EDITORIAL

"Cultivating understanding": Navigating the complexities associated with medicinal cannabis and implications for nursing practice

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In February 2016, the Australian Parliament legalised medicinal cannabis (MC) through the passing of the *Narcotic Drugs Amendment Act 2016*, which outlined the regulation overseeing the cultivation, production, and manufacture of cannabis for medical or scientific purposes.[1] This announcement came 12 months after the death of Dan Haslam, a young man from Tamworth who was utilising illicit cannabis for therapeutic purposes to manage the debilitating chemotherapy-induced nausea and vomiting (CINV) he experienced whilst battling bowel cancer. Alongside his mother Lucy, a retired registered nurse, they advocated and lobbied tirelessly to make such change possible; for this reason, the aforementioned Act was also named "Dan's Law" in his honour. While the Act was implemented 8 years ago, numerous challenges still exist for prescribers (medical doctors and nurse practitioners) as well as those, such as nurses, who provide patient healthcare in primary and community healthcare settings.

The *Cannabis* genus exhibits a broad phytochemical profile, with over 100 different cannabinoids such as cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC), and over 200 different terpenes.[2] Currently, MC products in Australia are typically standardised to contain one or more cannabinoids, mainly CBD and THC, which have been the primary focus of the majority of research over the last 60 years.

CBD is a non-intoxicating cannabinoid and demonstrates anticonvulsant, analgesic, neuroprotective, anxiolytic, and anti-inflammatory activity,[3] whereas THC, commonly associated with the characteristic feeling of being "high", demonstrates analgesic, anti-emetic, orexigenic, muscle relaxant and hypnotic actions.[4,5] These two cannabinoids are prescribed in varying concentrations and ratios across the vast majority of products available to Australian patients, with CBD-dominant, balanced CBD and THC, or THC-dominant products being primarily prescribed clinically according to current Therapeutic Goods Administration (TGA) data.[6] CBD is classified as an S4 prescription-only medicine when products contain at least 98% CBD and 2% or less of other cannabinoids, whereas THC-containing products are classified as S8 controlled drugs. MC products are further described in categories, which have been outlined in Table 1. It's crucial to point out that our understanding of what phytochemical compounds may be of medical interest within the *Cannabis* genus is constantly evolving, and it is likely that other minor cannabinoids, such as cannabigerol (CBG), cannabinol (CBN) and cannabichromene (CBC), or other classes entirely, such as the flavonoids (e.g. cannflavins), may also play an important role across different pharmacological targets and subsequent clinical indications.[7]

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Being an unapproved medicine, MC is accessible *via* 4 main pathways: the Special Access Schemes (SAS) A or B, the Authorised Prescriber (AP) Scheme or through participation in clinical trials.[6] SAS-B applications for MC usage in Australia are reviewed and approved by the TGA, with the prescriber needing to supply a suitable clinical justification, often including the failure of front-line medicines for the clinical indication being treated. Of the over 100 indications that MC has been approved for through the SAS-B pathway, the top 5 (in order of prevalence) include chronic pain, anxiety, sleep disorder, cancer pain and symptom management, and post-traumatic stress disorder (PTSD).[8] Whilst, historically, the majority of MC has been prescribed through the SAS-B pathway,[9] it should be noted that there are also two registered MC products in Australia; Sativex and Epidyolex,[10,11] approved for Multiple Sclerosis (MS), and as an adjunct for seizures associated with Dravet and Lennox-Gastaut syndromes, respectively. Given the wide range of indications MC can be prescribed for in Australia, it is highly likely that nurses will come across these botanical medicines whether working in aged care, community, or hospital settings.

Currently, to the best of our knowledge, NPs can prescribe S4 and S8 MC products *via* the Special Access Scheme (SAS) B pathway in South Australia, Northern Territory, Victoria, Queensland, New South Wales, and the Australian Capital Territory. Western Australia currently only permits NPs to prescribe S4 products, whereas Tasmanian-based NPs cannot prescribe any MC-based products at all. Furthermore, NPs are not eligible to access the Authorised Prescriber scheme, which allows medical practitioners to apply for approval for a specific unapproved MC product for a specific clinical indication and requires Human Research Ethics Committee approval or endorsement from a specialist college.

TABLE 1: MEDICINAL CANNABIS BY CATEGORY[12]

Category	Descriptor
1	CBD medicinal cannabis product (CBD≥98%)
2	CBD dominant medicinal cannabis product (CBD≥60% & <98%)
3	Balanced medicinal cannabis product (CBD<60% & ≥40%)
4	THC dominant medicinal cannabis product (THC 60% - 98%)
5	THC medicinal cannabis product (THC>98%)

One of the major clinical challenges is that cannabis, when used medically, is a complex intervention,[13] where, unlike most pharmaceuticals, there are likely to be multiple components contributing to potential therapeutic outcomes *via* polypharmacy.[14] This means that a 15% THC-containing product manufactured by one company based on a particular cannabis chemovar/variety (sometimes incorrectly referred to as a strain) may have quite different effects to a 15% THC product made by another company utilising a different chemovar/variety, as the overall pharmacological profile may be very different due to differences in the presence or ratio of other minor cannabinoids (e.g. CBN and CBG), and terpenes, all of which are proposed to have therapeutic effects.[15-17] While there is little evidence in the literature, both doctors and consumers have commented that while one product works for them, another one that is identical in terms of THC or CBD percentage does not. As such, this phytochemical complexity can be seen as both a strength and a weakness in the application of MC clinically. Another clinical challenge is that unlike most pharmaceutical drugs, which are developed from a top-down approach, starting with biological mechanisms, and working through various *in-vitro, in-vivo* and clinical studies to determine dosage, safety and efficacy, medicinal cannabis is already in the marketplace, and therefore a bottom-up approach is occurring, where research is working backwards to determine dosing, mechanisms, and efficacy. This is similar to other interventions that have not gone through a "pharmaceutical" development process including most herbal/complementary medicines and treatments such as acupuncture.[18] A key area where this impacts clinicians is that dosage forms (e.g. oral oil *versus* inhaled cannabis) impact the onset of effect and duration of effect and that dosage ranges are often tailored to individuals using a 'start low, go slow' approach to dosage finding rather than using a set dosage as would occur in more traditional pharmaceuticals.[19]

According to TGA data, the two primary dosage forms utilised across Australia are inhaled dried flower and oral oils.[6] Inhalation of cannabinoids and terpenes *via* vaporisation of dried flower provides a fast onset of action, typically within 5-10 minutes, but a short duration of effect, ranging between 2-4 hours.[3] Conversely, oral oils have a delayed onset of effect, ranging between 30-90 minutes, but a longer duration of effect of approximately 6-8 hours.[3] Additionally, cannabinoids and terpenes are highly lipophilic (fat-loving), and generally have low bioavailability, typically between 20-30% when used orally and 10-60% when inhaled,[3] adding another layer of complexity for both manufacturers and clinicians alike whether that is researching different methods to improve cannabinoid absorption characteristics, or optimising dose titration for patients.

Another added complexity facing MC prescription is that cannabis inhabits a unique place in Australia, being both an illegal drug and a legal medicine, and due to this, there are challenges associated with current drug-driving laws and workplace drug-testing policies. Across all Australian States and Territories bar one, the mere presence of THC in bodily fluids, irrespective of driver impairment or legal MC prescription, constitutes a criminal offence, with the only exception being Tasmania, where drivers using a legally prescribed MC product may not be charged if there are no signs of driver impairment. No test kit is currently available that can quantify the impairing effects of THC (like that of a breathalyser for alcohol), and due to the fact

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cannabinoids like THC are highly lipophilic, they can stay in the body for days to weeks depending on several factors, such as how often and how much cannabis is ingested, body fat percentage, and the sensitivity of the drug test being administered. Similarly, many employment sectors subject staff to routine drug testing, including defence, transport, building and construction, aviation and mining sectors, for which THC is a tested substance. Positive test results may result in termination of employment, regardless of whether MC is legally prescribed or not. As such, the impact of current drug-driving laws and workplace drug-testing policies are important clinical touch points to discuss with patients prior to MC commencement, which can in turn not only impact patient accessibility but may also contribute to reduced participant recruitment in clinical trials where THC is an investigational product.

Like any medicine, MC also has potential side effects, contraindications and drug interactions which are critically important for patient safety. Cannabis, whether illicitly or medically sourced, should be considered contraindicated in pregnancy and lactation due to a lack of available safety data, with a recent review citing potential for adverse maternal, foetal and long-term childhood development – largely due to the THC component.[20] Whilst more research in this field is urgently needed, THC can easily pass through the placenta, and due to its lipophilicity and low molecular weight, can also pass into breastmilk.[21] Moreover, cannabis has numerous clinically relevant side effects reported in the literature, from the most common such as drowsiness, dizziness, dry mouth, eye redness and cognitive effects, to the more rare orthostatic hypotension, psychosis, tachycardia and cannabis hyperemesis syndrome.[3] On the topic of psychosis, recent media reports suggest an increase in people utilising MC being admitted to hospital with psychosis across Australia,[22] with concerns being raised such as MC being too easy to access, particularly due to the advent of MC-specific telehealth clinics, a lack of evidence for certain clinical indications and irresponsible prescription practices by certain medicinal practitioners. Whilst acknowledging these concerns as potentially valid, a 2022 systematic review investigating the prevalence of long-term and serious harms associated with medicinal cannabis in chronic pain patients reported that very low certainty evidence suggests that adverse effects are common (26%; or 1 in 4 participants), but that serious adverse effects, including those that lead to discontinuation, accident, injury or dependence and withdrawal syndrome are less common, occurring in fewer than 1 in 20 people.[23] Other important clinical considerations are the impacts of cannabis use disorder, and addiction/dependence potential, with greater risk associated with THC-containing products, as CBD has little addiction potential.[24] Reported side effects are typically greater for higher THC dominant products compared to CBD dominant products, however, low and slow dosage titration under close medical supervision may mitigate the majority of these side effects from presenting clinically.

Currently, the majority of evidence relating to cannabis and drug interactions is based largely on *in-vitro* and *in-vivo* studies,[25,26] with the relevance and impact of such experimental findings still needing to be elucidated to determine the extent of clinical impact. Despite this, pharmacodynamic and pharmacokinetic are possible with MC products, although these are mostly theoretical or come from limited case reports.[27] THC exhibits more potential for pharmacodynamic interactions than CBD, particularly when co-administered with pharmaceutical agents related to analgesia and sedation (e.g. antihistamines), and other non-prescribed depressants such as alcohol. Conversely, CBD is more of a pharmacokinetic interaction risk and can inhibit certain enzymes that are involved in drug metabolism *via* the liver, namely CYP2C19, CYP2D6, CYP2C9 and CYP3A4 isoenzymes.[27,28] A recent systematic review in 2022 identified 19 pairs of drug interactions associated with MC, with one pair being a level 1 interaction (very high risk - warfarin) which may require medication adjustment and monitoring of the patients international normalised ratio (INR), and two pairs at level 2 (high risk - buprenorphine and tacrolimus).[27] Due to the fact that pharmacokinetic interactions are largely unpredictable until observed clinically, they are of far greater clinical concern, particularly for medicines that are classified as being of narrow therapeutic index, where the difference between the amount needed for benefit *versus* the amount that will cause harm are small.

Substitution effects, where prescribed medications are reduced or stopped entirely due to the effect of MC, are commonly reported amongst patient groups.[29-32] A common class of medication that is reduced with MC usage in those with chronic disease are opioid-based medications. Whilst such substitution effects, or pharmaceutical deprescribing, is potentially encouraging considering the side effect profile and addictive potential, a cause for concern is that many of these reductions or stoppages are done without the knowledge of the prescribing health professional.[30] This can be further exacerbated by the fact that many GPs are not comfortable managing MC prescriptions,[33] meaning that many patients may be accessing their medicinal cannabis from health practitioners who are not their normal primary care provider, such as telehealth cannabis clinics; one of our recent studies found that only 8% of people with endometriosis using medicinal cannabis were accessing this via their usual GP, compared to 63.5% using a cannabis clinic doctor.[34] When this is combined with difficulties in getting an appointment with a GP, or even having a regular GP to begin with, issues with polypharmacy and withdrawing from medications can be potentially problematic. Depending on the class of drug, abrupt cessation after long periods of usage can lead to withdrawal symptoms that range from unpleasant to potentially fatal.[35,36] A key factor in this lack of communication is that cannabis is not yet normalised as a medicine, and stigma is often associated with its use, with disapproval, marginalisation and discrimination, along with

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a loss of social status from the wider population, commonly described by those consuming MC.[37,38] The impact of cannabis-associated stigma has also been reported by other Australian research teams,[39] showing much is yet to be done to address the impact of stigma associated with this now legal medicine. This reduction in stigma is an area that nurses can, and do, provide a powerful voice in addressing through both education and advocacy.

To date, there has been a paucity of evidence on medicinal cannabis and the impact nurses have in its clinical application. However, a cross-sectional study of Israeli and American (i.e. USA) nursing students (n=387 / 87% female) reported that they would recommend cannabis as an option to their patients (91%) if allowed to do so, and believed that MC was associated with benefits to both physical (93.5%) and mental (87.8%) health.[40] Additionally, the majority of respondents reported that they had not received any formal education related to MC in their training programs, and highlighted the importance of MC education for nurses both in academic and clinical curricula,[40] a point further supported by other studies.[41-43] Whilst guidelines relating to nursing care and MC are sparse, the National Council of State Boards of Nursing in the USA has published guidelines on this topic in 2018,[44] and the Australian Cannabis Nurses Association (ACNA) have outlined the scope and standards of practice related to MC in 2023.[45]

Cultivating understanding about MC, and its integration into nursing practice, requires a multifaceted approach that should prioritise patient safety, education, and advocacy. Open dialogue with patients about cannabis consumption is vital to break down the negative effects of stigma, but also identify their concerns, treatment goals, preferences, and to manage expectations. Nurses can play a pivotal role in providing evidence-based education to patients and their families, and fellow HCPs, allowing for greater collaboration and more informed decision making. For nurses that are interested in learning more about MC as a medicine, the Australian Cannabis Nurses Association is a useful starting point to start the educational journey into this ancient, but still controversial, botanical medicine.

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