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Use of electronic medical records to monitor the safe and effective prescribing of medicinal cannabis: is it feasible?

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ABSTRACT

Background. General practitioners are well positioned to contribute to the pharmacovigilance of medicinal cannabis via the general practice electronic medical record (EMR). The aim of this research is to interrogate de-identified patient data from the Patron primary care data repository for reports of medicinal cannabis to ascertain the feasibility of using EMRs to monitor medicinal cannabis prescribing in Australia. **Methods.** EMR rule-based digital phenotyping of 1 164 846 active patients from 109 practices was undertaken to investigate reports of medicinal cannabis use from September 2017 to September 2020. **Results.** Eighty patients with 170 prescriptions of medicinal cannabis were identified in the Patron repository. Reasons for prescription included anxiety, multiple sclerosis, cancer, nausea, and Crohn's disease. Nine patients showed symptoms of a possible adverse event, including depression, motor vehicle accident, gastrointestinal symptoms, and anxiety. **Conclusions.** The recording of medicinal cannabis effects in the patient EMR provides potential for medicinal cannabis monitoring in the community. This is especially feasible if monitoring were to be embedded into general practitioner workflow.

Keywords: medication systems, electronic medical records, medicinal cannabis, patient safety, pharmacovigilance, physicians' practice patterns, primary health care, public health: practice, safety management.

Introduction

Pharmacovigilance is defined as the detection, assessment, understanding, and prevention of adverse drug effects (WHO 2015). Pharmacovigilance also includes the surveillance of drug pharmacology, prescribing practices, and product quality including that of the supply chain (Dal Pan 2014). The practice of pharmacovigilance can be applied to both registered and unregistered (novel) therapeutics. Pharmacovigilance is particularly important in the context of novel therapeutics, given how approvals have been expedited and given the number of post-market adverse events associated with their use (Downing *et al.* 2017; Dhruva *et al.* 2018).

The Australian Government legislated the use of medicinal cannabis as a novel therapeutic for the management of specific indications, such as chemotherapy-induced nausea and vomiting, refractory paediatric epilepsy, palliative care indications, cancer pain, neuropathic pain, spasticity from neurological conditions, anorexia and wasting associated with chronic illness (such as cancer) on 1 November 2016 (TGA 2022b). Although legalised, most medicinal cannabis products are not listed on the Australian Register of Therapeutic Goods (ARTG) as they are still considered an unapproved therapeutic by the TGA (2022b). To prescribe medicinal cannabis, health practitioners must obtain Therapeutic Goods Administration (TGA) approval via the Authorised Prescriber Online System or the Special Access Scheme (SAS) (TGA 2022b).

There are two types of prescribers who can provide their patients medicinal cannabis in Australia, an Authorised Prescriber, and a Special Access Scheme (SAS) prescriber. Authorised prescribers are medical practitioners who can directly supply medicinal cannabis to their patients via an Authorised Prescriber script, SAS prescribers are practitioners who are required to submit either a SAS-A or SAS-B application to the TGA

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for approval. For SAS prescribers, the SAS-A application route provides a pathway for medical practitioners to prescribe medicinal cannabis to their patients who are classified as seriously ill, and the SAS-B route provides a pathway for medical and nurse practitioners to prescribe medicinal cannabis to their patients for multiple clinical indications of varied severity. Currently, it takes up to 48 h for SAS prescribers to receive approval for their patient's scripts (TGA 2022b). From January 2017 to February 2022, 99.6% of SAS approved medicinal cannabis prescriptions were provided to patients via the SAS-B access scheme. Of these SAS-B applications, 217 030 were submitted to the TGA by 3929 prescribers on behalf of over 17 000 patients (TGA 2021a, 2022b). Fifty-two percent of the 217 030 applications were from prescribers based in Queensland (111 797), 20.5% (44 561) were from prescribers based in New South Wales and 20.0% (43 344) were from Victoria, 6.5% (14 096) were from prescribers based in Western Australia, and <1.5% (3148) of the applications came from prescribers based in South Australia, Australian Capital Territory, Tasmania, and Northern Territory (TGA 2021a). Across Australia, there is a large variation in prescribing rates between specialist physicians and general practitioners (GPs). Of self-reported practitioner specialty data for 118 798 applications provided by prescribers between January 2019 and May 2021, 59.2% (70 356) of the prescribers reported they were GPs, 8.3% (9884) reported they were specialist physicians, 7.4% (8743) reported they were cannabis clinic prescribers and 25.1% (29 803) did not report practitioner specialty to the TGA (2021a). GPs and specialist physicians reported they were specialists in the areas of general practice, psychiatry, pain management, neurology, anaesthesia, palliative care, oncology, rehabilitation, gastroenterology and in cannabis prescribing (TGA 2021a).

The pharmacovigilance of any therapeutic, including that of medicinal cannabis, incorporates the reporting of adverse events to the TGA's database of adverse event notifications (DAEN). From January 2017 to February 2022, 53 adverse events associated with medicinal cannabis have been reported to the DAEN for eight products (TGA 2021b). Considering the total number of prescription approvals by 1 October 2021 was 172 162, the reports of serious adverse events are almost negligible (TGA 2021b). Yet, current research indicates the incidence of adverse events due to medicinal cannabis is higher than is found in TGA DAEN reports (MacCallum *et al.* 2021).

Medicinal cannabis products contain one or a combination of two main ingredients from the *Cannabis sativa* plant, cannabidiol (CBD) and tetrahydrocannabinol (THC). THC, a psychoactive cannabinoid is currently classified as a Schedule 8 (controlled) drug in Australia (TGA 2022b). Formulations of CBD and THC compounds that contain <2% THC and pure CBD are considered non-euphoric and are classified as a Schedule 4 (prescription) medicine. However, with changes to legislation enacted in February

2021, where low-dose formulations of CBD (<150 mg daily dose) were reclassified to a Schedule 3 (pharmacist only) over-the-counter product, the use of CBD in Australia is likely to increase (TGA 2020). Although CBD is considered to have an acceptable safety and tolerability profile at lower doses, there are known risks associated with drug-to-drug interactions, especially when CBD is used concomitantly with other commonly prescribed drugs metabolised via CYP450 pathways (Hallinan *et al.* 2022a). These interaction concerns are additional to the risks associated with all other cannabinoid products, as evidence for the safe and optimal use of medicinal cannabis is still emerging. To date, most of the evidence is from observational data and open label studies, rather than from randomised clinical controlled trials (Stockings *et al.* 2018; Sarris *et al.* 2020; Kurlyandchik *et al.* 2021; Pawliuk *et al.* 2021). Notable exceptions include medicinal cannabis efficacy trials for patients with treatment-resistant epilepsy (de Carvalho Reis *et al.* 2020).

Calls for alternative methods of generating data on the efficacy and safety of medications, including medicinal cannabis, are increasing globally and in Australia (Currow *et al.* 2012; Freeman *et al.* 2019; Hallinan *et al.* 2021). At the same time, approaches that use longitudinal real-life electronic medical record (EMR) data and consumer data via social media and smartphone software applications to augment efficacy data, are growing in importance and acceptability (Charles-Smith *et al.* 2015; Pierce *et al.* 2019; Hallinan *et al.* 2021).

GPs, both prescribers and non-prescribers of medicinal cannabis, are well positioned to contribute to pharmacovigilance of medicinal cannabis via the EMR (Hallinan *et al.* 2021). EMR systems have been widely adopted by Australian GPs in recent decades (Hunter *et al.* 2020). The aim of this research is to interrogate general practice EMR data that is de-identified at the source by using rule-based digital phenotyping (Banda *et al.* 2018) to: (1) establish how many patients have a record of medicinal cannabis use; (2) ascertain the reason for prescription; and (3) detect adverse events that are potentially related to medicinal cannabis prescribing to determine the feasibility of the use of EMRs to monitor medicinal cannabis prescribing in Australia.

Methods

Digital phenotyping is defined as the use of data that are automatically generated by technical platforms to measure (or offer robust proxies for) human behaviour. Digital phenotyping, where a clinical condition or characteristic is ascertained through the application of a computerised keyword query or a logical expression into an EMR database, is increasingly being used to monitor a breadth of conditions for screening, diagnosis, and the monitoring of treatment effects (Richesson *et al.* 2013; Huckvale *et al.* 2019).

Using digital phenotyping, we examined EMR data from the Patron primary care data repository to identify the patient cohort (Boyle *et al.* 2019). Currently, the Patron database collects de-identified EMR data from over 144 general practice sites; of these, 91% are in Victoria, and the rest are in New South Wales and South Australia. The repository comprises around 721 GPs who work in general practices that use Best Practice™, Medical Director™, and ZedMed™ clinical software. With GP consent, patient EMRs are extracted from the practice clinical software, using the data extraction tool, GRHANITE™ (Boyle *et al.* 2019). The EMR data are de-identified locally and transmitted to the data repository via encrypted transmission. The GRHANITE™ tool de-identifies each patient by replacing the patients name with a unique patient identifier that links the patient to the individual visit in each patient table (Boyle *et al.* 2019). This unique identifier is applied before the data leaves the practice. Identifiers including patient address, date of birth, Medicare number, GP, and general practice names are either removed or de-identified prior to extraction to the data repository.

Records of patient visits between 1 September 2017 and 9 September 2020 were extracted from the Patron database in September 2020. This yielded structured and semi-structured EMR data contained in administrative, demographic, clinical, prescribing, and pathology tables relating to 1 164 846 active patients from around 561 GPs in 109 practices. Of these tables, the variables used for this analysis included reason for visit, current and past history, medication name (trade and generic), current medication history, past medication

history, prescription repeat, reason for prescription, gender, age, socio-economic indexes for areas of relative disadvantage (SEIFA), and Aboriginal and Torres Strait Islander (ATSI) status. The prescription table included information on dose, frequency, route, generic and trade name, and formulation. The data in the prescription tables were used to validate the structured/semi-structured information in the reason for visit/clinical table. Data from free text notes within the EMR were not included in this analysis.

A list of terms and key words used to describe medicinal cannabis was established using the knowledge base of the clinical researchers (CH and YB) and was validated following literature and internet searches (Table 1). Using these terms, Patron data were examined using structured query language (SQL) rule-based phenotyping and temporal abstractions to select entries related to medicinal cannabis (Agarwal *et al.* 2016) (Fig. 1). Rule-base phenotyping was used to capture key terms, as at the time of extraction, standardised coding terminologies had not yet been fully established in the Patron database. The EMR allows for the entry of structured data that are bounded by standardised parameters. In the case where fields are not available, such as in products that are not listed in the PBS, entries are written into the prescription fields by the GP and analysed as semi-structured data.

A literature review of peer-reviewed research, manufacturer product information, United States Food and Drug Administration (FDA) and TGA websites was conducted to search for the top five most recently reported medicinal cannabis-related adverse events. Adverse events that were

Table 1. Medicinal cannabis terms.

Correct term	Alternative spelling	Search
Medicinal cannabis	Medicinal cannabus; medicinal cannabis; medicinal cannibus; medicinal cannabus; medicinal cannebis	*cannab* *cannib* *cannub* *canneb
Medicinal cannabis	Medicinal cannabus; medicinal cannabis; medicinal cannibus; medicinal cannabus; medicinal cannebis	*medicin* *medicinal can*
Medical cannabis	Medical cannabus; medical cannabis; medical cannibus; medical cannabus; medical cannebis	*medical cann* *medical can*
Cannabidiol	Cannabidiol; cannibidol CBD; cbd; canabid; canibid; cbd oil	*cbd* *oil* *canabid* *canibid* *canubid* *canebid*
Cannabinoids	Cannabinoids; canabinoids	*canabin* *canibin* *canubin* *canebin*
<i>Cannabis sativa</i>	<i>sativa</i> ; <i>satvia</i>	*sativa* *satvia*
<i>Cannabis indica</i>	<i>indicia</i> ; <i>indica</i>	*indicia* *indica*
<i>Cannabis ruderalis</i>	<i>ruderalis</i> ; <i>ruderalus</i>	*ruderal*
Tetrahydrocannabinol	thc; tetrahydro	*cbd* *tetrahydr*
Cannabis	Cannabus; cannabis; cannibus; cannabus; cannabis; canabus; canabis; canibus; canabus; canebis	*canab* *canib* *canub* *caneb
Weed	Weed	weed
Hash	Hash	hash
Hemp	Hemp	hemp
Marijuana	Marijuana; marijuana; marigana; maridgana	*marij* *mariga* *maridg*

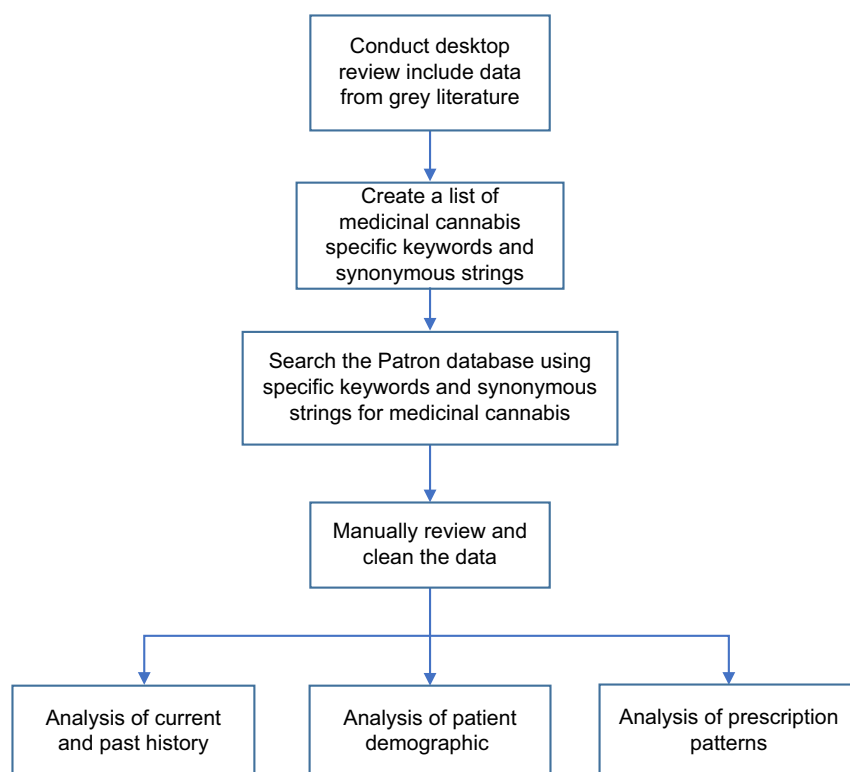


Fig. 1. Digital phenotyping flowchart for medicinal cannabis records in EMR.

outside a 90-day window following the medicinal cannabis prescription date were not included in the adverse event count, as it was deemed not possible to relate the event to medicinal cannabis use. The data in the past history, current history, and reason for visit tables were searched to exclude patient records with indicators of potential adverse events that could clearly be attributed to causes outside of medicinal cannabis use, such as a prior diagnosis or other clinical event.

Ethics approval

Ethics project approval was granted by the University of Melbourne and registered with the University of Melbourne Human Research Ethics Committee (Ethics ID: 2057596.1).

Results

Patron data trends were compared to SAS-B monthly approvals for medicinal cannabis from September 2017 to September 2020 (Figs 2, 3) (TGA 2022b). Using this process, 80 patients and 170 validated prescriptions were identified from EMRs, based on the medicinal cannabis entries made by 26 GPs from 27 general practices. Of the 170 scripts, four had an anatomical therapeutic code (ATC) and were registered on the Pharmaceutical Benefits Scheme (PBS) (Sativex-ATC N02BG10 and Epidiolex-ATC N03AX24). The other scripts required manual entry into the EMR fields by the GP. Of these semi-structured entries,

GPs entered the prescription medication trade names for nearly all visits (169/170, 99.4%); dose and/or strength were entered into the patient medication field on 61.2% (104/170) of the visits.

Most of the patients prescribed medicinal cannabis were female (55%), aged between 41 and 70 years (mean 57.3, range 19–96) and from socioeconomic areas of greater relative disadvantage (Table 2).

Forty-five of the 80 patients had a single prescription medicinal cannabis, and of the prescriptions with repeats, 18 patients had two repeats, seven patients had three repeats on the prescription, four patients had four repeats, four individual patients each had five, six, seven and eight repeats respectively, and one patient had 11 repeats on their prescription, and another had a prescription with 17 repeats.

The medical history most associated with medicinal cannabis prescribing were depression and anxiety, neurologic and other chronic pain, epilepsy, arthritis, cancer, insomnia, encephalopathy, gout, sleep disorder, stroke, and lastly, opioid dependence. The reason for prescription was poorly recorded, with only 29 reasons provided for 170 prescriptions. Of these reasons, 14 were for pain, four were for a mental health condition, three each were for multiple sclerosis and cancer, and two reports each were for nausea and Crohn's disease.

Regarding formulations, most were a combination of tetrahydrocannabinol (THC) and cannabidiol (CBD) (55.3%, 94/170), a lower number of prescriptions were for CBD

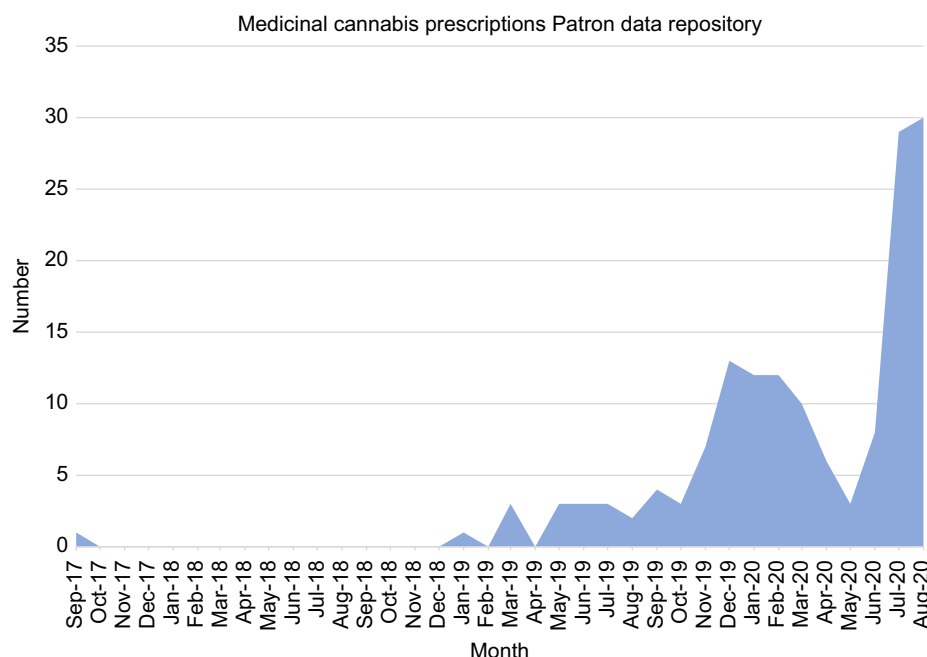


Fig. 2. Medicinal cannabis prescriptions in the Patron database, September 2017 to September 2020.

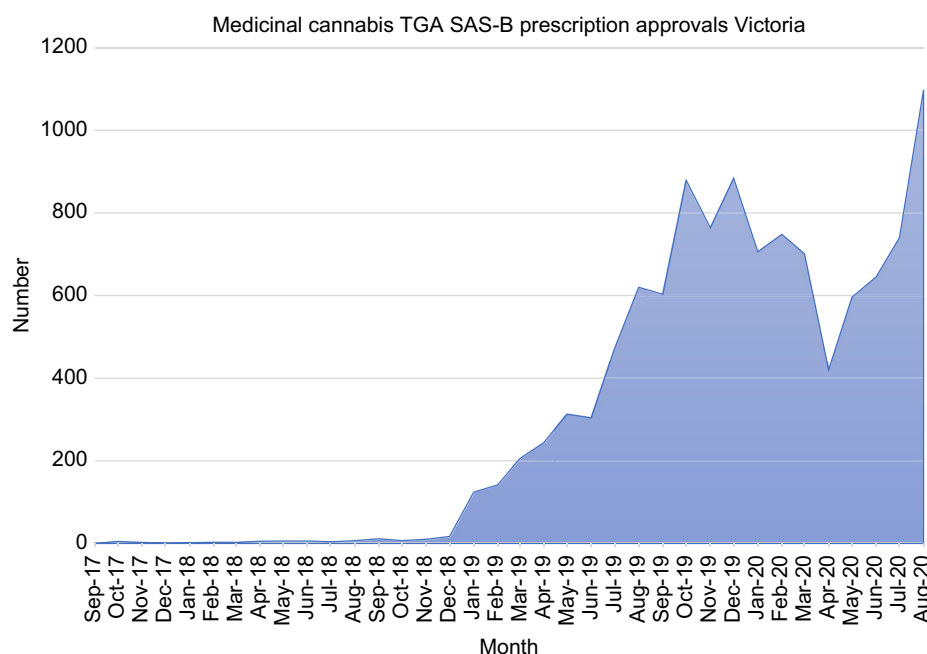


Fig. 3. Sourced: Medicinal cannabis TGA SAS-B approvals Victoria, September 2017 to September 2020. Source: Therapeutic Goods Administration (2021) Medicinal cannabis: role of the TGA. Available at <https://www.tga.gov.au/medicinal-cannabis-role-tga>.

only (35.9%, 61/170), and a minimal number were for THC only (8.8%, 15/170). Of the prescriptions, 84.1% (143/170) had a recording of cannabis strength and 40.6% (69/170) had recordings of patient dose (Table 3).

Of the 80 patients prescribed medicinal cannabis, nine showed symptoms of a possible adverse event within 90 days of a medicinal cannabis prescription. Depression was the most common symptom reported, with three

Table 2. Patient demographic.

Characteristic	n	%
Age (years)		
0–10	0	0
11–20	1	1.25
21–30	3	3.75
31–40	5	6.25
41–50	11	13.75
51–60	18	22.50
61–70	21	26.25
71–80	9	11.25
81–90	9	11.25
91–100	3	3.75
Total	80	100.00
Gender		
Female	44	55.00
Male	34	42.50
Not recorded	2	2.50
Total	80	100.00
ATSI status		
Neither Aboriginal nor Torres Strait Islander	53	66.25
Not recorded	27	33.75
Total	80	100.00
SEIFA Index of Relative Socio-economic Disadvantage IRSD – Quintiles		
1–2 (Area of greater relative disadvantage)	12	35.00
3–4	28	15.00
5–6	16	20.00
7–8	6	7.50
9–10 (Area of least relative disadvantage)	18	22.50
Total	80	100.00

patients (who did not have a record of a prior clinical history of depression) reporting depression. Two patients had a motor vehicle accident following a medicinal cannabis prescription, two patients reported gastrointestinal symptoms, nausea for one, and abdominal pain for the other patient. There was one patient record of anxiety with no prior record of anxiety in their history, and one record of an adverse events with no detail.

Discussion

The Patron database sourced for this research represents 10.3% of general practices in Victoria, and 2.6% of general practices in Australia (Health Direct Australia 2022).

Our analysis shows the demographic data for medicinal cannabis prescribing is consistent with that of Victoria and Australia at the time; namely, a greater association with middle-to-older aged females, from more disadvantaged locations (TGA 2022b). This research also shows prescribing trends for Patron general practices are very similar to trends in Victoria (Figs 2, 3). Using publicly available TGA data, we found from September 2017 to September 2020, there were just over 11 000 approvals for medicinal cannabis prescriptions in Victoria (TGA 2021a). Across the same period, there were 170 records of medicinal cannabis in the Patron database, which amounts to 1.6% of approvals in Victoria; this demonstrates the number of records of medicinal cannabis prescriptions in general practice EMRs is relatively low, especially considering the Patron database represents 10.30% of all Victorian general practices, and the large number of approvals in Victoria overall (Figs 2, 3).

There are several possible reasons for this. First, the recording of medicinal cannabis prescriptions by prescribing and non-prescribing GPs on the EMR is discretionary, as most medicinal cannabis is not on the PBS and thus needs to be manually entered into the prescription field. Second, the Patron repository currently collects only structured and semi-structured data that are entered into discrete data fields, which are bounded by automated responses, the unstructured EMR data, such as free-text narrative in clinical notes, were not accessible as a data source. Furthermore, as medicinal cannabis is not registered with the TGA, and is not universally considered as a medicine by all GPs (Hallinan *et al.* 2021), some clinicians may consider it a complimentary therapeutic or even a herbal product and, as a result, may not enter the information into the EMR. Finally, for medicinal cannabis that is not prescribed by a patient's usual GP, it is up to the patient to disclose medicinal cannabis use. It is well understood there is a stigma associated with 'cannabis as a medicine' (Hallinan *et al.* 2022b); hence, some patients may not disclose to their GP that they have been accessing medicinal cannabis. This would also apply to patients who have been accessing 'artisanal medicinal cannabis' (cannabis product that is not recommended by the TGA and prescribed outside of TGA guidelines) (Sulak *et al.* 2017; Lintzeris *et al.* 2020).

Of the 170 prescriptions, 26 unique reasons for visit were entered into the EMR. This is surprising, especially considering the TGA do not recommend medicinal cannabis as a first line treatment and the limited number of permitted indications that have TGA approval (TGA 2022b). Of the reasons reported, pain had the highest frequency with 33 reports of pain for conditions such as a motor bike accident (17), fibromyalgia (5), chronic pain (4), cancer pain (2), arachnoiditis (1), neuropathy (1), back pain (1), facial pain (1), and pain management (1). Prescribing for the treatment of PTSD (12), anxiety (3), Crohn's disease (3), insomnia (3), multiple sclerosis (3), sarcoma (3), osteoarthritis (2), breast cancer (2) and nausea (2) were

Table 3. Medicinal cannabis products recorded in Patron EMR September 2017 to September 2020.

Cannabinoid content	Composition		Route	Strength recorded		Dose recorded		Number of Entries
	THC	CBD		Yes	No	Yes	No	
Pure CBD	0 mg/mL	10 mg/mL	Oil	0	1	1	0	1
Pure CBD	0 mg/mL	25 mg/mL	Oil	4	0	0	4	4
Pure CBD	0 mg/mL	100 mg/mL	Oil	10	0	4	6	10
Pure CBD	0 mg/mL	34 mg/mL	Capsule	3	2	2	3	5
High CBD	0.15 mg/mL	3 mg/mL	Buccal spray	1	0	0	1	1
High CBD	5 mg/mL	10 mg/mL	Mixture	3	1	4	0	4
High CBD	5 mg/mL	20 mg/mL	Oil	12	0	2	10	12
High CBD	1 mg/mL	25 mg/mL	Oil	20	0	0	20	20
High CBD	2 mg/mL	25 mg/mL	Oil	0	2	2	0	2
High CBD	<1 mg/mL	100 mg/mL	Oil	0	2	2	0	2
Balanced CBD/THC	1.25 mg/mL	1.25 mg/mL	Buccal spray	6	1	1	6	7
Balanced CBD/THC	2.7 mg/mL	2.5 mg/mL	Oromucosal spray	1	1	2	0	2
Balanced CBD/THC	10 mg/mL	10 mg/mL	Oil	33	2	7	28	35
Balanced CBD/THC	10 mg/mL	12.5 mg/mL	Mixture	40	8	36	12	48
Balanced CBD/THC	25 mg/mL	25 mg/mL	Oil	2	0	0	2	2
High THC	18 mg/mL	<1 mg/mL	Flower-inhalant	3	0	0	3	3
High THC	20 mg/mL	<1 mg/mL	Mixture	2	2	2	2	4
Pure THC	25 mg/mL	0 mg/mL	Oil	3	3	3	3	6
Cannabis	Missing	Missing	Capsule	0	2	1	1	2
Total				143	27	69	101	170

reported 33 times. Progressive supra-nuclear palsy and medullary sponge kidney were each reported once in the EMR, initiation of medicinal cannabis and/or medicinal cannabis was listed 17 times. For all patients, an initial reason for prescription was entered into the EMR. The reason-for-visit field was not always completed when a patient had a repeat prescription; this may be due to medicinal cannabis not being on the PBS as discussed above.

There were potentially nine patients who possibly had an adverse event based on what is known about adverse events and cannabis (Abuhasira *et al.* 2018; Allan *et al.* 2018). Yet, it is difficult to ascribe the suggested effects with certainty as these associations are based on assumptions such as patient recall, the appointment date, and the default date set by the EMR rather than a valid adverse event 'signal'. This is an important area that requires further investigation.

Medicinal cannabis prescribing in Australia is on a trajectory that is clearly rising (Figs 2, 3). Best practice for the pharmacological management of clinical conditions is based on evidence from randomised controlled trials (RCTs), yet RCT evidence for medicinal cannabis is limited. Given this, novel approaches using real-world evidence, from non-interventional studies, registries, EMRs, and health service data, provides opportunities to gather information on

effectiveness and adverse events, and can be also used to inform the design of RCTs (Banerjee *et al.* 2022).

Our analysis that uses real-world evidence from EMRs demonstrates it is certainly feasible to track usage with digital phenotyping methodology. With this feasibility comes an understanding that the EMR provides opportunities to detect, measure, and monitor medicinal cannabis use. These opportunities include the provision of levers to GPs to facilitate the recording of quality data that includes the embedding of reporting mechanisms into GP workflow via automated prompts and drop-down menus. For example, the EMR could provide a drop-down list of medicinal cannabis formulation, indication, effectiveness, side-effects, and adverse events. Other EMR functionalities could include the installation of 'Point of Care' applications onto the EMR, where on-screen recommendations open automatically for patients on medical cannabis, which provide suggestions and alerts to the GP for enhanced vigilance through real-time monitoring.

The delivery of educational resources that are embedded within the EMR to guide GPs could also provide another valuable lever. GP guidance resources would deliver information on aspects of medicinal cannabis that are important to track in a patient, such as patient reports of: a reduction of

symptoms for which the medicinal cannabis was prescribed, improvements in daily functioning, the presence of side-effects (i.e. fatigue, nausea, dizziness) or adverse events (i.e. hallucinations), and drug-to-drug interactions. Other strategies shown to be of benefit in other health domains include an option for financial (i.e. immunisation) and non-financial incentives (i.e. continuing professional development – CPD points) to promote the recording and monitoring of medicinal cannabis prescribing by GPs (Fernholm et al. 2019; Hallinan 2019).

Other countries are increasingly engaging consumers in the reporting of medicinal cannabis effects through social media and software applications, including from smartwatches and smartphones. The use of this data is growing in importance and acceptability, especially with improvement in the app-literacy of patients (Charles-Smith et al. 2015; Pierce et al. 2019). This is worth considering in the Australian context given the rising prevalence of medicinal cannabis prescribing with each year.

This research was limited by the low number of medicinal cannabis prescribing approvals in Victoria (and Australia) prior to August 2020 (TGA 2022a), and by the number of Victorian general practices that were represented in the Patron database at the time. Notwithstanding, from mid-2020 onwards, there has been a rapid rise in the number of medicinal cannabis approvals, and an additional 40 general practices, including practices from NSW and Victoria, that are currently contributing to the Patron repository. With the growth in TGA prescription approvals, and an expanding number of general practices held in the Patron repository, this rapidly changing environment provides opportunities for, and the impetus to, re-test the feasibility of monitoring medicinal cannabis in the general practice EMR. Given this, we plan to repeat this analysis in October 2022.

For this research, we captured prescriptions that were manually entered as either structured or semi-structured data into EMR medication fields. Although this delivers valuable information for the monitoring of medications, the use of unstructured clinical free-text notes also provides many opportunities (Hong et al. 2018; Rojas and Capurro 2019). The technology to enable the use of unstructured text as a data source (i.e. doctors free-text notes) is currently emerging. As these technologies develop, the utility of the EMR as a data source will be optimised, and with this, the general practice EMR will become more widely used for the surveillance and monitoring of all types of therapeutics.

Conclusions

As novel therapeutics continue to emerge, real-time adverse event reporting is becoming increasingly important. However, such reporting can be a time- and resource-consuming activity for clinicians, regulatory authorities,

and drug manufacturers. Our proof of concept has demonstrated the recording of the effects of medicinal cannabis in GP EMRs provides a feasible option for the monitoring and surveillance of medicinal cannabis use in the community, especially if it can be embedded into a GP's workflow.

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Data availability. The data that support this study cannot be publicly shared due to ethical or privacy reasons and may be shared upon reasonable request to the corresponding author if appropriate. Data were analysed using Stata 16 software; coding is available on request.

Conflicts of interest. YB is a principal investigator for an industry-sponsored clinical trial of the pharmacokinetics of medicinal cannabis for Zelira Therapeutics Ltd.

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