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BMJ Open Implementation of medicinal cannabis in Australia: innovation or upheaval? Perspectives from physicians as key informants, a qualitative analysis

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ABSTRACT

Objective We sought to explore physician perspectives on the prescribing of cannabinoids to patients to gain a deeper understanding of the issues faced by prescriber and public health advisors in the rollout of medicinal cannabis.

Design A thematic qualitative analysis of 21 in-depth interviews was undertaken to explore the narrative on the policy and practice of medicinal cannabis prescribing. The analysis used the Diffusion of Innovations (DoI) theoretical framework to model the conceptualisation of the rollout of medicinal cannabis in the Australian context.

Setting Informants from the states and territories of Victoria, New South Wales, Tasmania, Australian Capital Territory, and Queensland in Australia were invited to participate in interviews to explore the policy and practice of medicinal cannabis prescribing.

Participants Participants included 21 prescribing and non-prescribing key informants working in the area of neurology, rheumatology, oncology, pain medicine, psychiatry, public health, and general practice.

Results There was an agreement among many informants that medicinal cannabis is, indeed, a pharmaceutical innovation. From the analysis of the informant interviews, the factors that facilitate the diffusion of medicinal cannabis into clinical practice include the adoption of appropriate regulation, the use of data to evaluate safety and efficacy, improved prescriber education, and the continuous monitoring of product quality and cost. Most informants asserted the widespread assimilation of medicinal cannabis into practice is impeded by a lack of health system antecedents that are required to facilitate safe, effective, and equitable access to medicinal cannabis as a therapeutic.

Conclusions This research highlights the tensions that arise and the factors that influence the rollout of cannabis as an unregistered medicine. Addressing these factors is essential for the safe and effective prescribing in contemporary medical practice. The findings from this research provides important evidence on medicinal cannabis as a therapeutic, and also informs the rollout of potential novel therapeutics in the future.

BACKGROUND

Cannabis was first used as a medicine as far back as 5,000 years ago.^{1 2} In the 19th and

Strengths and limitations of this study

- Fills an identified gap in the literature by reporting physician perspectives of the rollout of medicinal cannabis in Australia.
- The research aligns with conventions for 'quality' in qualitative research as reported in the COREQ checklist for the reporting of qualitative research. <https://doi.org/10.1093/intqhc/mzm042>
- Research was guided by a validated theoretical framework, the Diffusion of Innovations (DoI) model.
- Provides evidence around perspectives from Australian key informants only, and as a result, may not be generalisable to policy and practice in other countries.
- The purposive and snowball sampling techniques are non-random, and may not be generalisable across population groups who do not have experience and/or interest in, medicinal cannabis prescribing.

early 20th centuries, cannabis was widely used for medicinal purposes, yet by the mid-20th century cannabis was restricted by legislation enacted by the Single Convention on Narcotic Drugs, that re-classified it from a therapeutic medicine to a prohibited drug.^{1 3-6} This legislation not only criminalised the use of cannabis, but also contributed to a lack of evidence on its medicinal effects as procurement of cannabis for scientific studies was not permitted.^{1 6} Hence, during this time, the focus of cannabis research was around the recreational use of cannabis and associated drug policies, rather than that of cannabis for medicinal purposes.¹

Since the 90s, there has been a re-emergence of interest in the use of cannabis as a medicinal product. This has been driven by multiple factors that include: developments in the understanding of the endogenous cannabinoid system; the collateral effect of the opioid epidemic in the Western world; an increasing prevalence in cannabis use; community perceptions



that cannabis is relatively 'inert'; and the rapid expansion of the medicinal cannabis industry.^{1 6–8} Worldwide, community demand for access to medicinal cannabis products has followed this increased interest.

In 2019, the Director General of the World Health Organization (WHO) recommended the rescheduling of medicinal cannabis in the International Drug Control Conventions framework to facilitate the use of cannabinoid substances for medicinal and scientific purposes.⁷ This recommendation followed legislative changes across the globe where in the early 2000s, Israel (2001), Canada (2001), the Netherlands (2003) and later other countries, including Switzerland (2011), Italy and Czechia (2013), Australia (2016) and Germany (2017) legislated the use of medicinal cannabis under specified conditions.⁷ An increasing number of states in the United States (US) are also legalising cannabis for both medicinal and non-medicinal use, despite opposing US Federal Laws.^{7,8} The United Kingdom legalised medicinal cannabis in late 2018, and other countries such as Luxembourg are following suite with the introduction of pilot programmes for medicinal cannabis prescribing.^{7,9}

Legislation authorising the compassionate use of medicinal cannabis was endorsed in Australia by state and federal Governments in October 2016.¹⁰ The cultivation and production, research, and manufacture of medicinal cannabis in Australia were also decriminalised at this time.¹¹ On 1 November 2016, further amendments were made to the scheduling of medicinal cannabis products. These changes resulted in certain medicinal cannabis products, such as cannabidiol (CBD), being down regulated from a Schedule 9—prohibited substances category to a Schedule 8—controlled drug category by the Australian medicines regulatory body, the Therapeutic Goods Authority (TGA).¹⁰ To date, only two medicinal cannabis products, Sativex and Epidyolex, are included in the Australian Register of Therapeutic Goods (ARTG), all other medicinal cannabis products are classified as an unapproved therapeutic good, as they have not been assessed by the TGA for safety, quality and effectiveness.¹⁰

To address an increasing demand for medicinal cannabis in Australia, an online TGA approval system was introduced in July 2018 to enable a more streamlined process for lodgement of Special Access Scheme Category B (SAS-B) applications for the prescribing of unregistered medicinal cannabis preparations.¹⁰ Since then, from a baseline of 188 applications recorded in July 2018, there has been a 7,169 percentage increase in the number of SAS-B applications approved, with 13,666 approvals registered in the month of September 2021. A cumulative total of 172,162 applications have been approved since January 2017 (figure 1).¹⁰ Yet, notwithstanding this increase in prescribing, there is still discord between those who are in favour of medicinal cannabis and those who are not, and this potentially drives a chasm between patients and their physicians, as well as, physicians and their colleagues.

Medicinal cannabis exemplifies one of a suite of therapeutics that have been introduced with an ambiguous understanding of benefit and no clear evidence on clinical indications for its use. Other agents in this category include 'health supplements' such as probiotics,^{12 13} e-cigarettes as nicotine replacement therapy,¹⁴ and other illicit substances that are predicted to be of broader therapeutic value in the future, such as psychedelics for the treatment of anxiety and addiction.¹⁵

Rigorous research is required to contribute to the evidence underpinning the implementation of medicinal cannabis prescribing in any setting. Hence, the collection of information specifically relating to physicians' knowledge, concerns, and experiences of medicinal cannabis is imperative. To date, the majority of studies that have been published by a range of countries have highlighted remarkably consistent themes which include: health professionals lack of confidence in prescribing medicinal cannabis; the need for education about cannabinoid therapeutics; and differing attitudes to cannabis as a therapeutic agent.^{16–18} A systematic review undertaken by Gardiner *et al* in 2019, that synthesised research from 26 studies found in general, health professionals supported the use of medicinal cannabis in practice.¹⁶ Yet, the review also reported there was a lack of self-perceived knowledge about all aspects of medicinal cannabis, and also indicated health professionals were concerned about direct patient harms and indirect societal harms associated with medicinal cannabis use.¹⁶ To date, the majority of published evidence with a focus on physician perceptions has been collected using surveys and questionnaires, although a small number of studies have obtained evidence from interviews.^{19–25} Of the evidence from interviews, two studies examined physician insights around use of medicinal cannabis as a therapeutic agent.^{17 20} One study published by Braun *et al*, in 2018, conducted semistructured interviews with oncology experts from the US.²⁰ This research had a specific focus on physician perceptions of the use of medicinal cannabis in oncology and cancer care. The other published by Zolotov *et al*¹⁷ in 2018, used narrative analysis of data collected from interviews of 24 Israeli physicians with specialities in pain medicine, oncology, and family medicine.¹⁷ While these qualitative data provided vital evidence to the current research landscape, neither examined key informant perspectives on the important broader systemic issues, such as how the 'diffusion' of medicinal cannabis into medical practice is occurring.

In terms of the global context, the Australian approach to medicinal cannabis that began with the adoption of legislative changes to permit prescribing delivers a unique opportunity to gather important evidence for the factors which impact the rollout of medicinal cannabis. It also enables an examination of aspects of the rollout that influences the diffusion and dissemination of medicinal cannabis into contemporary clinical practice. Importantly, it provides an opportunity to investigate the health system and regulatory factors that are associated with

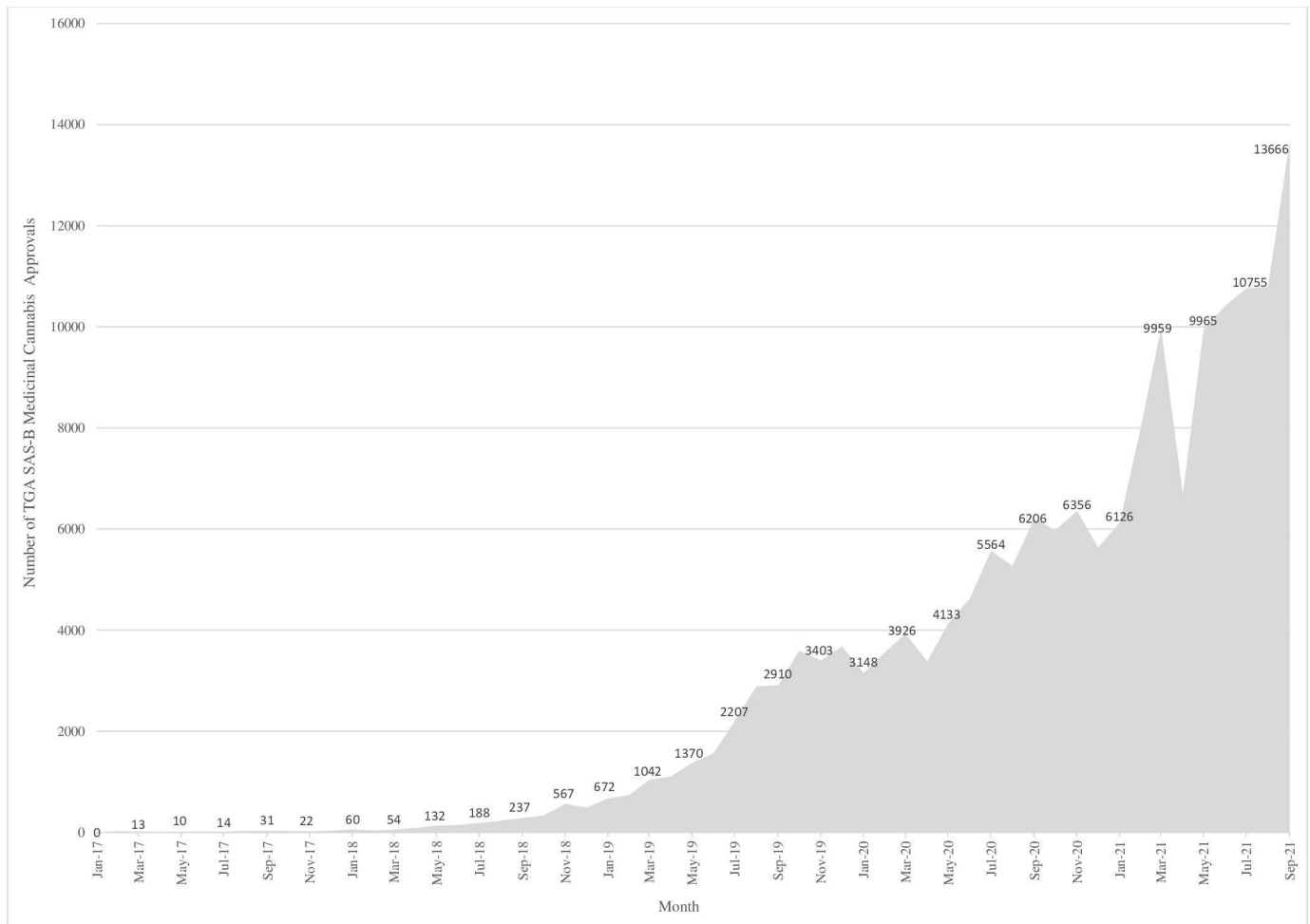


Figure 1 Number of Therapeutic Goods Authority (TGA) Special Access Scheme (SAS) Category B approvals of Medicinal Cannabis in Australia - January 2017 to September 2021. Sourced from <https://www.tga.gov.au/medicinal-cannabis-access-data-dashboard>.

the provision and monitoring of medicinal cannabis to patients. It is thus, timely to examine de novo, the ‘diffusion’ of medicinal cannabis to gain a greater understanding of the facilitators and barriers to the safe and appropriate dissemination of medicinal cannabis to patients by their physicians.

The theoretical model of the Diffusion of Innovations (DoI)²⁶ helps conceptualise both the implementation of medicinal cannabis globally, and the factors required to facilitate its safe and effective rollout. Originating in 1962, the framework explains how a product or idea can gain momentum and ‘diffuse’ through a social system, with the end result being that the product or idea is adopted and becomes a part of the social system.²⁶ This framework has previously been used in research relating to innovations in healthcare, medical sociology, and physician practice including that of prescribing.^{26–35} Medicinal cannabis has characteristics relevant to pharmaceutical innovations by virtue of its ‘medicinal’ name and by the requirement for it to be, in the main, prescribed by a medical professional for a health condition. With the application of medicinal cannabis to the DoI framework it becomes clear, key to adoption is the perception by both prescribers

and community, that medicinal cannabis is in fact, innovative. Pharmaceutical marketing, drug characteristics, government policies, and the behaviour of both medical professionals and their patients are additional factors that influence the uptake of a new therapeutic agent.³¹ The principal difference with medicinal cannabis is, that unlike other pharmaceutical innovations, it is not a molecule or compound for use in a single or small cluster of indications, and importantly, it has not emerged from a ‘traditional’ pharmaceutical company that has established research, development, and pharmacovigilance capabilities.

In this research, we aim to gain a deeper understanding of the factors that are associated with the diffusion of an unlicensed therapeutic into medical practice for which, strong consumer demand preceded the research evidence. Specifically, this research aims to provide evidence from key informant perspectives on the role of the prescriber. Also sought, were informant perspectives on the relevance of regulatory authorities in the prescribing of medicinal cannabis, and their views on the precedent that medicinal cannabis has set, in particular around consumer-lead medicine. Furthermore, we aim

Table 1 Interview guide

Theme	Question
Medicinal cannabis as an innovative medicine	Before we start, do you view medicinal cannabis as a (pharmaceutical) medicine, or do you feel it should be defined as another type of product?
Role for medicinal cannabis as a pharmaceutical	What do you see currently as the role for medicinal cannabis?
Experience with medicinal cannabis	Can you tell us a bit about your experiences around medicinal cannabis?
Rollout of medicinal cannabis in Australia	Take us through the processes of prescribing medicinal cannabis from when a patient presents, to when they leave and when you review their progress?
Overall attitude to medicinal cannabis in Australia	Is there anything that we haven't discussed yet that you think is important for us to know about? Such as a take home or 'chestnut' message.

to provide lessons to inform future policy and practice, especially with the introduction of other potential novel therapeutic agents into clinical practice. This is essential to informing both the rollout of medicinal cannabis and the way medicine is practised in the 21st century.

METHOD

Study design

A qualitative thematic analysis was used to investigate the narrative around medicinal cannabis prescribing in the Australian context. Informants were invited to participate in an in-depth interview, which was guided by a small number of open-ended questions (table 1). These questions were developed a priori, guided by DoI theory, and informed by conference presentations, webinars, grey literature, and publications on medicinal cannabis that were authored by clinicians, representatives from peak professional bodies, policy advisors, and researchers.^{17 24 36–40}

Exclusion and inclusion criteria

Key informants were invited to participate in this research based on their: (i) involvement in the development of health policy; (ii) prescribing experiences in clinical practice; and (iii) advocacy roles for and against medicinal cannabis. This provided evidence from both prescribing and non-prescribing key informants, as it was deemed important to understand not only the factors that influenced an individual to prescribe medicinal cannabis, but also the factors that influenced an individual not to prescribe. The interview focus was on medicinal cannabis products that can be prescribed via the TGA SAS-B scheme. Informant considerations around non-prescribed artisanal medicinal cannabis products, also referred to as bootleg medicinal cannabis, were included in the analysis, as these unregistered preparations are known to be sought by patients who cannot afford the medicinal cannabis product that clinicians generally prescribe via the SAS-B scheme.⁴¹ Informant reflections on medicinal cannabis use for recreational purposes, was excluded from the analysis because this refers to cannabis use from a very large and heterogenous cohort, many of whom have a prior history of cannabis use for non-medical purposes. Given it is difficult to differentiate

between cannabis use for recreational purposes versus cannabis use for health reasons, the scope of this study focused on use of cannabis for medical purposes only.

Recruitment

Key informants were selected using purposive and snowballing techniques. Initially, informants were selected following an environmental scan.⁴² The approach involved the opportunistic identification of informants from already established contacts such as physicians and researchers, as well as more focused scoping that involved the identification of individuals exposed to the policy, prescribing, and advocacy for and against medicinal cannabis use. This included those from peak professional bodies, government departments, and individuals who have contributed to the research evidence. Other potential key informants were identified following interviews using snowballing techniques. This involved invitation of the peers of interviewees upon their suggestion to do so. We excluded informants who were involved in the cannabis production industry, and those who worked in and/or operated speciality cannabis clinics or cannabis dispensaries. Informants were sent an email and a postal invitation; this recruitment methodology has been shown to increase response rates.⁴³ The informants who did not respond were followed up with either another email and/or a phone call. All informants were provided a patient leaflet information statement and a consent form prior to the interview. Consent was provided both verbally in the interview and as a signature on the consent form.

Interviews and analysis

Semistructured interviews, of an average duration of 1 hour, were conducted by two authors (CH and YB) either face to face, via video conference, or by telephone (table 1). All informants were notified that the interview would be recorded and transcribed verbatim. Notes were taken during the interview. Although the interviews were guided by open-ended questions, inductive probing was also employed to facilitate response heterogeneity.⁴⁴ Reflexive notes were developed on completion of the interview, this involved the critical analysis of the interview process by the interviewers (CH and YB). All interview data were deidentified and stored in a secure platform. Data were then managed in NVivo V.12.⁴⁵

Given the use of DoI conceptual model, analysis included both inductive and deductive coding. Coding was undertaken by two authors (CH and YB). This duplication provided the analysis, perspectives from different researcher backgrounds, and opportunities to refine the coding system and discuss coding disagreements.⁴⁶ Thematic saturation was ascertained after data collection, and was based on saturation of new information threshold, where there was no evidence of the emergence of new themes, beyond those already established.

Patient and public involvement

The study involved researchers with clinical and research experience from the Department of General Practice in the Melbourne Medical School at the University of Melbourne and St Vincent's Hospital, Melbourne. These researchers designed and conducted the qualitative research that involved interviewing clinicians, public health advisors, and representatives from peak body organisations.

RESULTS

A broad cross section of the medical community who had an interest in medicinal cannabis were sought. Twenty-six individuals were approached, twenty-three accepted, of these one withdrew for personal reasons, and another withdrew because of time constraints. Three individuals did not respond to any of the invitations, none of these potential informants were directly involved in the prescribing of medicinal cannabis. Of the informants who accepted, 13 were active prescribers, 4 were non-prescribers, and 4 were public health advisors. The 21 key informants included neurologists, rheumatologists, oncologists, pain specialists, psychiatrists, public health advisors, and general practitioners. All informants were based in the Eastern states and territories of Australia (Victoria, New South Wales, Tasmania, Australian Capital Territory, and Queensland). There were no informants from other states and territories of Australia (South Australia, Western Australia and Northern Territory) because at the time of the interviews there was minimal medicinal cannabis prescribing in these jurisdictions. Interviews were conducted between November 2018 and January 2019.

Factors Influencing the Diffusion of Medicinal Cannabis in Australia

A number of components in the DoI framework were described by the Key Informants in relation to Medicinal Cannabis .

Medicinal Cannabis as an Innovation

The information in this domain is depicted in the INNOVATION block (figure 2)

From the interviews, it was evident that key informants recognised the innovation of medicinal cannabis when

Box 1

...it doesn't work for everybody and for some people it has no benefits whatsoever...for some people, it has terrible side effects, but I believe that users are best able to work with their doctors if they think it is a benefit to them. It is one of those things that you kind of have to try. (I-013)

I am not the fearful cannabis (that) will kill you all, and I am not the cannabis (that) cannabis will cure you all. (I-015)

used for the treatment of conditions where a patient presents with debilitating refractory symptoms and a lack of response to current recommended therapies. Examples of conditions cited included childhood epilepsy, chemotherapy related nausea and vomiting, pain management for patients in palliative care, chronic non-malignant pain, and young people with anxiety. Some informants perceived medicinal cannabis as relatively 'inert', and therefore advantageous, especially when comparing adverse events to other therapeutics that have been used to treat the above conditions.

Several individuals reported on the positive benefits from medicinal cannabis that were either observed in their clinical practice, or derived from the scientific literature. Yet, often, articulation about the benefits were vague. One informant described the effects of cannabis as 'different' and 'special'. Several described that patients reported they 'just felt better'. On the other hand, some found not all patients benefited from medicinal cannabis, and in these situations prescribing of medicinal cannabis ceased (Box 1).

All informants referred to the prescribing of medicinal cannabis as being fraught with complexities associated with ambiguities around its effectiveness, the political process involved in its rollout, the patients and conditions in which it is prescribed, and the prescribing process itself.

Some informants were concerned about potential harms of medicinal cannabis, especially regarding its effects on the developing brain, risks associated with cognitive impairment in young people, as well as risks more generally, such as impairment in relation to driving. Most asserted medicinal cannabis should only be prescribed for conditions recommended by the TGA, and should be underpinned by a caveat that risks of harm should be considered relative to severity of the indication for its use. For instance, prescribing medicinal cannabis to a young child posed more of a concern than prescribing to a patient with terminal cancer as part of a palliative care regime.

Most informants referred to issues around the purity, concentration, and consistency of medicinal cannabis products. For example, they queried the reliability of medicinal cannabis preparations where concentrations of tetrahydrocannabinol (THC) and cannabidiol (CBD) may not match the dosages they wished to prescribe. Informants also reported some medicinal cannabis

Box 2

There's no reimbursement - no subsidy, I should say, and the companies are just taking advantage of the situation. I find it difficult to believe that it could actually cost \$650 a bottle for them to make it and sell it at a profit. (I-009)
(Costs)... to the order of a couple of grand a month. One to two and a half thousand per month. The one thousand is because it's an infant. It's prohibitively expensive. Broadly, if there's a family that are asking and meet that sort of criteria, severe and failed everything, I'm very happy to prescribe the private script. As long as they're properly informed and consented. It's a huge chunk of money for most people. (I-001)

companies appear to be naive of mainstream regulatory pharmaceutical practices that include, knowledge of how to store scheduled products safely (safe storage practice) and the imperative to report adverse events to the TGA.

A few informants also described ambiguities regarding where medicinal cannabis 'fits in' with contemporary medical models of care, such that, some informants viewed medicinal cannabis as an 'unregulated herb' rather than that of a medicine. Many reported concerns around the lack of empirical evidence for efficacy and lack of data around adverse events. Several informants reported on the financial burden incurred by patients wanting cannabis medicines. Some described costs as prohibitive, especially in situations where patients had been enrolled in trials that had come to an end. Informants also recounted lag times, particularly early in the rollout, where a request for cannabis and patient access to the product could take several months (Box 2).

The vast majority of informants reported on the great divide between the safety and quality of products that are derived from an unregulated market, where pharmaceuticals are not appropriately trialled and developed accordingly to TGA standards for approval. Some mentioned concerns about toxicology of the product and the need to titrate the product slowly to ensure the patient was not inadvertently receiving doses at 'toxic' levels. Others were concerned about the quality of the product because of uncertainty about the conditions of manufacturing (Box 3).

Many informants indicated they were involved in trialling the product where they were invited to participate in open-labelled trials by governments and medicinal cannabis companies. In these trials, the prescriber was the conduit between the patient and the cannabis product which had been supplied by the medicinal cannabis company. This provided an opportunity for patients

Box 3

The question is if it's grown outdoors - so, the first thing is, it has to be organic, there can be no chemicals or anything else used, herbicides, because if you're using for medicine. The second thing is it has to be consistent. (I-012)

Box 4

I'm a strong advocate for this being treated the same as any other medicine. In that way ideally cannabinoid trials would continue, just like any other medicine... (I-001)
Most of us - people are generating trial data but really in very specific... (conditions). (I-009)

to access medicinal cannabis cost free, and enabled providers a greater understanding of how to prescribe medicinal cannabis. It also provided experience in how best to monitor their patient's response, whether it be regarding symptomatic relief or in the management of adverse events (Box 4).

Diffusion and Dissemination of Medicinal Cannabis

The information in this domain is depicted in the DIFFUSION & DISSEMINATION block .

All informants discussed the requisite for explicit knowledge from professional and peer networks to inform prescribers on the effects and outcomes of medical cannabis. Many informants reported they gained explicit knowledge through access to peer reviewed publications and through government websites such as the TGA. They also described gaining knowledge from information provided to them by their peers, although a few informants reported they were not confident of the knowledge base of colleagues. The gaining of implicit knowledge by undertaking open-label trials and monitoring their patients who are on the trials, was viewed as beneficial, in that it informed their own clinical practice and contributed to the evidence base. Prescribing to patients provided further tacit knowledge. In this case informants reported unexpected effects, such as symptomatic relief in some patients who were prescribed only a very small amount of product, and minimal effects in patients who were prescribed large doses of the same product. The potential for placebo effect was also acknowledged, but this did not deter prescribers from continuing to prescribe medicinal cannabis (Box 5). Informants discussed concerns around prescribing medicinal cannabis when the exact quantity of CBD compared with the more psychoactive component THC was often not known or guaranteed. Many informants considered reported ratios between THC and CBD products not reliable, as the manufacturing of the product was not controlled by a pharmaceutical regulatory body. Most reported the paucity of validated evidence on the effects and adverse outcomes associated with medicinal cannabis use was a major limitation in the rollout of cannabis to patients.

Prescribers also indicated they had minimal explicit knowledge on the Special Access Scheme prescribing process, especially regarding how to prescribe an unregistered medicine to a patient. Notwithstanding this, all reported much implicit and tacit knowledge was gained

Box 5

The problem - I think that people - general public will have their views about it being useful for x and y because that's already out there. I think the medical profession, hopefully if the data gets better, will have a better idea about what it actually is useful for and what combinations of different compounds are... (I-018)

with each subsequent prescription application that was submitted and approved (Box 5).

The majority of informants perceived medicinal cannabis companies greatly facilitated the dissemination of medicinal cannabis by actively pursuing doctors and inviting them to either trial their product or prescribe to patients, via newly established cannabis clinics or cannabis dispensaries. Several reported medicinal cannabis companies frequently cited overseas 'successes' relating to the rollout of medicinal cannabis. Many informants mentioned the entrepreneurial nature of the medicinal cannabis industry, and also referred to the risks associated with the artisanal medicinal cannabis products, as well as risks associated with patients who can, or will, 'grow their own' cannabis, particularly if it becomes legalised.

Some informants referred to individuals they perceived as medicinal cannabis 'champions' in Australia. These 'champions' were viewed as active players in the pursuit of normalising medicinal cannabis access.

Informants frequently reported the process for prescribing was quite technical, especially regarding the necessary requirements for a prescriber to gain an authorised prescriber status by the TGA. Most reported that support was provided by the TGA around the process. Both the TGA and prescribers reported the technical process around prescribing were both labour intensive and burdensome in the initial rollout, they both also reported this improved over time (Box 6).

Health System Readiness

The information in this domain is depicted in the HEALTH SYSTEM READINESS block .

The vast majority of informants reported that the agency for change leading to the rapid evolution of cannabis from that of a herb, to that of medicine, reflected the political response to patient demand. Many also commented that this had caught much of the medical profession unaware. A striking number of informants referred to (without

Box 6

I think initially there were long processing times involved... It was very confusing to know what to do... I think it's much, much quicker than it used to be. (I-004)

There used to be quite a complex application... that would typically be rejected multiple times. (I-010)

...initially there were long processing times involved. It was very confusing to know what to do. (I-005)

Box 7

...the horse has bolted, in fact the horse has bolted so far it's over the horizon...given that the horse is a government horse, the jockey has fallen off'; 'the horse has bolted and left the cart way behind...the cart's sitting behind the barn at the moment'; 'after the horses have bolted, everyone's growing it and setting up'; 'I see a horse that's bolting...and a cart before the horse' 'a rather opportunistic cart before the horse, but good publicity move on behalf of the politicians. (1-002; 1-006; 1-008; 1-012; 1-015)

They (politicians)] were, in a way, pushed into this - I mean, it (medicinal cannabis) might act as a Trojan horse to some degree. (0-018)

...there's a bit of a Trojan horse dynamic here I think, where those who actually, really are dependent and need and want it because they're dependent, have now got an easy way of communicating, give it to me because I've got a medical problem. (0-018)

With the current trend of course we're going to end up with the legalisation of cannabis...That's clearly the hidden - that's the Trojan horse'. (0-013)

prompting) metaphors associated with 'the bolting horse' and the 'Trojan horse' where they felt the medicalisation of cannabis happened too rapidly, and also provided a way for recreational users to access legalised cannabis under the guise of a medicine (Box 7).

Some informants argued for the need for new governmental arrangements between legislative structures and the 'content experts' to drive the medicinal strategy forward. Most were open to expansion of the programme, yet all felt it was unhinged by the rapid and under-resourced rollout of the innovation, and by a lack of systemic monitoring (Box 8).

A number of informants expressed the view that medicinal cannabis is compatible with the way they work, citing the 'doctor-patient relationship' and 'a duty of care' to their patients, as reasons for considering prescribing medicinal cannabis. Some informants commented on the tenacity with which patients believed that cannabinoids would provide benefit, and remarked that this was an influential factor for them to take up prescribing.

Social influences were also cited by a number of informants. They noted that the families of children with chronic conditions, celebrities, advocacy groups, and politicians have been strong influencers to prescribe medicinal cannabis. The impact of social influencers on medicinal cannabis access was considered as unprecedented, especially considering the conventional ways in

Box 8

That's our challenge now - to re-think our legislative structures and how we manage problems so that we can reduce the induced indirect harm...the legal harms...(associated with) increasing access, availability, advertising, promotion, and cost incentives to increase consumption...That's our challenge. But who's going to lead this? I seem to be - not a lone voice, but I feel alone in that message I am sending. (1-013)

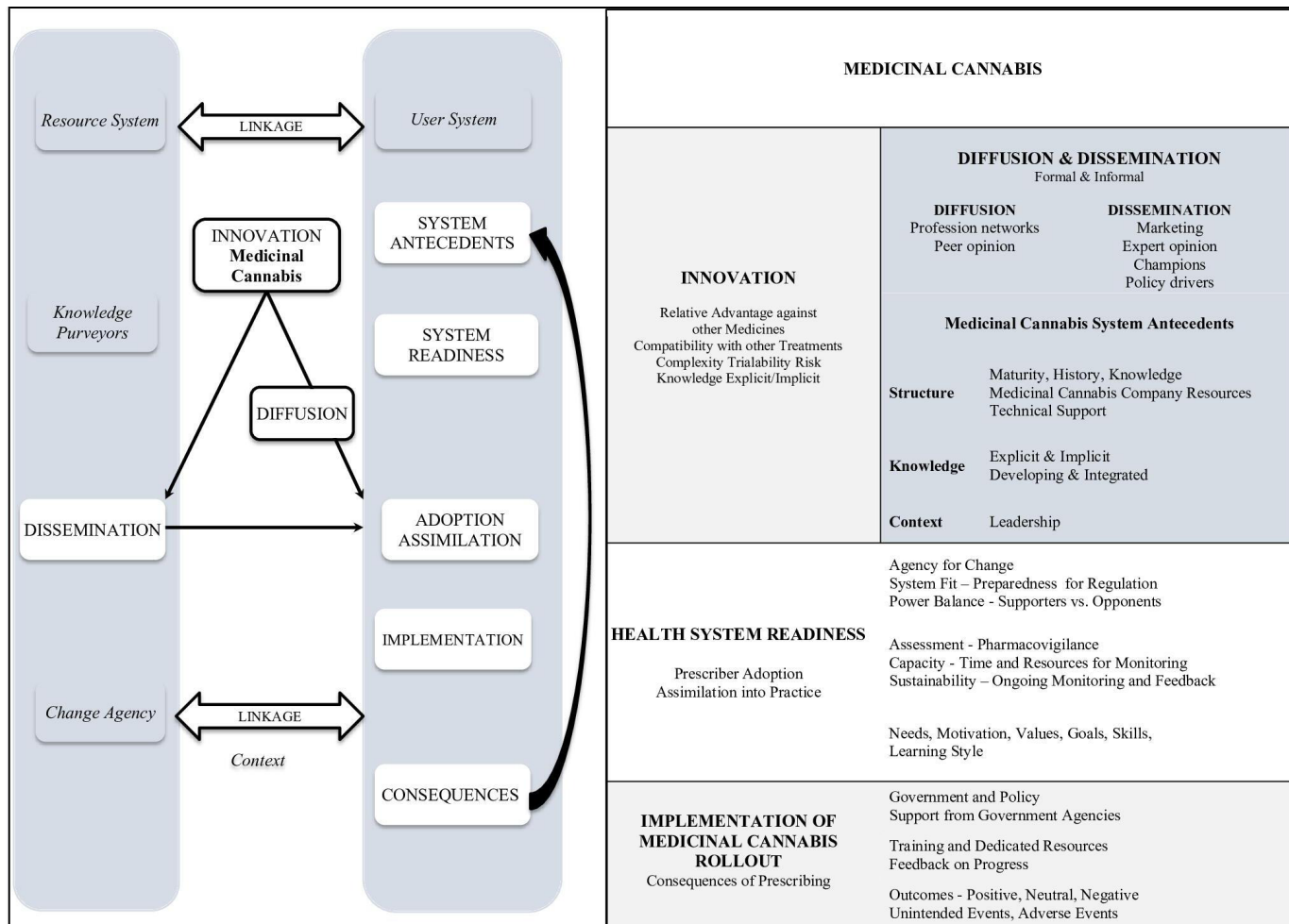


Figure 2 The Application of Diffusion of Innovations theory to the rollout of Medicinal Cannabis in Australia. Adapted from ncbi.nlm.nih.gov/pmc/articles/PMC2690184/.

which evidence based practices are established in medicine. Some informants felt the impact of social influencers on the medicinal cannabis space had benefits, particularly in raising awareness, and attracting philanthropic and (to a lesser extent) government funding, yet some informants also reflected on the disadvantages. These informants cited that pressure, even coercion, and a lack of acknowledgement of established processes for the safe introduction of a new therapeutic has, to some extent, created a division between the community and health professionals.

Implementation of Medicinal Cannabis Rollout

The information in this domain is depicted in the IMPLEMENTATION OF MEDICINAL CANNABIS ROLLOUT block (figure 2).

Many cited a lack of leadership and direction from the medical profession, governments, and government agencies in the initial stages of the rollout, although most of these informants also reported this improved with time. For example, the guidance documents published on the TGA website were described as beneficial and of those who had prescribed, all reported the streamlining

of the SAS-B application process most beneficial. One informant felt the TGA had done a remarkably good job navigating through the issues, especially considering the political pressure they were under, and the clinical reality of prescribing an unlicensed product to a patient. Regarding access to formalised education, all informants stated this was greatly needed, yet for those who prescribed, all reported they were competent even though they were for the most part, ‘self-taught’. They described this self-teaching as burdensome, in both time and effort, however they justified their efforts by indicating they were prepared to do so, because they felt they had a duty of care towards their patients.

Many informants acknowledged the need for a robust and nimble pharmacovigilance system for the reporting of adverse events so that they understood what to monitor for when undertaking a patient review. Most considered that the systematic monitoring of prescribing outcomes was vital for the safety of future patients, and many raised concerns about potential harms associated with the provision of medicinal cannabis to children and young people. All considered the system currently in place for pharmacovigilance was inadequate and described the need

Box 9

...the idea of proper pharmacovigilance. And that's safe prescribing, and it's a whole system that we just don't have in Australia... It would be good if we can make some changes because that'll have a benefit across the board. (I-001)

There is a dearth of knowledge. We need to have a prospective arrangement in order to supply pharmacovigilance that are also about outcomes - the profiles of people who are benefiting and not benefiting. So I think there's a bit of a direction of duty there. (I-018)

I think there's a high risk of a poorly regulated market, or limited regulation market, where patients, will be able to get maybe partially subsidised products that are probably manufactured well but don't have the trial backing. The way we make advances in medicine is through research. If it just falls down to anecdotal stories and claims, then we're not going to know the right doses... (I-001)

for systematic and sustained research around medicinal cannabis and its effect on humans (Box 9).

DISCUSSION

The rollout of medicinal cannabis as a therapeutic into the Australian community has not been streamlined, as confirmed by the Australian Senate inquiry into current barriers to patient access to medicinal cannabis that was reported on, in March 2020.⁴⁷ This study of 21 physician key informants, provides important evidence on the factors that have facilitated patient access to medicinal cannabis and the barriers that need to be addressed to support safe and effective access in the future. The key informants overwhelmingly acknowledged the complexity and shifting context of medicinal cannabis prescribing and also highlighted the need to incorporate a breadth of considerations into future policy that include public, political, economic, and health service perspectives.

The majority of informants viewed medicinal cannabis as an innovation. Several saw medicinal cannabis had therapeutic benefits, especially when used as adjunct treatment for conditions that do not respond to usual care. System antecedents in the context of medicinal cannabis were categorised in the DoI model as structure, knowledge, and context. Structure includes medicinal cannabis maturity, history, and distributor resources, and relates to the preparedness of medicinal cannabis companies to supply the market a quality product without prohibitive costs to the consumer. Knowledge relates to stakeholders pre-existing understanding of the endocannabinoid system including the pharmacology of cannabinoids, and context relates to medical leadership in the prescribing of medicinal cannabis. It was evident from the informant interviews that these system antecedents had largely been deficient in the rollout of medicinal cannabis.

The aspects of health system readiness reported by informants included evidence of agency for change which arose from multiple voices, with divergent interests. Voices included that of consumers who advocated

for access, politicians who responded to the public voice, regulators who advised, cannabis companies who supplied the product, and medical professionals who cared for their patients irrespective of their own stance on medical cannabis. Missing components of health system readiness related to lack of resources required to perform monitoring and feedback, and the staggered legislative changes around the various jurisdictions of Australia that impacted on the diffusion and dissemination of medicinal cannabis prescribing in clinical practice.

Prescriber adoption and assimilation into practice remains a stark gap in the diffusion of medicinal cannabis into the Australian community. Understanding the needs, motivation, values, goals, skills, and learning style of health professionals in relation to prescribing medicinal cannabis is an area that requires far greater attention. While addressing the most immediate needs such as prescribing guidance and streamlined regulatory approval have been important steps, there are other policy levers that are understood to impact on the uptake of an innovative therapeutic.^{48–52} Levers used to promote the safe diffusion of a therapeutic into clinical practice often incorporate a blend of financial and non-financial incentives that include direct remuneration, performance feedback, and the delivery of information technology systems. For example, financial incentives could incorporate the inclusion of general practitioner remuneration for the reporting and monitoring of medicinal cannabis prescribing. Similarly, digital workflow tools, such as general practice electronic medical record (EMR) software functions can facilitate the reporting of effectiveness and adverse events, through the application of automated prompts, to enable the monitoring of medicinal cannabis in clinical practice. Other notable factors in the DoI framework that will assist in the safe implementation of medicinal cannabis include training and education, dedicated resources for systematic monitoring at a national level, the use of patient reported outcome measures, and importantly, feedback on progress. All of these components that are vital for the detection, assessment, and prevention of adverse effects, provide opportunities for active and integrated pharmacovigilance to monitor prescribing and enhance patient safety.

Rapid changes in today's world are challenging the traditional ways that bodies such as regulatory agencies and medical colleges authorise and endorse clinical practice, and medicinal cannabis prescribing provides no exception. Notwithstanding the steps that have already been undertaken by these authorities to accommodate medicinal cannabis to date, the increasing demand for medical cannabis has exerted substantial pressures on these organisations to continually adapt and change how they operate.⁵³ To work through the issues highlighted by the informants in this study, ongoing dialogue between regulatory authorities, health professionals, and the community, both at the outset and throughout the process of the rollout was and is, vital. Of importance, is the acknowledgement from patients and prescribers that



there remains a paucity of knowledge around the side effects and adverse events of medicinal cannabinoids. This understanding will provide an impetus for both patients and prescribers to contribute real world data to pharmacovigilance systems. Equally, as has been proposed by others, the voice and experience of consumers needs to be incorporated into the way health professionals prescribe and the way regulatory authorities facilitate the provision of medicinal cannabis to patients.⁵⁴ Addressing these factors is essential for safe and effective prescribing in contemporary medical practice.

Strengths and limitations

The strength of this research is that it fills an identified gap in the literature by reporting physician perspectives of the rollout of medicinal cannabis in Australia. The research aligns with conventions for 'quality' in qualitative research as reported in the COREQ checklist for the reporting of qualitative research, and was also guided by a validated theoretical framework, the DoI model. The analysis provided this research perspectives from Australian key informants only, and as a result the research may not be generalisable to policy and practice in other countries. Although the purposive and snowball sampling techniques provides qualitative data around informant experience in policy, prescribing, and advocacy for and against medicinal cannabis, this strategy is a non-random technique, and may not be generalisable to population groups that do not have experience of, and or interest in, medicinal cannabis prescribing. Notwithstanding this, the themes from this research are valuable across all contexts, as they provide an understanding of the dynamics at play when access to an unapproved therapeutic precedes the establishment of scientific evidence from rigorous studies such as randomised controlled efficacy trials.

CONCLUSION

Medicinal cannabis marks a new era in the practice of medicine. Several informants were comfortable with the increasing trend for consumer-lead health advocacy in the medicinal cannabis space, yet at the same time, many expressed concern that this practice seemed to be at the expense of 'tried and true' methods of clinical care. They emphasised the prescribing of medicinal cannabis had the potential to move clinical practice away from a scientific paradigm, to that of demand driven care. Given this, an understanding of the multiple interacting factors known to influence the diffusion of pharmaceutical innovations is imperative, to facilitate the safe and effective implementation of medicinal cannabinoids into practice. Incorporation of consumer and physician experience into the way regulatory authorities facilitate the provision of medicinal cannabis, is needed. Consumers and prescribers also need to be willing to embrace innovative methods of pharmacovigilance to address gaps in the evidence for the indications for which medicinal cannabis is prescribed. We have shown that integration of

the factors that influence the diffusion of an innovation is critical to innovation success. Integration includes active communication, consultation, and dialogue between key stakeholders including consumers, prescribers, regulatory authorities, and politicians. This research highlights the tensions that arise and the factors that influence the rollout of cannabis as an unregistered medicine. Addressing these factors is essential for the safe and effective prescribing in contemporary medical practice. The findings of this research provides important evidence on medicinal cannabis as a therapeutic and also informs the rollout of potential novel therapeutics in the future.

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Contributors CMH made substantial contribution to the conception and design of the work, and as guarantor, accepts full responsibility for the conduct of the study. CMH is accountable for all aspects of the work ensuring that questions related to the accuracy or integrity of any part of the work were appropriately investigated and resolved. CMH and YAB substantially contributed to the acquisition of the data. CMH and YAB made substantial contribution to the analysis interpretation of data. CMH and YAB drafted the work. JMG provided oversight of the manuscript. YAB and CMH revised the manuscript critically for important intellectual content. CMH contributed substantially to the final version to be published. Final approval was gained from CMH, JMG, and YAB.

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