

Identifying a patient who may be at an increased risk of harm from pregabalin or gabapentin



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Canberra Script – The ACT’s new Real Time Prescription Monitoring (RTPM) system

Background:

Pregabalin and gabapentin (the gabapentanoids) are frequently prescribed in Australia to treat neuropathic pain and epilepsy. The gabapentanoids were traditionally considered to be non-addictive with a low potential for abuse however there is increasing evidence of misuse.

In 2021, the Therapeutic Goods Administration (TGA) added a Boxed Warning to the Product Information for both pregabalin and gabapentin to advise of the risk of misuse, abuse and dependence [1]. TGA recommend that health practitioners check for a history of substance use disorder and signs of abuse or dependence before prescribing pregabalin or gabapentin. TGA also recommend patients should be regularly monitored during treatment, particularly those with current or past use of opioids and/or benzodiazepines. In addition, TGA recommend that patients be monitored for increases in dosing or drug-seeking behaviours.

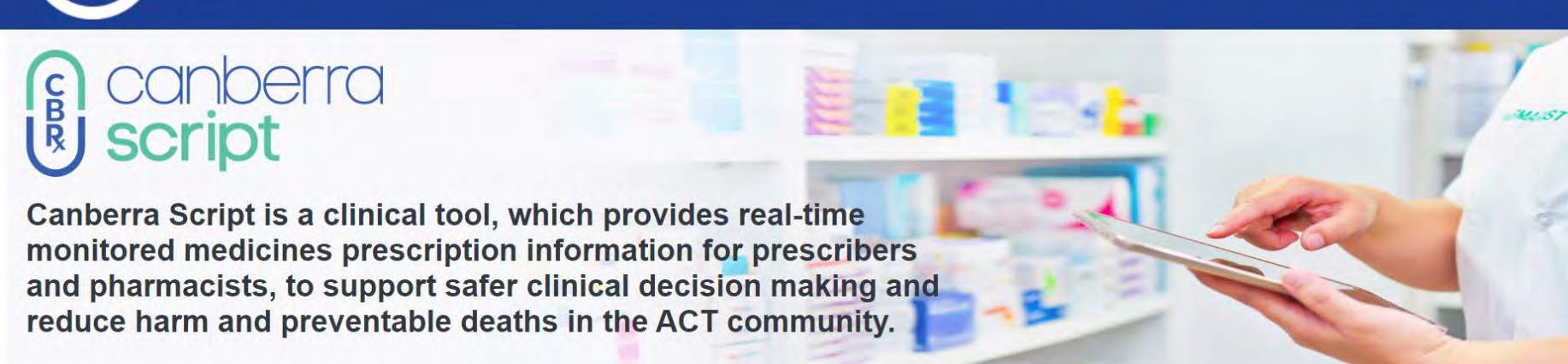
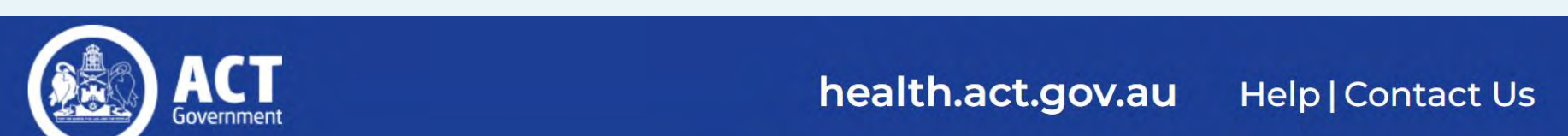
In 2020-2021, pregabalin was ranked number 13 in the top Pharmaceutical Benefits Scheme (PBS) Drugs, sorted by highest total prescription volume [2].

Objectives:

National Real-Time Prescription Monitoring (RTPM) is being implemented throughout Australia. RTPM aims to reduce the risk of harm from prescription medicines such as opioids and benzodiazepines. In recent years there has been an increase in harms and deaths related to gabapentanoids.

Results from an Australian retrospective cohort study published in 2019 found that there has been a dramatic increase in pregabalin use, poisonings and deaths in Australia since it became PBS subsidised in 2013 [3]. The study found one in seven Australians dispensed pregabalin appeared to be at high risk of misuse. There are a range of reasons why people may use gabapentanoids for non-medical use, including euphoric and dissociative effects. Pregabalin appears to have a higher addictive potential than gabapentin [3]. Australian coroners have been raising concerns about the increasing implication of pregabalin in deaths due to multiple drug toxicity [4].

Canberra Script, the ACT’s new RTPM System was launched in February this year.



Action:

While not all Australian jurisdictions currently include gabapentanoids in their RTPM, they are included as monitored medicines in Canberra Script.

Schedule 4 monitored medicine data was first collected in the ACT in October 2021. Prior to this only Schedule 8 medicines were monitored in the ACT. The data was available to pharmacists and prescribers from February 2022. There have been many concerning examples observed of excessive access to gabapentanoids observed.

The two patients with the highest dispensing events of gabapentanoids in the ACT in October 2021, were both males, aged between 35 and 45 with a history of opioid replacement therapy.

Patient 1: Dispensed 15 boxes of 56 pregabalin capsules in the month (840 capsules – approx. 4000mg/day) - 6 boxes 75mg; 6 boxes 150mg; 3 boxes 300mg
Presented prescriptions from 10 prescribers to 12 different pharmacies

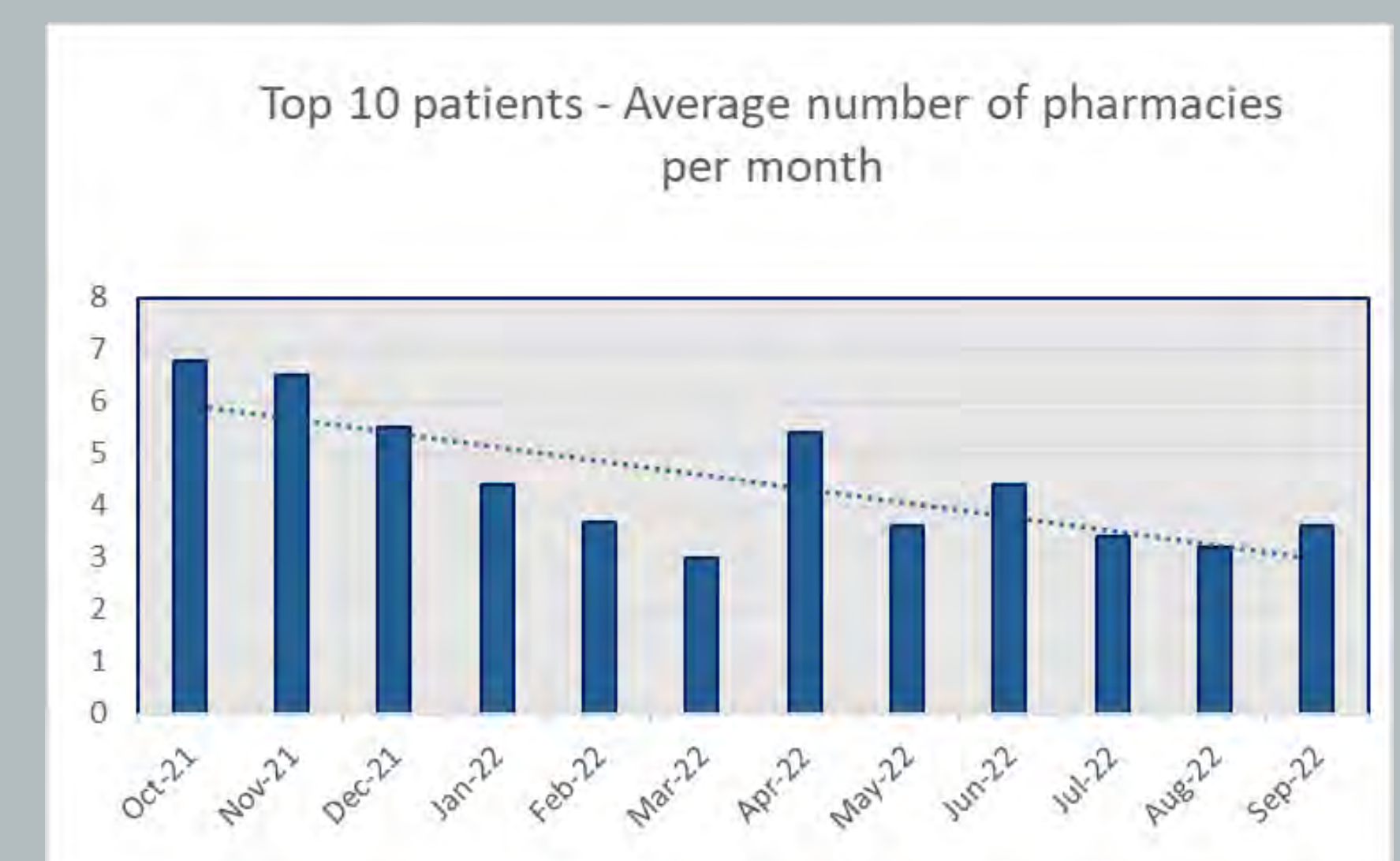
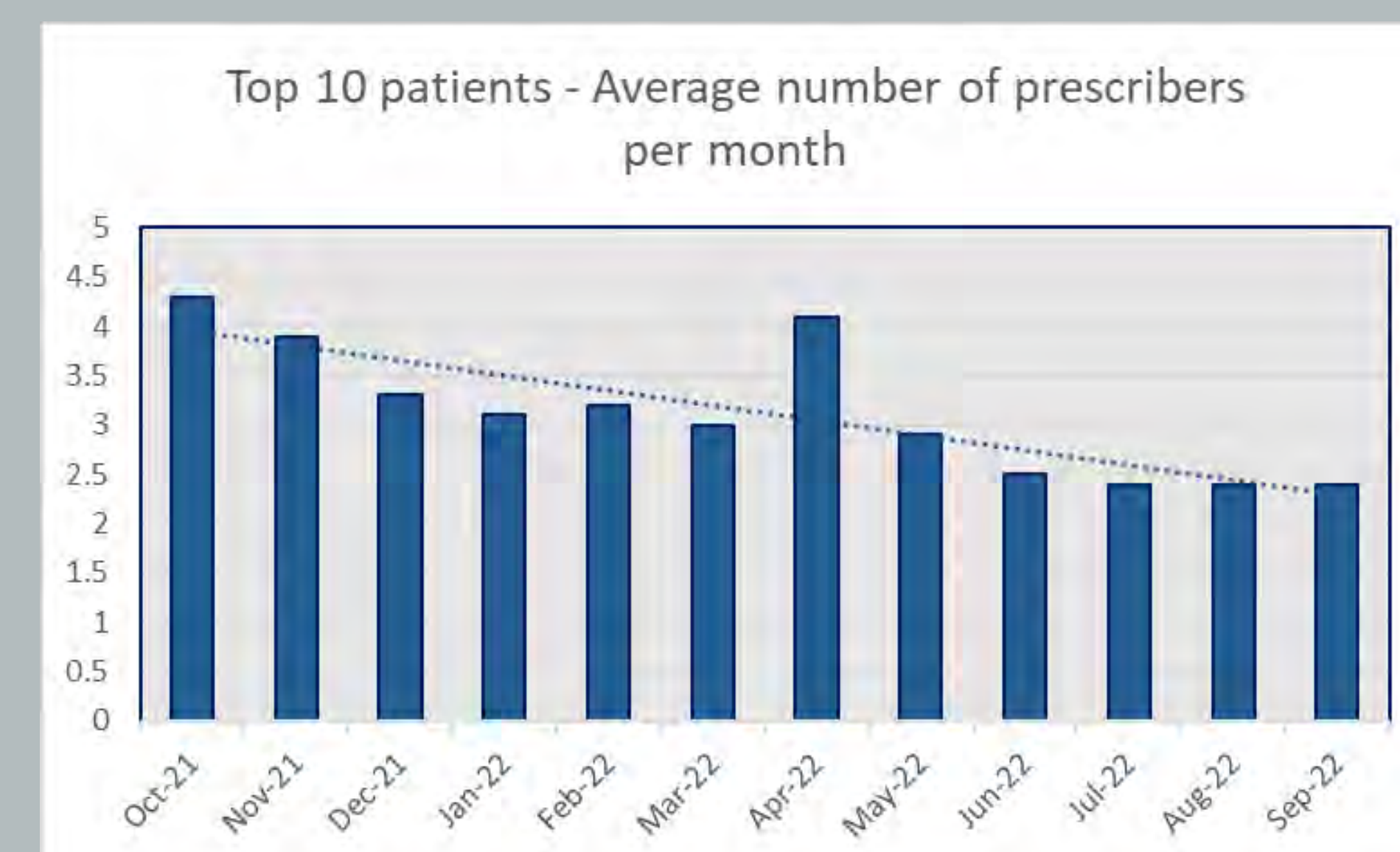
Patient 2: Dispensed 29 boxes of 56 capsules of pregabalin 150mg in the month (1624 capsules – approx. 8000mg/day)
Presented prescriptions from 7 prescribers to 17 different pharmacies

Evaluation:

When utilised regularly RTPM can help identify and manage patients at risk of harm. In the ACT, there is evidence of a decrease in the quantity of gabapentanoids dispensed to high-risk patients since the introduction of RTPM. Canberra Script monitors medicines supplied on either a PBS or a private prescription and has provided pharmacists and prescribers with an effective clinical tool to help minimise risk of harm from gabapentanoids.

When a patient obtains prescriptions for monitored medicines from multiple prescribers and/or multiple pharmacies, this can indicate an increased risk of harm.

The following graphs illustrate the change since the introduction of Canberra Script for the 10 ACT patients visiting the highest number of prescribers or pharmacies per month to obtain gabapentanoids.



Discussion:

Over the last decade, drug induced deaths in Australia have been more likely to be due to prescribed medicines than illicit drugs [5]. With RTPM being rolled out across Australia, prescribers and pharmacists have access to a new clinical tool to assist in optimising individual patients care. In addition, national RTPM will provide new population level data, which may help to determine broader strategies to minimise harm from monitored medicines in Australia.

It is complex to manage chronic conditions, such as pain. RTPM can play a key role to support more safe and effective care.

Before prescribing and dispensing pregabalin or gabapentin, it is important to consider the risk of central nervous system depression, and any history of substance use disorder or signs of abuse or dependence. Pregabalin users at a higher risk of misuse were more likely to be younger, male, co-prescribed benzodiazepines or opioids, have more individual prescribers and higher pregabalin strengths dispensed [3].

Prescribers and pharmacists are encouraged to utilise RTPM to identify and manage patients who may be at risk of harm or dependency from gabapentanoids.

References:

1. Therapeutic Goods Administration (TGA). Pregabalin and gabapentin. Safety advisory -enhanced warnings relating to abuse and dependence. Canberra: TGA; 2021. Available online at: <https://www.tga.gov.au/alert/pregabalin-and-gabapentin> (accessed October 2022).
2. Pharmaceutical Benefits Scheme (PBS). PBS expenditure and prescriptions report 1 July 2020 to 30 June 2021. Canberra: Australian Government Department of Health; 2021. Available online at: https://www.pbs.gov.au/statistics/expenditure-prescriptions/2020-2021/PBS_Expenditure_and_Prescriptions_Report_1-July-2020_to_30-June-2021.pdf (Accessed October 2022)
3. Cairns R, Schaffer AL, Ryan N, Pearson SA, Buckley NA. Rising pregabalin use and misuse in Australia: trends in utilization and intentional poisonings. *Addiction* 2019; 114: 1026-1034.
4. Tuohey C, Nichels K. A tragic loss Pregabalin prescribing risks. *Medicine Today* 2022; 23: 43-46