

SCV: CC2024-18

CC2023-11

Coroners Court of Victoria 65 Kavanagh Street SOUTHBANK, VIC 3006

BY EMAIL: team14@courts.vic.gov.au

Dear Coroner Ryan,

# Re: Gary Burgess Coroners recommendations (COR 2021 006200)

In July 2023, Safer Care Victoria (SCV) accepted recommendations related to the investigation and findings into the tragic death of Gary Burgess. I'm writing today to provide you with an outcome for your records.

Your Honour directed the following to SCV.

- 1) review the details of this case and the recommendations made to Peninsula Health, in order to consider whether some / all / additional process improvements in clinical care for patients taking clozapine should be implemented across all acute care health services state-wide.
- 2) consider the utility of developing a guideline focused on education and improved clinical care delivery primarily for non-psychiatric health practitioners for the management of constipation in patients on clozapine (and other antipsychotics), similar to the documents from NSW Health and SA Health.

## Advice regarding recommendations

#### **Recommendation 1**

SCV met with Peninsula Health to determine whether the recommendation improvements they initiated, might be considered across the sector. The service advised they had updated their site-specific clinical practice guideline and created a standardised bowel escalation plan for all patient receiving clozapine. SCV felt this action had the potential for sector implementation, particularly if it supplemented existing frameworks and guidelines already in place. It would be up to each healthcare service to determine how best to incorporate Peninsula's improvements within their own system.

Specific to Peninsula Health, the service identified a reliance on individual treating clinicians, including nonpsychiatric health practitioners to request specific bowel charting in circumstances of clozapine prescribing. Peninsula Health was exploring if this could be automated through their electronic medical records (EMR) system. Practically, health care services would need to determine how best to automate a bowel escalation plan to include the commencement of a bowel monitoring chart. Some health care providers would find this a challenge, particularly with the differences in EMR platforms across the sector.

#### **Recommendation 2**

When SCV accepted Your Honours recommendation, SCV's intent was to devise a simple and effective tool to guide clinicians who prescribe Clozapine. This was more complex than expected and it was determined any SCV guidance produced would be limited in transferability across services and between clinicians. The context was considered too broad to develop a usable guideline that would be functional across multiple clinical disciplines and in multiple patient settings and services. SCV's opinion, is that the documents from NSW and SA Health formed part of a suite of tools to support Clozapine management and was not fit for purpose within an adapt/adopt approach.

Instead, SCV embarked on a series of communication pieces designed to improve clinical understanding and promote the uptake of clozapine related learning, leveraging SCV key contacts and organisations to support this approach. Examples included the distribution of a *Clozapine and GI hypomobility Alert (attachment 1) and a link to the clozapine* learning modules, accessible by Health Services. SCV utilised input from our organisations Principal Pharmacy Advisors and their sector connections to deliver on this information dissemination.

As well, the 2022-2023 Annual Sentinel Event Report (attachment 2, page 26) used the themes of Mr Burgess event as a case study to spotlight potential risks with Clozapine use. The Annual Sentinel Event Report highlights key insights from real events, including lessons learnt, and service level and system-wide improvements which other services can learn from.

SCV would like to thank His Honour for highlighting this important issue and the opportunity to action the directed recommendations. Should you have any queries, please contact Jodyanne See, Senior Project Officer for coronial matters on

Yours sincerely

Ms Louise McKinlay

Chief Executive Officer

Safer Care Victoria

Date: 11 /11/ 2024





# Clozapine and gastrointestinal hypomotility

In 2022, the product information and consumer medicine information (CMI) for all clozapine products were updated to include a boxed warning on clozapine-induced gastrointestinal hypomotility. However, serious and fatal events associated with clozapine-induced constipation continue to be reported.

## Situation

- Clozapine is an atypical antipsychotic medicine used for treatmentresistant schizophrenia.
- Due to its potent anticholinergic action, clozapine can cause gastrointestinal hypomotility, ranging from mild constipation (common) to severe complications such as intestinal obstruction, faecal impaction, megacolon, paralytic ileus and death if left undiagnosed and not treated promptly.
- The risk is further increased in patients who are:
  - Co-prescribed with other anticholinergic medicines and/or medicines that can cause constipation (e.g. opioids)
  - o Taking higher doses of clozapine
  - Have a history of bowel disease or bowel surgery



## Clinical recommendations and suggested actions

- Inform patients taking clozapine about potential common and rare side effects, including constipation.
- Screen patients for constipation before starting and during treatment with clozapine.
- Provide patients with guidance on how to prevent constipation, including dietary and lifestyle advice.
- Consider the use of prophylactic laxatives when starting clozapine in patients at high risk of constipation (e.g. older patients).
- Avoid the concurrent use of medicines that can cause constipation where possible.
- Use a bowel chart (electronic or paper) for patients and residents in hospital, residential care facilities, and where appropriate.
- Advise patients to seek medical attention immediately if they experience constipation or any sign of slowed bowel activity:
  - o No bowel movements, less bowel movements than usual, or difficulty passing a stool
  - Nausea and/or vomiting
  - o Bloating, tenderness or swelling of the abdomen
  - Stomach pains or spasms
- Treat suspected constipation promptly to prevent severe complications. Ensure local clozapine guidelines detail treatment options and an escalation pathway (i.e. when surgical intervention may be required).
- Report any suspected and confirmed cases of clozapine-induced gastrointestinal hypomotility at your organisation and/or directly to the <u>Therapeutic Goods Administration</u> (TGA).



- 1. <u>Clozapine safety advisory constipation: a potentially serious side effect</u>. TGA April 2022.
- Clozapine and gastrointestinal hypomotility with severe complications. Medicines Safety Update. TGA April 2022.
- 3. Clozapine monograph. AMH Online, accessed June 2024
- Recognition and prompt treatment of clozapine-induced constipation. Safety Information alert. NSW Health February 2022.