprenorphine-naloxone: 30.4% of clients
	Long acting injectables: not available	Long acting injectables: 10.3% of clients	Long acting injectables: 4.3% of clients
Prescribing setting	Public prescriber: 35.1% of clients	Public prescriber: 57.8% of clients	Public prescriber: 0.5% of clients
1	Private prescriber: 54.2% of clients	Private prescriber: 30.8% of clients	Private prescriber: 93.9% of clients
	Correctional facility: 10.7% of clients	Correctional facility: 11.4% of clients	Correctional facility: 5.6% of clients
Dosing setting	Public clinic: 20.3% of clients	Public clinic: 17.0% of clients	Public clinic: none
	Private clinic: 10.2% of clients	Private clinic: none	Private clinic: none
	Pharmacy: 51.6% of clients	Pharmacy: 71.6% of clients	Pharmacy: 91.8% of clients
	Correctional facility: 10.5% of clients	Correctional facility: 11.4% of clients	Correctional facility: 5.6% of clients
	Other: 7.3% of clients	Other: none	Other: 2.6% of clients
COVID-19 data			
First case of COVID-19 reported	25 <sup>th</sup> January 2020	12 <sup>th</sup> March 2020	25 <sup>th</sup> January 2020
Total cumulative case numbers <sup>3</sup>	4,734 (57.99 per 100,000 persons)	118 (27.37 per 100,000 persons)	20,365 (304.19 per 100,000 persons)
Total cumulative deaths <sup>3</sup>	56 (0.61 per 100,000 persons)	3 (0.70 per 100,000 persons)	820 (12.24 per 100,000 persons)
Main lockdown periods during	National lockdown (23 <sup>rd</sup> March – 28 <sup>th</sup> of April	National lockdown (23 <sup>rd</sup> March - 1 <sup>st</sup> of May	National lockdown (22 <sup>nd</sup> March – 11 <sup>th</sup> of May 2020): non-essential
2020: this table only reports the	2020): non-essential businesses closed and	2020): non-essential businesses closed and	businesses closed and stay at home orders in place
lockdown measures directly related	stay at home orders in place	stay at home orders in place	The 'second wave' (29th June – 8th of November 2020): non-essential
to pharmacotherapy policy in 2020,	The 'Northern Beaches cluster' (19th		businesses closed and stay at home orders in place. Initially this was
including limits on movement away	December 2020 – 9th January 2021): stay at		imposed to ten 'hot spots' in Metro Melbourne and grew to include all of
from home and the closures of	home orders in place for the Northern beaches		Melbourne and the Mitchell Shire.
businesses. It excludes other public	starting on the 19 <sup>th</sup> of December, and ending		The 'lockdown of the towers' (4th July – 18th July 2020): around 3,000
health measures, for instance limits	on the 2 <sup>nd</sup> of January for the southern part of		residents of a public housing estate were not allowed to leave their home
to household and public	the Northern Beaches, and January 9 <sup>th</sup> for the		under any circumstances. For most residents this lasted for five days, but for
gatherings, mandates on mask	northern part.		11% of residents (33 Alfred Street) this lasted two weeks.
wearing, closures of schools,			The 'hard lockdown' (2 <sup>nd</sup> August – 27 <sup>th</sup> of October 2020): this was imposed
international travel bans and			for Metropolitan Melbourne. It included curfews where persons had to
quarantine, state border closures,			remain at home between 8pm and 5am (mandated between the 2 <sup>nd</sup> of
vaccinations etc.			August and the 27 <sup>th</sup> of September 202). Persons also had to stay within a
			5km radius of their home. The 5km radius was imposed between the 2 <sup>nd</sup> of
			August and the 18 <sup>th</sup> of October 2020, at which time it was extended to a
			25km radius. The 25km radius was in place until the 8 <sup>th</sup> of November 2020.

'Stay at home orders' refers to government guidance to only leave home for essential reasons, including: shopping for food or essential items, medical care or compassionate needs, exercise, and work or education that cannot be performed from home.

Note 1: Population estimates are sourced from the ABS National, state and territory population, June 2020 ABS cat. no. 3101.0 (Australian Bureau of Statistics, 2020).

Note 2: Pharmacotherapy treatment data sourced from the National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection, 2020 (Australian Institue of Health and Welfare, 2020).

Note 3: Includes total cumulative count as at 31st December 2020 (Australian Government Department of Health, 2021).

#### The backdrop to the policy changes

#### Context: COVID-19

The global COVID-19 pandemic and the associated interventions including the public health measures have been experienced as seismic shifts in all aspects of life on earth. In Australia, while case numbers have remained relatively low (see Table 1), the public health measures have impacted people's work, leisure, relationships, and the ways people are governed. The policy environment in early-mid 2020 was described as one where "public health trumps all things" (# 11). The two contextual features arising from COVID-19 at the time of this study which were conducive to the policy changes were a "sense of urgency" and a "common purpose". <sup>7</sup>

In terms of the "sense of urgency", given the relatively low case numbers in Australia, particularly in NSW and the ACT (see Table 1), it was mostly anticipated news about COVID-19 from other countries which prompted the "sense of urgency":

"[From the news overseas], it was obvious that even the normal functions of society were starting to stop... we knew we had to push really hard to have a strategy in place, otherwise we'd have [all clients in the state] potentially going without their pharmacotherapy." (# 11)

One participant, having been in another country with high COVID-19 case numbers, spoke about coming from the future:

"I just can't tell you how coming from the future helped me do the work. You know, it was like freedom of movement will be restricted. How are we going to authorise the people on [pharmacotherapy] to go to the clinic every day? (# 5)

The sense of urgency was a "key ingredient" in the policy-making process: "you put the word COVID in the title and people felt like they had to respond earlier" (# 21). It meant that "people were making time for meetings.... working long hours to draft up new guidelines and, I don't know, there was a sense that we're all working together, [user group], the [health services], the [health department], patients" (# 10). It also meant that people were providing "quick unfiltered feedback" (# 21), and everyone was "empowered to solve the problem with a time pressure on it" (# 5) rather than the usual "cop out" practice where policy change is "everyone and no one's responsibility" (# 5).

Perhaps related to this sense of urgency, participants also spoke about a "common purpose" when explaining how the policy changes to pharmacotherapy were made in a rapid manner. There was a strong sense that the "common purpose" was made available by the apprehended COVID-19 crisis in Australia, and having pharmacotherapy declared an "essential health service":

"I think everyone was working towards the common sense of purpose. There was a ... I guess we had this underlying assumption and agreement and recognition that the provision of [pharmacotherapy treatment] is an essential health service." (# 2)

<sup>&</sup>lt;sup>7</sup> We are aware that both a sense of "common purpose" and "urgency" has since appeared to wane, an aspect for further analysis.

There was also a sense that the "common purpose" was unique to the emergency conditions of the pandemic and not something normally seen in the sector:

"So, there was definitely something special about this in the middle of a pandemic, that we were all working together more beautifully than normal rather than people pointing fingers and being angry." (# 21)

The newfound "common purpose" amongst the sector was cited as one of the main reasons why policy change was able to occur: "because of the crisis everyone was really driven and motivated and working towards the common sense of purpose and I think that's how we were able to achieve what we did" (# 2). One benefit of having a common purpose was that it brought people together, which again was conducive to policy change:

"The fact that everybody has come together with a pretty common purpose makes all the difference really.... some of the things which are done maybe on the basis of you know old biases and judgements or you know moral judgements if you like go, out the window and so that's enabled us just to be much more objective around what can be done and what might be the harms and what might not be." (# 22)

"In this situation we weren't dealing with conflict between stakeholders, because everyone was really working towards that common sense of purpose." (# 2)

"Something happened in government and I don't know if it was from leadership or where it was from, but [it] was that good enough is good enough, and that was the thing. Like it didn't have to be perfect, it didn't have to be 100%, and part of the narrative that we went in on was that we will back you to take the risk. What we won't do is throw you under the bus if it's not perfect. Like let's do the thing together." (# 5)

There was also a sense that past emergencies, for example bushfires, contributed to the sense of urgency, given the known system failures at that time. Like COVID-19, during the Australian bushfires of 2019/2020 "people were trapped at home, couldn't go outside, the air quality was really bad, moving around [was limited]" (#5). This meant that concerns were already elevated, and "people were already really sensitive and fearful because through that process [the bushfires], several people in the community had problems accessing pharmacotherapy maintenance" (# 5). Participants recalled pharmacotherapy not being prioritised during the bushfires which meant "it became obvious that we were going to have to agitate fairly hard with the right people in order to not be in a situation where Australia locked down and potentially pharmacies were closing without notice" (# 11).

#### Context: Stigma and discrimination

Participants frequently characterised pharmacotherapy treatment as "punitive", "prohibitive", "rigid", "restrictive" and "regulated". This could be why any movement in this area was characterised as a success:

"so they did the agent [delivering medications] thing... wow, wow how fucking revolutionary. And that's revolutionary, believe it or not, that's revolutionary in pharmacotherapy land." (# 11)

The interview accounts reinforced the pre-existing stigma and discrimination against clients of pharmacotherapy maintenance. This came to the fore when new policy options were being considered. For example, in terms of the collection and delivery of medications, governments emphasised that the medications should be delivered by clinicians, and the collection of medication by agents (friends or family) was a last resort option because of the perceived misadventure that may arise:

"It's really quite common for people on these drugs to come in and say, "I lost it [my medication], my dog ate it." They come up with every excuse under the sun and so I was expecting that we would start to get this problem if we were going to start having arrangements for the collection of doses and unsupervised dosing. We would end up getting patients claiming that they never got it and wanting either a second dose and that would pose a risk of double dose for themselves or on the flipside of that, you know, the patient's partner or girlfriend or boyfriend would, you know, we would speculate that they would take the doses themselves just based on our experience." (# 2)

The mistrust of pharmacotherapy clients was evidenced by one participant recalling that pharmacies were unwilling to deliver the pharmacotherapy medications under the broader COVID-19 Home Medicines Service program. Outside the program itself, clients were also perceived to be more likely to be targeted by police. This was heightened in the context of lockdowns where people could only leave home for essential reasons:

"Nothing to do with pharmacotherapy, state [public health] policies really, in many, many cases, put the fear of God into people, because the fines were huge and if you were employed, my God, they would be hard enough to pay, but if you were unemployed, I don't know and, you know, people were getting, you know, we had reports of people that were targeted and charged for traveling in areas where they shouldn't be, even when people were like, we actually had cases of people being charged when they were on a train going to get a dose and things like that." (# 7)

#### Context: Pharmacotherapy flexibility an existing issue

Discussions which preceded the pandemic were also seen as important. A substantial evidence-base, built over many years of research, had demonstrated the importance of increasing the flexibility of pharmacotherapy treatment. This evidence-base included concrete policy proposals and had been part of a wider policy conversation for some years:

"We have been tossing around the same issues for at least three years about how do we improve access, where do we do, is it prescriber training, is it prescriber engagement, is it dosing points, what do we do differently, and all of that has been slow... we looked at some legislative amendments to make it easier for prescribers, we have looked at pharmacy change, the takeaway limits [...] and all of that takes 6 to 12 months every time." (# 21)

There was also a sense that fostering a more flexible pharmacotherapy treatment program was a low priority for governments until COVID-19:

"[Increased takeaway dosing] has kind of been not a high-priority conversation until, from a government perspective in particular, until we got to COVID, and then we had COVID and

governments had to kind of think fast to figure out a way to ensure that people had ongoing access to pharmacotherapy, particularly in the context of having to self-isolate and all of that sort of stuff." (# 14)

The policy changes were felt to be something that was continually yet to come, and always in the pipeline. For example, one participant mentioned that there had been conversations between the state government and service providers around expanding outreach programs, and whilst they "got funded in COVID, we've been talking to the government about it for 12 months" (# 15). In terms of the changes around prescribing which were lifted by the TGA during the pandemic, one participant noted that there has been "a push over the last, I'm going to say 5 years or so, to reduce training requirements, so that more people can prescribe pharmacotherapy and reduce some of those kind of burdens around that" (# 13). The increased expansion of depot buprenorphine is another example that preceded COVID-19. As noted by one participant: "there's more involved with COVID right, there's also the fact that depot products are available, so that's also been a game changer for the system" (# 1). In the prison system particularly, "they had already started putting patients on to depot buprenorphine, but they just massively sped that up [during COVID] ...because they prefer it, because it's less administration resources and it's not divertible." (# 15)

In summary, the COVID-19 pandemic made available a sense of urgency and common purpose in early-mid 2020 in Australia, which was described as being unique and ultimately conducive to policy change. Existing contextual features, including the stigma and discrimination against people in receipt of pharmacotherapy maintenance and a long history of discussions around increasing the flexibility of pharmacotherapy treatment, were described as being an important part of the story.

#### How were the policy changes made?

We focus on four areas when describing how the policy changes were made: (1) the initiation of the policy changes (what prompted or triggered action); (2) the formal committees centred around the policy changes; (3) the more tight-knit conversations that happened outside the formal committees; and (4) other features of the policy processes, including managing uncertainty.

#### The initiation of the policy changes

We consider whether policy processes were initiated as a top-down or a bottom-up process, for both agenda-setting (getting the issue up as an area for attention) and for policy change itself (getting a new policy instigated). A diversity of patterns was observed across the three jurisdictions for both agenda-setting and policy change, including bottom-up and top-down agenda setting, and bottom-up and top-down policy change.

In the case of bottom-up agenda-setting, clients of the programs and their representatives "rang the alarm":

"... holy fuck we're going to be in serious deep shit guys, help, help, help..." (# 11)

"Clients were coming in [to XXXX] or ringing in and with significant concerns about continuity of treatment during any lockdown...we had maybe 20 or 30 people drop-in or ring up and like hyperventilating that they were going to lose their takeaways and they weren't going to be able to dose." (# 11)

Where clients had driven the agenda, government then stepped up to take charge of policy changes:

"the government agencies that were in charge of policy and policy changes, were actually very responsive, you know, to the concerns of the consumers where most of the, I'd say most of the concerns actually came from the consumers." (# 3)

However, elsewhere, the agenda was being set by government, where participants perceived that even before the first COVID-19 cases were detected in Australia, there was health department awareness of the issue, and presentations being made to inform stakeholders. For example, an existing government-convened alcohol and drug committee was provided with early information about COVID-19 and early modelling results:

"...a really effective explanation of how pandemics spread and what effective tools we have to mitigate that spread and then ... applied that in our circumstances and gave us some modelling showing what it would look like if we did nothing compared to what it would look like if we put in certain mitigating actions." (# 10)

One participant suggested it was "the first time that I started hearing about COVID... I hadn't paid much attention to it [COVID-19] and she rang me and said, no you've got to come to this [the presentation] and so I went right away and that was kind of the start of it" (# 1). The presentation was described as "such an effective presentation... no one left the room without looking pale and with a sudden sense of urgency that they needed to ... and this was really before, I don't even know if we had any cases in Australia at that point." (# 10)

We observed strong government leadership of the policy response when government had set the agenda:

"It kicked off at the beginning of the year [2020].[...] At the end of February [2020] what [the jurisdictional government] started doing right then was talking to all the clinical directors of the [health services].[....] Early discussions were again you know – we are going to have to get our house in order around here and in particular what we need you to do is think about preparedness planning [....]." (# 12)

The above participant goes on to describe the establishment of government meetings from the first week in March 2020.

In contrast to either a client-driven or government-driven agenda-setting process, clinician-led agenda-setting was also observed:

"So we initiated within that broader [committee], a small project team, and it was a great project team ... people with lots of experience of service delivery, two pharmacists and you probably know these people who were just terrific, just terrific and really enthusiastic ... Okay. Whatever comes out of this broader group, we will collate it we'll collect it we'll drop what we're doing, we will put out communications we'll liaise with [health department], if there's things that need to be drafted, this little project team can draft it and we can then put it up so that was the genesis of a really effective little working group that then met at least weekly or via Zoom to drive the work." (# 6)

Where clinicians led the agenda-setting, they appeared to also lead the policy change process:

We also invited [health department] to be involved. Now, whether or not they didn't have the resources or were too busy, or all of the above, they weren't as involved as closely as I think we would have liked and I think that created some issues in the end." (# 6)

The importance of clinicians driving the policy change was noted by another participant:

"The [health services] really were the ones who drove you know in each of their services that change from seeing people face-to-face to doing all the interventions via telephone or via video teleconferencing where they could [...] and the home delivery or the mixture of you know the issues to do with home delivery was probably driven a lot by the local services and you know changing the frequency with which people are seen and that was also driven by them to some extent." (# 22)

While each jurisdiction had different processes, mobilising occurred across state borders. In this case study, this was particularly so amongst treatment providers and consumers, not governments. The only key policy document developed at the national level (to our knowledge) was the national interim guidance for opioid pharmacotherapy during COVID-19, which was developed outside the scope of governments. Federal government structures were de-centred in the pharmacotherapy reform processes. Arguably state government structures were also de-centred where agenda-setting and policy development occurred amongst clients and clinicians.

#### Formal committees and the figure of the table

There are a range of existing structures in Australia to support the inclusion of diverse voices and needs in the policy-making process. Embedded in these structures are a range of established formal committees which routinely meet, including advisory groups, working groups, and consumer panels. The sole remit of some of the existing committees is opioid pharmacotherapy treatment, while others cover all types of alcohol and other drug treatment services. These formal committees have diverse representation from all areas of the sector, including state governments, public and private treatment providers, drug user organisations, general practitioners, pharmacists, regulators, and so on. In the interview accounts, participants often spoke about the importance of these formal committees when accounting for the policy-making process. In so doing, the figure of the *table* was often used when describing the events and processes associated with these formal committees.

In terms of the policy changes to pharmacotherapy treatment in the context of COVID-19, it was often suggested that the formal committees did not actually meet very often in the period that coincided with the policy changes. Nevertheless, the formal committees and the figure of the *table* were often talked about in the interviews when describing how the policy changes were made. It appeared that having a "seat at the table" (# 15 and 11) was more important than the actual meetings themselves. It provided members with a certain status in the drug policy field, which meant that state governments had to ensure that the members were "comfortable" with whatever policy changes were proposed, even if those conversations happened "out of session":

"For this particular project, look we did a lot of out of session discussions with [the formal committee], so we knew that those members had to be comfortable, because that's our official pathway of approval for anything [pharmacotherapy] related. I think we only had one

actual meeting of [the formal committee] in that period when we were developing the documents, whereas [another group] were meeting weekly, but talking about a whole raft of issues. It's not that I think one was better than the other, but I am pleased I had access to the [other group] that I normally wouldn't have." (# 21)

This suggests that although the formal committees met infrequently during the period that coincided with the policy changes, the committees were still the government's "official pathway of approval" (# 21). This meant that "members had to be comfortable" (# 21) with whatever policy changes were proposed and consulting with them was seen as a requirement. Relatedly, another benefit of the formal committees was that they provided governments with an existing, established group of relevant stakeholders:

"I guess because of [the formal committee] we did have that established network of local stakeholders whom we could quickly and easily draw upon and convene to start working through these issues." (# 2)

This suggests that, in the context of these policy changes, having "a seat at the table" was very important. As will be seen in the following sections, the ad-hoc meetings which occurred when things were taken *off the table* so to speak, included the same people who had a seat at the formal committees. Thus, the seat provided members a status in the field which meant that they were seen to be important in the policy-making process — even though these policy-making processes happened outside the standing formal committees.

#### Out of session conversations and the figure of the huddle

If the *tables* provided an established network of actors who needed to be consulted, the out of session conversations appeared to be where policy discussions and decisions took place. This happened in all jurisdictions. It often involved existing formal committees being repurposed and changed to focus on COVID-19 related matters, or new groups emerging as an accessory to existing formal committees.

When describing the out of session conversations we use the figure of the *huddle*. We borrow the term *huddle* from the NSW Ministry of Health. In early March 2020, they started what they called "COVID huddles", which initially acted as out of session conversations involving internal employees, but later morphed into much larger communities of practice in the context of the broader public health response in NSW (Lyons, Cox, & Clements, 2020). In the below section we use the term *huddle* more generically, without specific reference to the NSW "COVID huddles" but as a term to describe out of session processes.

Recalling that the backdrop of the COVID-19 pandemic made available a "sense of urgency" and "common purpose", we see these two contextual features characterise the *huddles*, suggesting that the *huddles* were adaptive to context. This is evident in the following description provided by one participant when explaining participation in the *huddles*:

"People always made time to participate and particularly everyone participated [in the huddle], so it was a good opportunity for *people to all be on the same page* which was really important. I mean, I think, because it's not necessarily a strength of [the government] to have you know *short punchy meetings*, you know, that *really quickly address the issues* 

without too much you know *extraneous discussion* and it was an important sort of *different structure* I suppose for us." (Emphasis added, # 22)

In this description we see that the *huddles* are described as being "a good opportunity for people to all be on the same page" (# 22). This suggests that a "common purpose" was emergent through the *huddles*. The meetings were also described as "short punchy meetings" that "really quickly address the issues" (# 22). This suggests that a "sense of urgency" was also emergent through the *huddles*. It was also stated that these features provided a "different structure I suppose for us" (# 22), which suggests that the *huddles* of participation were a new form emerging in response to the COVID-19 pandemic. But despite the importance of COVID-19 for the emergence of the *huddles*, these ad-hoc modes of engagement were also made possible by the networks and committees embedded in existing institutional structures which have informed drug policy for decades (Mellor, Kearnes, Lancaster, McLauchlan, & Ritter, under review). The "same network of actors" who participated in the *tables* also participated in the *huddles*. Without the network of actors established around the enduring *tables*, the rapid institutional flexibility which set the context for the *huddles* would have not been possible.

The "common purpose" which was emergent through the *huddles* also made available transformative experiences. More specifically, for people participating in the *huddles* it fostered a sense of togetherness. The interviewees who were involved in the *huddles* described them as "fun", "inspiring", and "amicable" experiences, involving "shiny, happy people wanting to have hugs at meetings" (# 14).

Importantly, this sense of togetherness seemed to have the potential to travel beyond the immediate context of the *huddles*:

"We've been really empowered and energised by getting together and working together in that way and it's shown us that we can formulate, you know, those sort of responses going forward." (# 14)

This participant has suggested that "getting together and working together" (# 14) is something that can be preserved "going forward", which reveals how the "common purpose" and the transformative experiences of togetherness which were made available through the *huddles*, also have the potential to impact how things are done in the everyday.

Another characteristic of the *huddles* was that they had a problem-solving focus. The *huddles* were often characterised as having a "brainstorming and problem-solving approach" (# 1) and being a "troubleshooting forum". The *huddles* were also where "solutions to tricky problems" (# 10) were made:

"The huddle for example was where we worked through the policy issues for amending takeaway doses, because it seemed like the solution seemed a no-brainer." (# 12)

It is striking that amending takeaway doses has been described as a "no-brainer" in this context, especially because this policy issue has historically engaged diverse views.

Moreover, the "common purpose" seemingly meant that people could discuss policy issues in an "objective" way without "old biases and judgements":

"The fact that everybody has come together with a pretty common purpose makes all the difference really [....]some of the things which are done maybe on the basis of you know old biases and judgements or you know moral judgements if you like go out the window and so that's enabled us just to be much more objective around what can be done and what might be the harms and what might not be." (# 22)

The *huddles* opened up different experiences, and we see in the above quote an account of being "objective" instead of basing discussions on "moral judgements".<sup>8</sup> One participant suggested that in the *huddles* people were able to discuss "what the true COVID agenda is versus what, like individual players' agendas might be" (# 18).

While the *huddles* afforded different experiences and a sense of shifts in decision-making processes, some of the existing, underlying issues, such as stigma and discrimination did not get attended to:

"It was so difficult, because we just didn't have enough time, these policies had to be developed so quickly, like we literally had a week to get them together and to get the draft together. [...] I've talked about forgetting the important stuff, the judgment and the stigma, like that was just bad enough anyway, COVID aside, but when you're adding COVID, it just ramped up and so you know, like what I'm saying before, you know, pharmacotherapy consumers were fined on a train going to get a dose.[...] The whole stigma and discrimination was something I wish we'd spent a lot more time talking about..." (# 7)

The rapid nature of the policy changes might have silenced conversations of stigma and discrimination which have historically underscored discussions of takeaway dose modifications and other pharmacotherapy related issues.

#### Other features including managing uncertainty

Operations moved from "business as usual into crisis mode" (# 11) — "I said, guys, this isn't a normal thing, this is a crisis, we need to think in that frame of mind, we need to be working at a different level" (# 11). This crisis mode did many things: it created an "authorising environment" ("because of the situation, it's evolving quickly, and so a lot of the normal processes of checks along the way became much less rigorous and that's enabled rapid change" (#22)); it was easier to get funding (senior bureaucrats were "a bit less concerned about the money than they normally would" (# 21)); there was a shorter chain of command ("my management line instead of going our normal sort of method through up to the [senior person], it went slightly sideways path to the CHO" (# 21)); and timeframes were shorter ("I think some of the bureaucratic processes and timeframes that we would normally be operating under just were broken down somewhat, because we had to get this done so quickly" (# 2)).

The rapidly changing COVID-19 policy environment is characterised by uncertainty. There were and continue to be many unknowns about COVID-19, and in this case study, uncertainty needed to be managed. The goal of managing uncertainty looked to be connected to the broader public health response:

<sup>8</sup> We note that this appears to bifurcate moral judgement and objective decision making, both concepts could be subject to critique and further analysis.

"I think the internal processes I mentioned, how we link into the broader kind of, because there's a huge juggernaut for the public health emergency response that is going on and the you know ... it's how we link into that and make sure that there's a source of truth, because one of the things that we were very attuned to at the beginning is if we are saying "do a." but then the whole of the [jurisdiction] health system says, "do a plus b" that could cause confusion particularly during when senses are heightened during a crisis, people really were quite panicky to begin with." (# 12)

In relation to opioid pharmacotherapy treatment, COVID-19 presented a lot of "what-ifs" which animated policy-maker's concerns. In the early-2020 there were not answers to these concerns:

"What happens when my pharmacy shuts?" "What happens when my pharmacy shuts and the pharmacy is closed?" "What happens when I go to the clinic at the hospital and the hospital is locked down?" And for a good few weeks, no one had any answers to those questions, including the pharmacies and the hospital clinics and us, because no one had had to deal with it before." (# 14)

Other examples of "what-ifs" included questions about whether pharmacies would remain open in increasingly restrictive lockdown conditions, how isolation rules would impact on access, and how increased policing of public health orders would affect clients. These questions were animated by the uncertainty brought forward by COVID-19:

"Anyway, so there was a lot of concern, I think, by consumers about possibilities that might happen as a result of COVID-19, like *what if*, you know, the pharmacy they attended to actually had to be shut as an emergency, you know." (# 3)

""What if, what if a pharmacy is shut and there's 100 clients there and they can't get dosed?" (# 20)

"What if someone's, you know, a positive with COVID-19, or that, you know, they've been tested and stay in isolation. If they've got to stay in isolation, how are they going to get their doses?" (# 17)

"How are we going to authorise the people on [pharmacotherapy] to go to the clinic every day? You'll need to give them a card. What happens when they get stopped by the police?" (# 5)

These what-ifs and uncertainties were seemingly aired and managed by convening ad-hoc meetings and discussions (the *huddles*). The interview accounts described the emergence of a problem solving/troubleshooting approach in these settings:

"We have had a regular weekly [meeting], so that's with all those actors that I told you about, so that we literally had every week, "how are things going, what's going on?" It was almost like a troubleshooting forum." (# 12)

There were also signs that the what-if approach facilitated policy action:

"What happens when someone quarantines for 14 days, what happens when someone has to go into ... what happens when someone gets tested and has to stay home for 4 days and

we had to push ... I mean, we had the meeting and they said, "yeah, we'll do something about it". (Emphasis added, # 11)

In this description we see what-if concerns discussed at a single meeting, and from this *single* meeting there was a decision to act ("yeah, we'll do something about it").

While the policy changes settled some uncertainties, other unexpected contingencies emerged:

"Even when we had written ... I mean, we wrote some of those procedures, like the third party pick-up specifically for that kind of a scenario that you know, "what if someone can't get to the pharmacy?" but we never imagined that people were going to be locked in their houses right." (# 20)

While a lot of the uncertainty concerned COVID-19 in this case study, uncertainties and assumptions about pharmacotherapy maintenance that pre-dated COVID-19, including misadventure around the collection of takeaways doses, also surfaced:

"What we've found throughout this period is there was a lot of apprehension initially, particularly amongst clinicians about, you know, what if we loosen up access and there's more takeaways and what if people start overdosing on them and, you know, they get into the hands of the wrong people and everything goes to hell in a hand basket." (# 14)

#### Who was involved and who did the work?

There is an existing group of 'usual suspects' in the opioid pharmacotherapy policy environment: state government departments, drug user organisations, and public and private opioid pharmacotherapy treatment providers. Despite some instances of the net widening (see below), participants noted that it was the "usual suspects" or the "standard group of people" (# 1) involved in policy discussions.

There was a sense that "robust kind of relationships" (# 12) or "good working relationships" (# 1) already existed, with the difference in this case being that people were "empowered to solve the problem with a time pressure on it" (# 5) rather than the usual "cop out" practice where policy change is "everyone and no one's responsibility" (# 5). As one person noted:

"It's kind of like when you're at uni and you didn't do your assignment till the last minute and then you had a stroke of genius because you were in the zone. I think that's what COVID has kind of done." (# 14)

Similarly, another participant noted:

"You know, suddenly it was like how do we keep people alive, what do we need to do, how do we change the systems, what's ... people were able to be really pragmatic, and that was the fundamental thing. It was basically the same people that did it. It was super-weird. [laughs] It was just like, yeah, but they've got it in them and they clearly can do it and they want to do it and they did it." (Emphasis added, #5)

In this rapid policy environment, membership in some groups was based on "a coalition of the willing" (# 17) or "who's going to do the work" (# 6). This is different to the usual rules of

representation and inclusion which are associated with existing ways of convening. The same person who suggested they picked people based on "who's going to do the work", provided the following reflection:

"I asked the group, I think either online or in person, I think I might have asked them in person when we first brought this group together. I said, okay, do we need any, do we need a pharmacist in this group? Do we need a pharmacist and pharmacy expertise in this group? And [a pharmacist], and [another pharmacist] said, yeah, we're pharmacists". [laughs] [....] I didn't know their background, but I knew their expert ... I knew their talent and their capability [....] we had probably two of the most qualified pharmacists for this project in the room, not that I knew that." (# 6)

This might suggest that membership in this group was initially based on the person's "talent and their capability" and "who's going to do the work", rather than taking representation as the starting place. Relatedly, it was a matter of "do we have the right people in the room" (# 20), which is different to asking whether there are the *designated* people in the room:

"We weren't kind of like departmentally appointed people. You know, they didn't say okay, we weren't tasked with doing this this work of the department, it was so, wasn't so much top down the department saying, "okay, form a working group develop policies on this, this and this", it very much came more bottom up, you know, so really, and I think, based on relationships." (# 17)

There appeared to be a few people who did the "heavy lifting" of drafting and distributing policy guidelines and documents surrounding opioid pharmacotherapy treatment. Depending on where people worked, this heavy lifting was carried out in lieu of ordinary activities or in addition to their day jobs. For some government employees the heavy lifting involved being taken offline from their current duties. There were also examples where priorities changed and some previously high priority projects (one example given was policy development on services for pregnant women) were put on hold in order to focus on pharmacotherapy maintenance policy given COVID-19. In contrast, for those who worked outside of government, there was no option to put ordinary work on hold. Instead, they had to work additional hours:

"Nothing was funded.[...] We're all drafting documents late at night around our jobs. [We] spent a whole weekend and 15 hours on a Sunday making sure that that document was good." (# 14)

People outside of government talked about being "exhausted" and "under-resourced" and having to do work on "weekends" or "late at night" or in "evening teleconferences". Small additional funding was allocated in one instance for someone to draft policies, but as outlined in the below description, this did not offset the extra burden this person experienced:

"Actually, things were happening so quickly, that I ended up just working for the whole weekend doing all the documents, because the [person] who was going to help me, I didn't want to bother her on the weekend and they sent it out on Friday night saying, "we really need a draft of this by Monday", so yeah, very quickly documents were drafted, initial documents were drafted." (# 20)

Talking about another policy process they were involved in, the same participant said:

"Look, I was involved with that, but I would say much more of an ad hoc basis and it wasn't clear who was advising that and what the response was and I had to ... like you know, I kind of ... of course, this always happens on a Friday right, so over the weekend again I was on the phone trying to and talking to various people about what might happen and my sense around that is, I guess because of the timing of it, there wasn't a lot of time to prepare." (# 20)

In addition, there was a sense that drug user organisations had to juggle a lot of issues in addition to sitting on committees and participating in policy discussions:

"I mean, it's always been an issue, but I think it's even more of an issue now that those peer organisations are so desperately under-resourced whenever a crisis happens, because you know, it's so critical and it was ... [a drug user group] are getting all the calls from these consumers saying, "you know my doctor won't do X or I can't do Y or I've got these takeaways prescribed and the pharmacist won't give them to me", like they are aware of all the issues on the ground, because they were working with all these individuals to solve them and so but they were also flat out trying to solve all these issues. People didn't want to take on new clients and they weren't seeing people face to face, doctors were moving to telemedicine, so all these changes were happening and it was starting to get harder to access a prescriber, so as it gets harder to access prescribers, more people are calling [the drug user organisation] and asking for help and at the same time they are being asked to contribute to all of these committees." (# 20)

While the "standard group of people" (# 1) were often said to be involved in the policy discussions, there was also a perception that the net had widened in this context. This involved the inclusion of different types of service providers, including "infection gurus" and other alcohol and drug treatment staff: "we are more connected to more individual staff, services and the broad sector than we were pre-pandemic" (# 6). For example, one participant who described the discussions going "broader than the [pharmacotherapy treatment] crowd we probably normally would have chatted to" (# 21), suggested that there were benefits to consulting both pharmacotherapy providers and residential service providers in the one group:

"It was this group that went actually, if we are normally sending either our resi rehab clients or a staff member from resi rehab to go and collect those doses, is there any reason we can't use the delivery option ... setup? And we went, no that sounds really efficient to us, so if you want to use it, go ahead, and we wouldn't have thought to do that". (# 21)

Here we see the benefits of involving people outside the usual "pharmacotherapy crowd". In this case the inclusion of residential rehabilitation providers led to a novel policy response which was "really efficient" but may not have been thought of in the absence of said discussions.

#### **Consumer participation**

The context for this study is broader interest in modes of community participation in policy making and policy reform processes, in the context of the unfolding COVID-19 pandemic. In our study it is

notable that one of the most common ways in which our participants thought about public and community participation was through the notion of 'consumer participation'. The critical importance of ensuring that consumers had a "voice at the table" (# 5 and 12) or a "seat at the table" (# 15 and 11), and at best "being at the table from the beginning" (# 11) was consistently emphasised throughout our research. And of course, there are compelling reasons why this emerged in our research. Since the 1980s, a key element of public advocacy around drug policy reform has been concerted efforts to ensure the representation of consumers across the panoply of institutional fora devoted to drug treatment, hepatitis C, harm reduction, discrimination and stigma, and drug law reform (Australian Injecting and Illicit Drug Users League, 2012). Our research is therefore set in the context of a longer running story. Many of our participants, for example, emphasised that this achievement was a "hard graft" and "not something that I think we as [a drug user organisation] can take for granted." (# 1)

As described below, drug user organisations now have a seat at the table:

"So, like 10 years ago, [one drug user organisation] were like off on the side as like, I don't know, the annoying consumer group that said things that people didn't like, that were annoying and were kind of on the outside. So, this kind of process over the last decade was about kind of bringing them in to give them equal status within the field.[...] We as a sector have worked really hard to make sure that [the drug user organisation] is *at the table* and a respected like *voice at the table*, like a trusted voice, like if someone wants to know what's going on in [pharmacotherapy treatment], talk to them and they will tell you what the good bits are and the not so good bits". (Emphasis added, # 5)

In the interviews, it was clear that this has involved a shift in the way that those who represent people who use drugs are viewed in drug policy processes. They are no longer seen to be "standing on the outside, criticising and throwing pig's blood" (# 14). Rather they are now "respected", "embedded", "enmeshed", "mainstream", and "active" in policy activities surrounding pharmacotherapy treatment in Australia. (These words come from across many interviews: # 1, # 3, # 5, #14, # 15, and # 16).

As mentioned above, the formal committees functioned by way of offering an established network of actors who needed to be consulted; drug user organisations were seen to have a seat at the formal committees in each jurisdiction and were therefore seen to be part of the "established network of local stakeholders" (# 2). This meant that they played an important role in relation to the policy changes to pharmacotherapy treatment in the context of COVID-19:

"[One named drug user representative] was our link to getting stuff done in that space, [the drug user representative] is very acquainted with the [pharmacotherapy treatment] program in [jurisdiction], sits on [formal committees], you know, got the document reviewed by people actually on [pharmacotherapy treatment] programs which is great." (# 21)

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<sup>&</sup>lt;sup>9</sup> We note that this is a dynamic often identified in participatory work – outsiders become insiders, whilst also maintaining the reflexivity that enables them to move between these positions; another area for potential analyses (Chilvers, 2008).

As further testament to the established role of drug user representatives in the drug policy field, one policy document which was developed rapidly in response to COVID-19 was "held up" due to the concerns of drug user representatives around patient choice:

"... not inadvertently providing advice that favoured one treatment modality over another and particularly around things like depot buprenorphine.[...] We had big discussions about, yes, in the context of COVID, you might want to talk to your clients about depot buprenorphine and whether that's suitable for them, but you don't want to necessarily assume that that's the first port of call. You still want to go through the process of treatment matching and ensure horses for courses." (# 14)

Even though the policy document was ready to be finalised it got "held up for some time" (# 14) and revised to ensure it was sensitive to concerns around client choice. The same participant suggested that this was only possible because of the way "[drug user] organisations like ours are genuinely included in our sector" (# 14).

While having a "seat at the table" (# 15 and # 11) was important in terms of being a part of the local network of actors, the practices associated with the *tables* appeared to have delimiting effects particularly for those who represent people who use drugs. <sup>10</sup> The formal committees favoured professionalism and being courteous and appeared to devalue the expertise of drug user representatives in policy processes. More specifically, in the interviews, drug user representatives were described as people who could not "bang their head on the table" (# 3), but instead needed to understand "the committee process, you know, understanding compromise, understanding the realities of, you know, working with achievable outcomes rather than ideal outcomes" (# 3). Part of proving this "expertise" involved being "kept to that very high standard... [drug user representative] professionalism has to be a step above ... certainly you have to demonstrate that you can bring something to the table."(# 11)

We see here a particular form of participation required – one that understands "compromise" and consists of "professionalism". This no doubt favours certain knowledges and expertise over others. As a case in point, one participant initially attempted to bring the fears of COVID-19 expressed by the community to a particular formal committee, and despite being "courteous and diplomatic" in the first instance and doing the "background work" and raising it as an "agenda item", this did not work and they were given the "fob off", which necessitated a different form of participation that involved an impassionate personal story told outside the committee "in the corridor":

"It got to the point where I used a personal story [....] I never do things like that, that's crazy you know [....] these are the games you play at meetings, you use the way the meeting is formulated, the rules of the meeting to put agenda items on and make sure they go through to the right area." (# 11)

<sup>&</sup>lt;sup>10</sup> We further note that this is not unique to the drug policy field. Hard won gains in securing citizen and community participation in policy making processes have, in many instances, become highly bureaucratised and institutionally inflexible. (Chilvers & Kearnes, 2015; Wynne, 2006)

Despite the participant going through the rituals bounded by the formal policy processes the fears of COVID-19 expressed by the community were dismissed at this committee and required intervention outside the committee itself ("in the corridor").

#### **Communication and knowledge sharing**

There were also a range of other practices that were carried out during the policy-making process, including enhanced communication and information sharing practices.

State governments engaged in top-down communication, for instance providing "one page summaries" for services around new procedures and policies:

"Setting up some communication lines between the delivery service, the dosing pharmacies and the prescribers, writing essentially a procedure for the pharmacies to go through as well as a procedure for the people collecting it and overall policy documents so that everyone was comfortable. We realised later on almost nobody read that, so the one-page summary was handy" (# 21)

In line with the *tables* and more formal meeting structures, governments also played a role in providing an opportunity for treatment services to share information and their "collective wisdom":

"The aim of those meetings were to provide people the opportunity to contribute to what needed to happen in terms of policy changes and the way services were provided, but also provided a forum for people to share information around what they were doing and you know if they were doing things which ... sort of everybody could learn from each other and also to you know ask questions of each other so that you know people could use a collective wisdom." (# 22)

Presentations about COVID-19 and the implications for drug treatment and pharmacotherapy maintenance were also provided. In the below quote, webinars provided the opportunity not only for factual information but also a way to address expectations of service providers:

"We also had webinars for the sector as well and we had some discussions in those webinars about the effect on consumers and just kind of through that, kind of highlighted this idea that you know often when someone turns up for treatment, it's kind of the expectation that they want to stop using drugs and you know, and that should be their goal and so there was also this discussion that you know, during COVID actually, people might turn up and just want to go on pharmacotherapy to prevent withdrawal and to kind of hold them while drugs aren't available and that people providing treatment should be aware that that's a real legitimate and appropriate health response and it's okay for people not to have a goal." (# 20)

Drug user organisations played a crucial role in communicating lived experience to clinicians and government, as well as communicating information to potential clients of pharmacotherapy maintenance:

"Yeah, consumers played a really important role particularly in disseminating communication out to their networks that there are options being made available for people

to continue to have their treatment if they are required to isolate and quarantine. So one of the key messages that we wanted to get out to consumers was "if you are instructed to isolate or quarantine, don't panic, we will find a way to get your dose to you, do not attend the dosing clinic or pharmacy." (# 2)

One drug user organisation also set up a "consumer support line":

"The other thing that [drug user organisation] was able to do at the time is that we were able to negotiate with them an amendment of their contract with us in another area that clearly was being underutilised and so they set up like a consumer support line as well that we were able to offer people, because you know there was a lot of angst that was going, particularly during lockdown." (# 12)

Another emergent feature of the policy processes was a significant amount of cross-jurisdictional communication; sharing policy developments but also leveraging the changes in one jurisdiction to assist with change in another jurisdiction:

"So it was after that first [meeting] where the [government] said, "we are not going to give you anymore takeaways, it's not an option" and in my mind that was the only humane option, so at that stage I reached out to [people in other states] and I said, "listen, we need to start sharing some information. What's happening [in another state], surely this is paralleled in [this other state]?" (# 11)

The same participant explains that sharing information across jurisdictions assisted efforts to advocate for policy change:

It [the meetings] brought us all together in a way to push through like a common front, so we could all go to our meetings and when they said, "this is outrageous, you junkies don't deserve anything" we could say, "well man, like this is what they're doing in [this state] and what they're doing in [another state], so why are we so different?" (# 11)

News and policy changes from overseas were also important. As outlined earlier, news about the severity of COVID-19 from different countries ("coming from the future") led to a sense of urgency in Australia. Further, another participant who was responsible for drafting policy suggested that alongside information from local treatment services, it was also international policy which informed policy decisions at the state level in Australia:

"The US had put out their document around allowing more takeaways. We started to see some international discussions of how other people were handling it and I think in our ... we reviewed all of that literature, so I think we put together ... we actually had to put together a report. [...] So part of the work we did, we got those drafted documents and part of the scope of work that was around that was reviewing best practice around what other people were doing with COVID..." (# 20) 11

<sup>&</sup>lt;sup>11</sup> This participant goes on to reflect on the temporal relationship between evidence and policy decision-making, complicating linear views of evidence-based policy. Further analysis of the role of 'evidence' (in the traditional sense of the word) would be fruitful.

It was also clear that evidence was not accessed solely through the usual literature review process. The same participant went on to suggest that various types of knowledge to inform policy change was shared via social media:

"So I guess that's where a lot of the knowledge sharing was happening, is through those structures that were in existence anyway. And Twitter [...] Yeah, I mean so [drug user organisation] for example, were really starting to push out messaging to people through Twitter and I don't know if they're on Facebook, but using social media and through their website, hearing a lot of stuff about what was happening with pharmacotherapy internationally. There's a whole bunch of people who I'm in touch with who are in [named country] and so hearing about pharmacotherapy through those networks, so yeah, social media for sure played a role in terms of being ... just seeing people talk about what was happening in different settings. (# 20)

Appreciation of the importance of language was noted. There were examples demonstrating attention to how information was communicated:

"In our team is also someone whose background is comms, you know communication and she went, well if that is the thing you are releasing for the agents and the clients, it needs to read more like this, what you have written is the pharmacist talking to the doctor whereas it actually needs to be the government talking to the year 8 reading level" (# 21)

"[Drug user organisation] was very helpful in nuancing the language and key messages for people on treatment, so you know sometimes wording can come across even with an unintentional message or it can come across as patronising, etc, and we wanted to make sure that that community was supported as well." (# 12)

In some cases, communication about existing policy guidance (not any changes that were being made) was an important part of the COVID-19 story. For example, pre-existing guidance on the allowable length of prescriptions needed to be communicated more effectively:

"I guess it wasn't a change in policy, but it was a communication or clarification for people around the length of a prescription, so legally a prescription can be written for up to 6 months and so there was kind of an acknowledgement and encouragement that prescribers couldn't write longer prescriptions with the intent that they might have a tele medicine review or a pharmacist review in the interim, so that if something did happen, if that pharmacist ... sorry, if that prescriber became sick or that clinic was shut and they couldn't see people, that there was like a longer date prescription to take the pressure off during that kind of crisis period, so that was the other change, but it wasn't a change, it's always been legal to do, but it was kind of providing information around that that was an option that people could take up, so that would reduce the pressure if a prescriber became unavailable due to COVID." (# 20)

#### **Policy implementation**

On the one hand, opioid pharmacotherapy maintenance is highly regulated due to the nature of the drugs, and there are clear rules and requirements for Schedule 8 drugs. On the other hand, like most clinical practice, clinicians exercise their judgement, and clinical guidelines are only that, guidelines rather than rules. As a result, there are many grey areas, and "lots of different interpretations, it seems, sometimes about [pharmacotherapy] policy" (# 16). Participants often talked about "unwritten rules" and "grey areas" when talking about the implementation of the policies. There was also a sense that treatment services do "their own thing" which is based on communication between themselves:

"So, everyone kind of does their own thing, and that's why, you know, at the front-line manager's level, you share things with each other because someone will say, "Yeah, anyone got a, you know, an example of a risk assessment for takeaways? Has anyone got some infection control guidelines they're using?" stuff like that, yeah." (# 16)

Concerningly, it seemed that these "grey areas" might have disadvantaged clients in this context. While there was little doubt that reducing the risk of COVID-19 infection was the most important priority, in its implementation the new takeaway policies may perpetuate discrimination. There were concerns that only clients with an established relationship with their provider or those who "could argue their case" were able to experience the increased treatment flexibility:

"Definitely the priority was about COVID transmission, especially the safety of the chemists and the health workers given they would be seeing so many people every day and then during their lockdown as well, I think that that was definitely a consideration. Having said that, I don't think it trumped instability. So, if someone was highly unstable, they might be able to get away with a couple of takeaways on the weekend, but that might be about it. That's the sort of sense that we got." (# 9)

So, in the context of an environment where "public health trumps all things" (# 11), suggested in this last quote is that public health trumped all things except concerns about patient instability. The same participant goes on to say that the interim guidelines developed in response to COVID-19 were "really just about checking lists for stable people, rather than providing more takeaways to so called unstable people" (# 9). The same point was made by another participant:

"I suspect that a lot of the [clients] on the lower tier [i.e. high risk] in [jurisdiction], I suspect they still have to turn up [to the clinic] every day." (# 5)

In this way, while the changes to the guidelines encouraged more flexible delivery models and in doing so might have "smashed some stigma and discrimination barriers" (# 11), we see here that this might not have been the case for so-called 'unstable' clients, thereby perpetuating experiences of discrimination.

Another aspect of variable implementation arose from differences between clinicians, rather than perceived differences between clients. There was variability in who was willing to provide more flexible models of treatment delivery. Drawing on data collected by treatment services, one participant (# 17) suggested that providers who were "part of drafting these policy reforms" were

more likely to provide more flexible treatment, whereas other prescribers were less likely to do so. It was also the case that "older prescribers were reluctant to start or restart people on pharmacotherapy without a face to face consult" (# 7).

Participants also noted a myriad of small implementation issues. One example was the container required for the takeaway doses. The reuse of takeaway bottles was not permitted during COVID-19 due to infection risk, and the cost for new bottles rested with the client:

"The whole thing about the reuse of takeaway dose bottles, that was something that I wish we had raised in the pharmacy discussion. I never ... I just didn't for a second consider that people would have to come up with an extra, you know, \$12 to \$14 a week to pay for their doses and I mean, yes okay, Centrelink increased the amount of money available for people on what was New Start allowance, now Jobseeker's allowance and that sort of stuff during COVID and that was great, but I mean, that was great and that helped, but just that other little stuff, but the impact on the consumers of the whole stigma and discrimination was seen something I wish we'd spent a lot more time talking about, but the problem was, it wasn't the time and I'm not good at thinking of everything." (# 7)

One highlighted aspect of policy implementation concerned the necessary infrastructure requirements to facilitate the policy changes. An issue raised across all jurisdictions was the need for an accurate list and contact details for all current patients, as well as accurate details of all the clinical providers and prescribers. This essential infrastructure was required in case some services had to close down due to a COVID-19 outbreak and patients had to be relocated. This infrastructure was missing. As described by one participant:

"I mean there are a whole lot of issues in the background there ...around you know establishing information and lists of prescribers and pharmacies, so if one fell over we had the capacity then to engage others and we had written to GPs and we had written to pharmacies around the fact that they may be needed to, well firstly, you know, to inform us early if they were going offline and secondly they may be needed to take extra people if someone else goes down so to speak, so that was also part of it." (# 22)

This missing infrastructure was not unique to one jurisdiction:

"There is no established communication mechanism with pharmacotherapy prescribing GP's [in jurisdiction], most people don't even know who they are, because the doctors are allowed to be confidential. So, we know who the high-volume prescribers are but we don't know, like the entire kind of list of people prescribing and I don't think the [health department] does either." (# 18)

Linked to the absence of this kind of infrastructure, we were given moving examples where clinicians took extra care to ensure that clients were covered, and able to receive their medication:

"There was one pharmacy that was particularly close to [lockdown site] ... you know, the guy sort of went back in on a Sunday and checked through all his books and made sure you know of there was anyone sort of unaccounted for and tried to sort of follow up if there was kind of action required, but it was much more ad hoc in terms of that lockdown and it was more

people kind of ringing other people they knew going, "are you on it, like do you know what's happening? Is someone taking care of this?" (# 20)

There are specific regulatory requirements for Schedule 8 drugs, and the preparation of takeaway doses. While these can differ by jurisdiction, one implementation that arose was the inability of nurses to prepare takeaway doses. Given that pharmacists were not necessarily available, this created a roadblock to implementation of revised takeaway guidelines. There were efforts to change the regulations to allow nurses to prepare takeaway doses, but this was not successful:

"So, yeah we had to work out what are the obstacles to nurses preparing takeaway doses, and there were federal and state obstacles in the legislation. So, just one thing like that took hours and hours of negotiation to try to resolve, and we didn't. That was a failure. We never got that one through." (# 10)

There were other noted implementation challenges, partly connected to the particular concerns about Schedule 8 drugs of dependence. For example we were told that plain clothed security officers were required to accompany clinicians delivering medications. This was compounded by attitudes towards clients on this treatment and their housing situation:

"They were alarmed at the idea of nurses wandering the streets with methadone in their bags to deliver to ... like the stigma and discrimination in the way they worded it was, you know, "Oh, they're going into public housing blocks which are overrun by criminals while they've got drugs of addiction in their pockets." (# 10)

The above examples were not the only ways in which clinical services and peer-based services demonstrably problem-solved and took additional care in ensuring continuity of medication. Some services also took the opportunity to address other aspects of supportive care. For example, flexible use of the additional resources provided to respond to COVID-19 was noted. Funding provided to facilitate delivery of medications to COVID-19 affected clients, was also used to deliver medications to residential rehabilitation centres and people in the community with general mobility issues who had trouble accessing treatment. Food and other essential items were also delivered to clients under the same scheme. It was noted that increasing the flexibility of pharmacotherapy treatment programs and policies would free up staff who had previously spent time dosing, to be able to engage in more case management and consultation liaison with other services.

There was also an example of services adapting to the COVID-19 situation in ways that extended the policy guidelines. This was described as "on the ground policy" (# 7) and involved people being provided medications in their cars:

"We ended up developing this kind of like, on the ground policy [...] So, the person would if they had a car, they would drive to the pharmacy, they would park right outside the front, if they could, ring the pharmacist when they arrived and describe the type of car that they were in and where they were parked, we would always make sure that the client would text a photo of themselves to us, which we would get to the pharmacy by email. So, the pharmacy knew in a lot of cases ... so these were people that were coming from different areas or moving to a different pharmacy. If the pharmacy didn't know what the person looked like, that's what we would do and then the pharmacist would come out, everybody

would be wearing masks and gloves and all of this sort of stuff and the windows would be up in the car and then the pharmacist would give the takeaway doses, be they methadone or Suboxone, prepared and in a bag and labelled and then they would put the doses on the bonnet of the car and then they would get step right back from the car, so all of this stuff had to be negotiated. The pharmacist would step right back from the car, the person would get out of the car and pick up the package and then the pharmacy would have to photograph the person picking up that ... that was your signing for doses." (# 7)

Some policy implementation occurred before the formal revised guidelines were communicated. This partly reflects the point about clinical discretion inherent to all guidances, but also the elevated concerns by clinicians that they needed to act quickly: "well before any of those kind of you know formal moves happened". (# 20)

In some cases, changes made by clinicians that appeared to precede formal policy announcements created both a further impetus for formal policy change as well as additional stress:

"People started to provide more takeaways and then the pharmacists were really uncomfortable to do this, because there wasn't any policy, so they are ringing up the [regulatory committee] and [...] feedback from the [regulatory committee] saying, "we are getting all these phone calls from pharmacies, we are you know ... it's being talked about that you should give patients more takeaways because of COVID, but there's no policy and it's in contravention of policy, so they are not comfortable to do it and that's causing all this tension" and so I think that also added to the urgency in terms of some of these changes were already being implemented by individuals without the support of any kind of policy document or procedure.." (# 20)

Acting before formal policy change announcements was particularly important in responding to sudden and unplanned lockdown of specific sites. As quoted earlier:

"There was one pharmacy that was particularly close to [specific lockdown site] that ... you know, the guy sort of went back in on a Sunday and checked through all his books and made sure you know of there was anyone sort of unaccounted for and tried to sort of follow up if there was kind of action required". (# 20)

# The permanency of the policy changes

Participants expressed enthusiasm to make the policy changes permanent. In this context we see the policy reforms described herein as the start of something new, rather than the end of a hard fought battle. There was an optimistic sense that there is a lot to "learn from the COVID period" (# 14) and the many "COVID silver linings" (# 4) presented by the pandemic. Historically a punitive treatment program, participants stated that we have seen "the shackles removed in one fowl swoop" (# 1) and "smashed some stigma and discrimination barriers" (# 11), and "lo and behold the sky hasn't fallen in" (# 14). The changes were said to likely increase "treatment retention" and "compliance" and increase treatment seeking, particularly from those people who had trouble accessing treatment under more regimented provisions. Reflecting this attitude from the sector, a submission has already been made to Australian and state and territory governments which recommends that the policy changes referred to in this case study become permanent (AOD Coalition, 2020).

Despite an enthusiasm to make these changes permanent, the current formulation of the policies, regulations, and guidelines in NSW, ACT and Victoria, by definition, indicate that the changes are temporary and dependent upon there being a public health emergency. In the ACT, the regulatory changes to the pharmacotherapy maintenance program are tied to emergency planning and can only be used when there is declared public health emergency. Similarly, in NSW and Victoria, all the guidelines specify arrangements during the COVID-19 pandemic. So, in all cases, the policy changes as they stand are only applicable during the COVID-19 pandemic. More guidelines and regulations would need to be developed in order to make these changes permanent.

In terms of whether these changes become permanent, it was said to be dependent upon several factors. Any "evidence of harm" associated with takeaway dosing was a major concern that would disrupt the permanence of these changes. Governments remain "vigilant" and "have a system setup to try and detect early complications from takeaway doses including you know through the Poisons Information Centre" (# 22). This involves "rapid routine surveillance of ED presentations for methadone or buprenorphine poisoning" (# 22). Other factors that would determine the shape of these policy changes in the future included "elections" and whether or not there was a "community outcry" (# 4). There are echoes here of the prevailing stigma towards and discrimination against people receiving these treatments.

There was also a sense that whilst the pandemic has necessitated successful and quick policy responses, in the longer-term context, this "patchwork response to get through this crisis period" (# 13) would need more work. It was said that "it would take some more discussion in our sector in a big way to make it a more flexible model" (# 14). While pharmacotherapy treatment programs have become more flexible, this is only "the icing on the cake" not the "cake itself", because it "hasn't solved the problem of the elephant in the room, which is there is just not enough bloody capacity in the drug treatment sector in Australia for all the people who need it" (# 14). So, while increasing flexibility might improve treatment retention, treatment seeking, and treatment compliance, this does not address the current large unmet demand.

Further, with more people being provided depot buprenorphine in the community, and the demand expected to increase as the cohort of depot buprenorphine clients in prisons are returned into the community, there is concerns that this will create a "bottleneck" in terms of who manages these clients once they "stabilise" and move from public clinics and residential settings (# 16). There was a pre-existing shortage of GP prescribers willing to manage pharmacotherapy treatment clients, because "firstly, they're not comfortable prescribing it; secondly, they don't know how to access supply" (# 10). But also, managing "chronic complex medical problems" is not economical for general practitioners in the context of "6-minute medicine", which is the minimum amount of time you need to see a client before claiming a certain item number, and if "you see a patient for less than 6 minutes, then you claim a lower item number" (# 3). In principle it means that longer GP consultations are reimbursed at a lower cost per minute, disincentivising care for people who require more time with their doctor. And in the context of COVID-19, GP practices have reduced their income, and "as economic pressures start to get worse and worse; you know, GPs obviously are going to vote with their feet as well and say we're just not going to do difficult stuff because, you know, we can't afford to" (# 3).

## Insights to inform future policy making

Distilling all the above accounts has led to a list of 14 key insights. The insights speak to the actions of three different types of policy actors (viz the bureaucrat, the drug user representative, and the clinician). Some insights may be more applicable to one set of actors than another, but we assume a model of policy-making where it is the network of mutually-dependent actors that achieves policy reform.

## (1) Recognise that many ideas and solutions are already there

The problem(s) with opioid pharmacotherapy maintenance treatment and the restrictive nature of the guidelines and regulations were well-known. There were also well worked out and articulated solutions that were available. This reminds us that many ideas are already floating around, held in peoples' minds or listed as past agenda items in committees. Many new ideas have been subject to research and analysis (that may languish in old issues of journals, or in disciplinary siloes). A crisis precipitated the opportunity for existing ideas to be revisited. One insight therefore is the opportunity to mobilise existing ideas in the absence of a public health crisis. We suggest value in establishing mechanisms for old ideas to be re-surfaced (for example putting them on meeting agendas) such that they can be considered under routine policy-making conditions.

## (2) Be receptive to new ideas which emerge through flexible problem framings

Whereas past attempts to change the regulations had been stymied by perceptions of the risks outweighing the benefits, in the circumstance of COVID-19 the imperative to act opened-up risk framings to instead focus on what might be possible, in an evolving situation of need. The pandemic also facilitated a wider conception of both risks and benefits and created the conditions where different forms of knowledge became relevant (for example, 'let's think about what transport people use to get to the pharmacy'). Multiple and diverse forms of evidence, and ways of thinking about the problems became available. Mobilising capacity for flexible problem framings allows for intervention pragmatism and policy responsiveness, even in the midst of uncertainties. The tendency for policy to be fixed (stultified) should be resisted, with regular, ongoing assessment of new possibilities and new ideas given flexible problem framings.

## (3) Create flexible problem-solving venues (huddles)

Our research has shown that the pre-existing formal decision-making venues (the *tables* of participation) presaged new flexible forms of problem-solving and decision-making venues (the *huddles*). Bringing this new form to routine policy-making may have value. In practical terms this may involve meeting without set agenda items and employing strategies to facilitate and enable more innovative problem-solving. Making room for uncertainty and "what-ifs" might be one way to facilitate a problem-solving approach. Sometimes simply changing the physical environment for meetings can engender more flexible problem-solving.

## (4) Review formalised systems (such as committees, and who has a seat at the table)

The existing policy-making structures enabled the *huddles* to emerge. It was often the case that the same network of actors who participated in the *tables* also participated in the *huddles*. This then suggests that it is vital to consider membership of committees in times of routine policy-making. Our

findings suggest that we might forgo the usual 'representation' role of committee members, and ask 'do we have the right people in the room?'.

#### (5) Allow new lights to shine

While we observed in this research that the 'usual suspects' who participate in the formal preexisting decision-making processes were engaged in the new form of the *huddles* and were central actors to the policy changes, there were also new voices that emerged. Some of these voices played dynamic roles. This suggests that making the space for new voices, and providing encouragement and support for new natural leaders to emerge may improve routine policy-making.

#### (6) Build relationships

The research revealed that rather than seeing relationship-building and trust as peripheral, and a nice 'added extra' to good policy-making, these were essential to effective policy-making in times of crisis. This suggests that investment and resources put into building interpersonal knowledge, trust and relationships is a vital part of good policy infrastructure.

## (7) Assign resources and labour

The distribution of resources and labour was uneven. In most cases, non-government and drug user representatives were not resourced to undertake the additional policy development work (though service provision was resourced). While some other actors could put existing projects on hold, the NGO and drug user groups could not. This meant significant labour and long working hours for these policy stakeholders. Ensuring that labour and resources are equitably spread amongst key policy actors and stakeholders is essential.

## (8) Increase the sense of responsibility and empower participation in policy-making

An apparently powerful intervention early in the COVID-19 pandemic was to hold so-called "insider briefings" about COVID-19, for all policy stakeholders (including government and non-government and peer organisations). This appeared to create a strong sense of shared responsibility and empowerment. Using the idea of "insider briefings", open to anyone, is a potential strategy to increase participation, increase responsibility, facilitate new voices, and create an environment where no stakeholder is left behind.

#### (9) Back innovation, back people, and create systems capable of innovating

A strong message was the sense of support and being "backed" in decision-making. Acknowledging risk and uncertainty seemed inevitable under COVID-19: the key challenge is how to recognise risk and uncertainty in times of routine policy-making and not let that stymie innovation. Systems capable of innovating have components of all the insights here. When innovation is allowed to occur, backing people is essential. Processes which harness innovation (including being less risk averse, backing and funding proactive people, allowing uncertainty and "good enough" policy) will facilitate improved routine policy-making.

(10) Ensure that the people in the system responsible for implementing the changes are part of the decision-making processes

One participant suggested that providers who were part of drafting of the policy reforms were more likely to provide more flexible treatment, whereas other practitioners were less likely to do so. This suggests that it is important to facilitate the presence of those responsible for implementation in the decision-making process. Whilst this is impractical in its entirety, there are key clinicians and service providers who should be involved in the decision-making in order to enhance implementation. Champions, opinion-leaders, those with the highest caseloads are all ways of identifying the most important clinicians to engage in policy design.

## (11) Don't sacrifice good patient-centred clinical practice

In the haste to reduce face-to-face contact (or other risk factors) for COVID-19 or other future emergencies, an eye on patient-centred practice is required. One of the solutions available under COVID-19 involved the rapid scale-up of a relatively new medication option – depot buprenorphine. The research and clinical experience with this new medication (which involves weekly, fortnightly, or monthly injections administered subcutaneously by a healthcare provider, doing away with the need for daily dosing) was underway before COVID-19. Given the need to reduce face-to-face contact, depot buprenorphine was a perfectly situated solution. The positive aspect of this has been scale-up and increased access to new treatment options, especially to under-served populations such as people in prison; the risk is that patient choice is compromised. Maintaining patient choice is vital.

#### (12) Think systemically

COVID-19 forced consideration of people's daily lives — not just as patients, but as people in the context of the physical and social world. This broader context highlighted, for example, that treatment access relies on a range of infrastructure (such as public transport). Logistics questions became paramount (for example for those with disabilities). A different way of thinking about the lives of people receiving pharmacotherapy maintenance was enabled. It highlighted the multiple governmental worlds (of health services, employment services, transport services, housing services) that patients navigate and negotiate daily. Under routine conditions, taking a systemic perspective in policy-making not only forces a reframing, it enables proactive problem-solving.

## (13) Reduce system fragmentation

Relatedly, system fragmentation stood in the way of new solutions. The bureaucratic structures and silos (for example the BBV and AOD silos) were able to be reduced (in some instances) to allow more effective problem-solving. One observation was the way Zoom enabled much greater participation in policy discussions from diverse (and geographically dispersed) stakeholders. Future policy work should continue to use video conference as a mode of engagement which could facilitate system defragmentation and the wider inclusion of diverse voices. Experts and peers also mobilised across state borders to share information and guidelines, which in turn gave purchase to advocacy efforts and facilitated shared learning. Reducing system fragmentation is much easier said than done (and has been a longstanding policy agenda). Strategies to reduce fragmentation at the macro (state), meso (community) and micro (client) level would all enhance routine policy-making.

#### (14) Organise as a community

One of the comparisons that has been made is between the policy response to HIV in the mid-1980s and the COVID-19 response today. Community mobilisation was key to the HIV response, where

community action and expertise were relied on as central to the policy process. This involved community organising and new configurations of power, which have been maintained such that HIV policy continues to innovate. Alcohol and other drug communities are not (yet) as well mobilised, empowered or resourced, despite a strong history of drug user activism in Australia. The long-term goal is to have a powerful, resourced, and mobilised community that drives innovation.

#### **Conclusions**

This case study of opioid pharmacotherapy maintenance policy-making in a time of crisis, revealed that policy-making processes can adapt and change. In the context of a public health emergency, that emerged in the context of wider recognition of shortcomings in the policy settings regulating opioid pharmacotherapy treatment, seemingly intractable policy problems were addressed rapidly, in ways that were flexible and inclusive. A number of insights have emerged that can inform policy-making under routine conditions. There is little reason to think that these insights do not also apply to other aspects of alcohol and other drug policy, and also to health policy more generally, and indeed to all domains of policy work: education, transport, social welfare and so on.

At time of writing, some of the policy reforms in relation to opioid pharmacotherapy maintenance have been wound back; others are still in place. While the aim of this report was not to provide an evaluation of the effectiveness of the policy changes that have occurred over the last 18 months, evaluations being conducted in each of the jurisdictions studied here will clearly be crucial. Our research points to the need for policy evaluations to address the insights pertaining to decision making processes, and the collaboration between actors and organisations, that we detail in this report in addition to assessing the substance of policy changes.

There continue to be crises, whether they are triggered by a health crisis (pandemic), an economic crisis (a recession), or an environmental crisis (floods, bushfires). Indeed scholarly literature and analysis points to the fact that routine policy-making processes are unlikely to serve as effective structures for decision-making in times of multiple and overlapping crises (Anderson, Grove, Rickards, & Kearnes, 2020). New forms, people and processes need to be mobilised to respond rapidly and effectively. Innovation is key. Yet what is also clear is that we need innovation (and better policy) every day (Lancaster, Rhodes, & Rosengarten, 2020). Waiting for the next crisis to mobilise better policy-making is not the solution. We are surrounded by enduring crises: people in receipt of opioid pharmacotherapy are marginalised and can experience crises in the everyday, for instance unstable housing and unemployment. Beyond individuals receiving treatment, the system itself is in chronic crisis; for instance the large unmet demand for opioid pharmacotherapy treatment, or the shortage of prescribers (Jones et al., 2021; Ritter, Gomez, & Chalmers, 2019). There is a continuing urgency to improve policy responses, through better, more innovative processes that surface new and existing ideas, engage in collaborative problem-solving, have participation from varied existing and new stakeholders, take risks, and back people to implement them.

## References

- ACT Health Directorate. (2020). Medicines, Poisons and Therapeutic Goods (Opioid Dependency Treatment (ODT) Contingency Guidelines) Approval 2020. Retrieved from <a href="https://www.legislation.act.gov.au/ni/2020-409/">https://www.legislation.act.gov.au/ni/2020-409/</a>
- Amato, L., Davoli, M., Perucci, C. A., Ferri, M., Faggiano, F., & Mattick, R. P. (2005). An overview of systematic reviews of the effectiveness of opiate maintenance therapies: available evidence to inform clinical practice and research. *Journal of Substance Abuse Treatment, 28*(4), 321-329. doi:https://doi.org/10.1016/j.jsat.2005.02.007
- Anderson, B., Grove, K., Rickards, L., & Kearnes, M. (2020). Slow emergencies: Temporality and the racialized biopolitics of emergency governance. *Progress in Human Geography, 44*(4), 621-639. doi:https://doi.org/10.1177/0309132519849263
- AOD Coalition. (2020). Urgent Policy and Funding Needs in the Alcohol and other Drug Sector in Response to COVID-19 Submission from a coalition of Australian alcohol and other drug services. Retrieved from <a href="https://www.aodneeds.org.au/pdf/Urgent\_policy\_funding\_needs\_alcohol\_drug\_sector\_COVID-19.pdf">https://www.aodneeds.org.au/pdf/Urgent\_policy\_funding\_needs\_alcohol\_drug\_sector\_COVID-19.pdf</a>:
- Australian Bureau of Statistics. (2020). National, state and territory population tables. Retrieved from <a href="https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release">https://www.abs.gov.au/statistics/people/population/national-state-and-territory-population/latest-release</a>
- Australian Government Department of Health. (2021). Coronavirus (COVID-19) current situation and case numbers. Retrieved from <a href="https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers">https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/coronavirus-covid-19-current-situation-and-case-numbers</a>
- Australian Injecting and Illicit Drug Users League. (2012). The Involvement of Drug User Organisations in Australian Drugs Policy—A Research Report from AIVL's 'TrackMarks' Project. Canberra, Australia
- Australian Institue of Health and Welfare. (2020). National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection. Retrieved from <a href="https://www.aihw.gov.au/about-our-data/our-data-collections/nopsad-collection">https://www.aihw.gov.au/about-our-data/our-data-collections/nopsad-collection</a>
- Berends, L., Chalmers, J., & Lancaster, K. (2015). Trust, agency and control: Perspectives on methadone takeaway dosing in the context of the Victorian policy review. *Drug and Alcohol Review, 34*(5), 483-486. doi:https://doi.org/10.1111/dar.12287
- British Columbia Centre on Substance Use. (2020). *COVID-19: Information for opioid agonist treatment prescribers and phrmacists*. Retrieved from <a href="https://www.bccsu.ca/opioid-use-disorder/">https://www.bccsu.ca/opioid-use-disorder/</a>:
- Chilvers J. (2008). Environmental Risk, Uncertainty, and Participation: Mapping an Emergent Epistemic Community. *Environment and Planning A: Economy and Space*, 40(12):2990-3008
- Chilvers J. & Kearnes M., (2015). 'Public participation in science and technology: why the failure to launch?', The Guardian, <a href="https://www.theguardian.com/science/political-science/2015/dec/17/public-participation-science-technology-failure-to-launch">https://www.theguardian.com/science/political-science/2015/dec/17/public-participation-science-technology-failure-to-launch</a>
- Connock, M., Juarez-Garcia, A., Jowett, S., Frew, E., Liu, Z., Taylor, R. J., . . . Roberts, T. (2007). Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation. *Health Technology Assessment*, *11*(9). doi:https://doi.org/10.3310/hta11090
- Crawford, S. (2013). Shouting through bullet-proof glass: Some reflections on pharmacotherapy provision in one Australian clinic. *International Journal of Drug Policy, 24*(6), e14-e17. doi:https://doi.org/10.1016/j.drugpo.2013.07.004
- Department of Health of Human Services. (2020). Coronavirus (COVID-19) Response: Pharmacotherapy services: information for prescribers and dispensers Retrieved from <a href="https://www.dhhs.vic.gov.au/sites/default/files/documents/202006/COVID19-pharmacotherapy-services-information-prescribers-dispensers.pdf">https://www.dhhs.vic.gov.au/sites/default/files/documents/202006/COVID19-pharmacotherapy-services-information-prescribers-dispensers.pdf</a>
- Dunlop, A., Lokuge, B., Masters, D., Sequeira, M., Saul, P., Dunlop, G., . . . Haber, P. (2020). Challenges in maintaining treatment services for people who use drugs during the COVID-19 pandemic. *Harm Reduction Journal*, *17*(1), 1-7. doi:https://doi.org/10.1186/s12954-020-00370-7
- European Monitoring Centre for Drugs and Drug Addiction. (2020). *Impact of COVID-19 on drug services and help-seeking in Europe*. Retrieved from <a href="https://www.emcdda.europa.eu/publications/ad-hoc/impact-of-covid-19-on-drug-services-and-help-seeking-in-europe\_en\_">https://www.emcdda.europa.eu/publications/ad-hoc/impact-of-covid-19-on-drug-services-and-help-seeking-in-europe\_en\_</a>
- Farhoudian, A., Baldacchino, A., Clark, N., Gerra, G., Ekhtiari, H., Dom, G., . . . Demasi, M. (2020). COVID-19 and substance use disorders: Recommendations to a comprehensive healthcare response. An

- international society of addiction medicine practice and policy interest group position paper. *Basic and clinical neuroscience*, *11*(2), 133. doi:https://doi.org/10.32598/bcn.11.covid19.1
- Fraser, S., & valentine, k. (2008). *Substance and substitution: Methadone subjects in liberal societies*. Basingstoke: Palgrave Macmillan.
- Grebely, J., Cerdá, M., & Rhodes, T. (2020). COVID-19 and the health of people who use drugs: What is and what could be? *International Journal of Drug Policy, 83*, 102958. doi:https://doi.org/10.1016/j.drugpo.2020.102958
- Harris, M., & Rhodes, T. (2013). Methadone diversion as a protective strategy: the harm reduction potential of 'generous constraints'. *International Journal of Drug Policy, 24*(6), e43-e50. doi: <a href="https://doi.org/10.1016/j.drugpo.2012.10.003">https://doi.org/10.1016/j.drugpo.2012.10.003</a>
- Jones, N. R., Nielsen, S., Farrell, M., Ali, R., Gill, A., Larney, S., & Degenhardt, L. (2021). Retention of opioid agonist treatment prescribers across New South Wales, Australia, 2001–2018: Implications for treatment systems and potential impact on client outcomes. *Drug and Alcohol Dependence, 219*, 108464. doi:https://doi.org/10.1016/j.drugalcdep.2020.108464
- Lancaster, K. (2017). Confidentiality, anonymity and power relations in elite interviewing: conducting qualitative policy research in a politicised domain. *International Journal of Social Research Methodology*, 20(1), 93-103. doi:https://doi.org/10.1080/13645579.2015.1123555
- Lancaster, K., Rhodes, T., & Rosengarten, M. (2020). Making evidence and policy in public health emergencies: Lessons from COVID-19 for adaptive evidence-making and intervention. *Evidence and Policy*, *16*(3), 477-490. doi:https://doi.org/10.1332/174426420X15913559981103
- Lancaster, K., Seear, K., & Ritter, A. (2018). *Reducing stigma and discrimination for people experiencing problematic alcohol and other drug use*. DPMP Monograph Series No. 26. Sydney: National Drug and Alcohol Research Centre.
- Ling, W., Shoptaw, S., & Goodman-Meza, D. (2019). Depot buprenorphine injection in the management of opioid use disorder: from development to implementation. *Substance abuse and rehabilitation, 10,* 69-78. doi:https://doi.org/10.2147/SAR.S155843
- Lintzeris, N., Deacon, R. M., Hayes, V., Cowan, T., Mills, L., Parvaresh, L., . . . Leung, M. C. (2021). Opioid agonist treatment and patient outcomes during the COVID-19 pandemic in south east Sydney, Australia. *Drug and Alcohol Review*. doi:https://doi.org/10.1111/dar.13382
- Lintzeris, N., Hayes, V., & Arunogri, S. (2020). *Interim guidance for the delivery of medication assisted treatment of opioid dependence in response to COVID-19: a national response*. Retrieved from <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19/interim-guidance-delivery-of-medication-assisted-treatment-of-opiod-dependence-covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a">https://www.racp.edu.au/docs/default-source/news-and-events/covid-19/interim-guidance-delivery-of-medication-assisted-treatment-of-opiod-dependence-covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a">https://www.racp.edu.au/docs/default-source/news-and-events/covid-19/interim-guidance-delivery-of-medication-assisted-treatment-of-opiod-dependence-covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a">https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a">https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: "https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: "https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf?sfvrsn=e36eeb1a 4: <a href="https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf">https://www.racp.edu.au/docs/default-source/news-and-events/covid-19.pdf</a>
- Lintzeris, N., Lenne, M., & Ritter, A. (1999). Methadone injecting in Australia: a tale of two cities. *Addiction,* 94(8), 1175-1178. doi:https://doi.org/10.1046/j.1360-0443.1999.94811757.x
- Livingston, N. A., Ameral, V., Banducci, A. N., & Weisberg, R. B. (2021). Unprecedented need and recommendations for harnessing data to guide future policy and practice for opioid use disorder treatment following COVID-19. *Journal of Substance Abuse Treatment, 122*, 108222. doi:https://doi.org/10.1016/j.jsat.2020.108222
- Lyons, N., Cox, C., & Clements, V. (2020). Value of clinical engagement in the NSW Health response to COVID-19. *Australian Health Review*, *45*(3), 306-307. doi:https://doi.org/10.1071/AH20165
- MacArthur, G. J., Minozzi, S., Martin, N., Vickerman, P., Deren, S., Bruneau, J., . . . Hickman, M. (2012).

  Opiate substitution treatment and HIV transmission in people who inject drugs: systematic review and meta-analysis. *bmj*, 345. doi: <a href="https://doi.org/10.1136/bmj.e5945">https://doi.org/10.1136/bmj.e5945</a>
- Magwood, O., Salvalaggio, G., Beder, M., Kendall, C., Kpade, V., Daghmach, W., . . . O'Shea, T. (2020). The effectiveness of substance use interventions for homeless and vulnerably housed persons: a systematic review of systematic reviews on supervised consumption facilities, managed alcohol programs, and pharmacological agents for opioid use disorder. *PLoS ONE [Electronic Resource]*, 15(1), e0227298. doi:https://doi.org/10.1371/journal.pone.0227298
- Marsden, J., Darke, S., Hall, W., Hickman, M., Holmes, J., Humphreys, K., . . . West, R. (2020). Mitigating and learning from the impact of COVID-19 infection on addictive disorders. *Addiction*, *115*, 1007-1010. doi:https://doi.org/10.1111/add.15080
- Mattick, R. P., Breen, C., Kimber, J., & Davoli, M. (2014). Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database of Systematic Reviews*(2). doi:https://doi.org/10.1002/14651858.CD002207.pub2

- Mellor, R., Kearnes, M., Lancaster, K., McLauchlan, L., & Ritter, A. (under review). Established tables and emergent huddles: Exploring the processes of participation associated with the policy changes to opioid pharmacotherapy treatment in Australia in the context of COVID-19. *International Journal of Drug Policy*.
- Nielsen, S., Larance, B., Degenhardt, L., Gowing, L., Kehler, C., & Lintzeris, N. (2016). Opioid agonist treatment for pharmaceutical opioid dependent people. *Cochrane Database of Systematic Reviews*(5). doi:https://doi.org/10.1002/14651858.CD011117.pub2
- NSW Health. (2020). COVID-19 Information letter for Opioid Agonist Treatment Community Prescribers. Retrieved from <a href="https://www.health.nsw.gov.au/aod/Pages/covid-19-oat-prescriber-info.aspx">https://www.health.nsw.gov.au/aod/Pages/covid-19-oat-prescriber-info.aspx</a>
- NSW Ministry of Health. (2020a). *COVID-19 Information letter for Opioid Agonist Treatment Community Prescribers*. Retrieved from <a href="https://www.health.nsw.gov.au/aod/Pages/covid-19-oat-prescriber-info.aspx">https://www.health.nsw.gov.au/aod/Pages/covid-19-oat-prescriber-info.aspx</a>:
- NSW Ministry of Health. (2020b). *Pharmacies supplying OTP for patients in self-isolation from COVID-19*. Retrieved from https://www.health.nsw.gov.au/aod/pages/covid-19-otp-delivery-procedure.aspx:
- Peacock, A., Uporova, J., Karlsson, A., Price, O., Gibbs, D., Swanton, R., . . . Farrell, M. (2021). *Australian Drug Trends 2020: Key Findings from the National Illicit Drug Reporting System (IDRS) Interviews*. Sydney: National Drug and Alcohol Research Centre, UNSW Sydney.
- Pharmacy Programs Administrator. (2020). *Program rules: COVID-19 Home Medicines Service*. Retrieved from <a href="https://www.ppaonline.com.au/wp-content/uploads/2020/03/COVID-19-Home-Medicines-Service-Program-Rules.pdf">https://www.ppaonline.com.au/wp-content/uploads/2020/03/COVID-19-Home-Medicines-Service-Program-Rules.pdf</a>:
- Platt, L., Minozzi, S., Reed, J., Vickerman, P., Hagan, H., French, C., . . . Hutchinson, S. (2018). Needle and syringe programmes and opioid substitution therapy for preventing HCV transmission among people who inject drugs: findings from a Cochrane Review and meta-analysis. *Addiction*, 113(3), 545-563. doi:https://doi.org/10.1111/add.14012
- Radcliffe, P., & Stevens, A. (2008). Are drug treatment services only for 'thieving junkie scumbags'? Drug users and the management of stigmatised identities. *Social science & medicine, 67*(7), 1065-1073. doi:https://doi.org/10.1016/j.socscimed.2008.06.004
- Ritter, A., & Di Natale, R. (2005). The relationship between take-away methadone policies and methadone diversion. *Drug and Alcohol Review, 24*(4), 347-352. doi:https://doi.org/10.1080/09595230500263939
- Ritter, A., Gomez, M., & Chalmers, J. (2019). Measuring unmet demand for alcohol and other drug treatment: the application of an Australian population based planning model. *Journal of Studies on Alcohol and Drugs, Supplement*(s18), 42-50. doi:https://doi.org/10.15288/jsads.2019.s18.42
- Substance Abuse and Mental Health Services Administration. (2020). *Opioid treatment programs (OTP) quidance*. Retrieved from https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf:
- Treloar, C., & valentine, k. (2013). Examining structural violence in opioid pharmacotherapy treatment in Australia: Sweating the "small stuff" in a liberal paradise. *International Journal of Drug Policy, 6*(24), e11-e13. doi:https://doi.org/10.1016/j.drugpo.2013.04.010
- van de Ven, K., Ritter, A., & Stirling, R. (2021). *The impact of the COVID-19 pandemic on the non-government alcohol and other drug sector: future implications*. DPMP Monograph No. 34. Sydney: UNSW Social Policy Research Centre
- Wynne, B. (2006) Public engagement as a means of restoring public trust in science hitting the notes, but missing the music? *Community Genetics* 9(3): 211-20

## THE DRUG MODELLING POLICY PROGRAM

This monograph forms part of the Drug Policy Modelling Program (DPMP) Monograph Series.

Drugs are a significant social and health issue. The aim of the Drug Policy Modelling Program (DPMP) is to create valuable new drug policy insights, ideas and interventions that will allow Australia and other nations to respond with alacrity and success. DPMP addresses drug policy using a comprehensive approach that includes consideration of law enforcement, prevention, treatment, and harm reduction, and we take a multi-disciplinary approach.

DPMP conducts rigorous research that provides independent, balanced, non-partisan policy analysis. The areas of work include developing the evidence-base for policy; developing, implementing and evaluating dynamic policy-relevant models of drug issues; and studying policy-making processes.

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DPMP strives to generate new policies, new ways of making policy and new policy activity and evaluation. Ultimately our program of work aims to generate effective new drug and alcohol policy. I hope this Monograph contributes to drug policy and that you find it informative and useful.

Professor Alison Ritter, Director, DPMP