

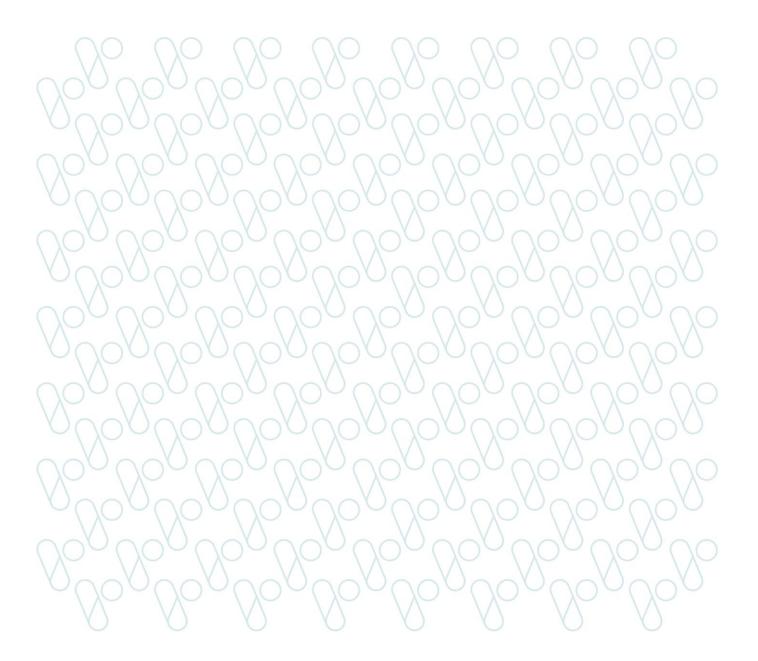
October 2023

# Albury Wodonga region colonoscopy recall

Final report

**OFFICIAL** 





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# **Abbreviations**

CRM	Customer relationship management system
Department	Victorian Department of Health
iFOBT	Faecal immunohistochemical test
NSW	New South Wales
Peter Mac	Peter MacCallum Cancer Centre
Recall	Albury Wodonga region colonoscopy recall
VAHI	Victorian Agency for Health Information

# **Acknowledgements**

#### **Acknowledgement of Country**

Our office is based on the land of the Traditional Owners, the Wurundjeri people of the Kulin Nation. We acknowledge and pay respect to their history, culture, and Elders past, present, and emerging. We acknowledge Aboriginal people as Australia's first peoples and as the Traditional Owners and custodians of the land and water on which we rely. We recognise and value the ongoing contribution of Aboriginal people and communities to Victorian life and how this enriches us. We embrace the spirit of reconciliation, working towards the equality of outcomes and ensuring an equal voice. For this land always was, and always will be, Aboriginal Land.

#### Acknowledgment of lived experience

Safer Care Victoria respectfully acknowledges consumers, families, carers, friends and loved ones who have experienced or have been impacted by sentinel events. We are deeply sorry for their distress and grief. We bear witness to their stories in the sincere hope of improving care for others.

#### Our thanks

The recall was a multi-state, interdisciplinary collaborative that drew on key partnerships and expertise for resolution. Safer Care Victoria could not have delivered these outcomes without dedicated support from the health sector. We would like to extend our thanks to all our partners and the dedicated healthcare professionals who worked tirelessly to achieve this outcome.

We would like to sincerely thank:

- the clinicians and specialists who donated their time and expertise
- Peter MacCallum Cancer Centre
- Albury Wodonga Health
- Albury Wodonga Private Hospital
- Insight Private Hospital
- Austin Health
- St Vincent's Health
- Department of Health
- Victorian Agency for Health Information
- NSW Ministry of Health
- Clinical Excellence Commission NSW.

## **Executive summary**

In January 2023, in conjunction with the Department of Health, Safer Care Victoria commissioned and led the Albury Wodonga region colonoscopy recall. The recall was initiated in response to concerns raised by Albury Wodonga Health about a surgeon's clinical practice ('Surgeon A').

An independent clinical review into the surgeon's practice identified that some colonoscopies performed and supervised by Surgeon A may have been incomplete. Incomplete procedures indicate risk for missed diagnoses including colorectal cancer. On evaluation of the findings of the review, it was determined that any patient who had received a colonoscopy performed or supervised by the surgeon between 2018 and 2022 would require reassessment. A total of 1934 patients across 3 health services were identified as receiving a colonoscopy performed or supervised by Surgeon A during this time.

The Albury Wodonga region colonoscopy recall program was publicly announced on 12 January 2023. The aim of the recall was to identify and contact patients, to perform clinical assessment, and to provide appropriate follow-up care if required. A total of 1934 impacted patients were identified and contacted, 1750 patients required clinical assessment and 1443 were referred for specialist medical review. A total of 1084 patients received follow-up colonoscopies.

Repeat colonoscopies identified 7 cancers. Each of these individuals are now receiving interventive care and have a positive prognosis<sup>1</sup>. The repeat colonoscopies facilitated early clinical intervention for over 500 patients, resulting in beneficial health outcomes including cancer prevention. The recall formally closed on 31 July 2023, after 200 days in operation.

<sup>&</sup>lt;sup>1</sup> A prognosis is a prediction about the likely course of a disease.

## About this recall

#### Background

In July 2022, Safer Care Victoria received a sentinel event<sup>2</sup> notification from Albury Wodonga Health. The sentinel event related to a patient diagnosed with colorectal cancer. The cancer was an unexpected outcome as the patient had undertaken several colonoscopies between 2017 and 2022 which should have detected early signs of colorectal cancer. The colonoscopies were performed by Surgeon A.

This event, in combination with other concerns raised regarding the surgeon's practice, led Albury Wodonga Health to request advice and support from the Department of Health (the department) and Safer Care Victoria. In partnership with Safer Care Victoria, Albury Wodonga Health commissioned an independent clinical review of the surgeon's practice. Albury Wodonga Health issued an interim restriction to prohibit Surgeon A from performing any procedures at this hospital until the conclusion of the review.

The independent review was completed in late December 2022 and found that some colonoscopies performed and supervised by Surgeon A were incomplete3. This may have resulted in missed diagnoses, including colorectal cancer. A thorough review of other procedures undertaken by Surgeon A such as breast, thyroid, and skin cancer surgeries, found that patient follow up for those clinical procedures was not required.

Surgeon A was practicing across Albury Wodonga Health, Albury Wodonga Private Hospital and Insight Private Hospital. These services are located across Victoria and NSW. All three health services placed appropriate restrictions on Surgeon A's practice following notification of the events.

In response to the outcomes of the independent clinical review, Safer Care Victoria and the department launched the Albury Wodonga region colonoscopy recall (the recall). The recall was publicly announced on 12 January 2023 and was delivered in conjunction with multiple partners and clinical experts.

#### Colonoscopies

More than 900,000 colonoscopies are performed in Australia annually (Australian Commission on Safety and Quality in Health Care 2020).

Colonoscopy refers to the examination of the entire large bowel using a camera in a flexible tube or colonoscope. A colonoscopist visualises the bowel while removing polyps or tissue samples where required. Colonoscopies are performed as a screening tool for at risk populations, surveillance for those with previous colorectal cancers or polyps, and as a diagnostic tool for those displaying symptoms.

<sup>&</sup>lt;sup>2</sup> A sentinel event is an adverse patient safety event that results in serious harm or death of a patient while in the care of a health

<sup>&</sup>lt;sup>3</sup> Incomplete colonoscopy refers to a colonoscopy that did not involve visualisation of the entire colon.

#### Scope and purpose

Safer Care Victoria and the department commissioned a panel of experts, led by the Peter MacCallum Cancer Centre (Peter Mac) to determine the scope of the recall. This panel determined that the scope of the recall would include all patients who had a colonoscopy performed or supervised by Surgeon A from 1 January 2018 to 31 December 2022. In considering this time frame, the panel of experts agreed that any patient who received a colonoscopy prior to 1 January 2018 and remained asymptomatic would have very low risk of carrying significant pathology<sup>4</sup>.

The purpose of the recall was to:

- identify all patients seen by Surgeon A for colonoscopy during the identified period
- assess patients to clarify if further investigation or treatment was required
- ensure all patients requiring investigation or treatment receive appropriate follow up care.

Additionally, the recall governance group was particularly committed to gaining lessons and insights from this recall, including opportunities for improving colonoscopy services. The recall process was designed to identify findings and lessons to improve the safety and quality of care including the development of guides and resources for any future patient recalls.

<sup>&</sup>lt;sup>4</sup> In the context of abnormal colonoscopy results, the term 'significant pathology' refers to the presence of findings or conditions that require further medical evaluation or intervention.

# Recall governance and oversight

Safer Care Victoria established a governance group to provide executive oversight and strategic governance to the recall. The governance group was chaired by the Chief Executive Officer of Safer Care Victoria/Victorian Chief Quality and Safety Officer, with members including representatives from Safer Care Victoria, the department, NSW Ministry for Health, Clinical Excellence Commission NSW, Albury Wodonga Health and experts from Peter Mac. The governance group reported to the Secretary of the department and sought subject matter expertise as required.

The governance group commissioned and oversaw five workstreams to deliver the operational outcomes of the

- 1. patient assessment and recall
- 2. colonoscopy review and delivery capacity
- 3. customer relationship management system (CRM) and telephony
- 4. communications and media
- 5. systems safety and learning.

Supporting these workstreams and providing advice to the governance group were subject matter experts who provided specialist advice and input across all workstreams. Subject matter experts included:

- a consumer representative, who maintained a consumer perspective throughout the recall ensuring valuable advice for best communication and resources to support impacted patients
- Victorian Agency for Health Information (VAHI), provided data and reporting expertise, including a live data dashboard
- Digital Health Branch from the department led the design of patient record and recall processes as well as the design and build of CRM and telephony services
- Information and Digital Solutions Branch from the department advised on secure storage and transfer of records, and operationalisation of the CRM
- clinical specialists, who provided clinical expertise
- legal services, who offered legal advice and support.

## **Workstreams**

#### Patient assessment and recall

The patient assessment and recall workstream was responsible for identifying, contacting, and assessing impacted patients and managing their journey across the recall process. The workstream oversaw the following aspects of the recall:

- data and reporting, including identification of all in-scope patients from hospital records
- patient contact including
  - letters
  - a dedicated public support line run by Healthdirect Australia
  - a dedicated clinical call centre sponsored by Peter Mac
- specialist clinical advice.

#### Colonoscopy review and delivery capacity

The colonoscopy review and delivery capacity workstream oversaw the delivery of care to all impacted patients including ensuring service capacity and care coordination. The workstream comprised of representatives from the department, participating health services, and Safer Care Victoria.

Guiding principles underpinning the colonoscopy recall included a patient-centred response, agility, consistency and collaboration including a multi-agency approach.

The responsibilities of the workstream included:

- identifying delivery capacity across the system, to ensure patients received appropriate, timely care that was close to home and equitable
- ensuring the systematic documentation of patient care and outcomes
- development and standardisation of high-level processes for patient care, including travel for patients requiring care outside of the Albury Wodonga region.

#### CRM and telephony

The CRM and telephony workstream were established to advise on and oversee patient contact and recording of patient information in an electronic health record. Liaising closely with the patient assessment and recall workstream and the colonoscopy review and delivery capacity workstream, their purpose was to:

- coordinate the implementation of the patient (Healthdirect) support line,
- coordinate the clinical call centre
- to monitor and oversee development and performance of the patient management system.

#### Communications and media

This workstream developed an overarching, multifaceted communication strategy underpinning the delivery of the recall program. The workstream was essential for ensuring impacted patients received respectful, timely and clear communication that supported high-quality assessment, diagnosis and treatment.

The communications and media workstream coordinated and aligned communication from key stakeholders, including participating health services, Safer Care Victoria, and the department. In addition to an informative media campaign, the communications and media workstream oversaw messaging to impacted patients as well as stakeholders including general practitioners, Primary Health Networks and community organisations.

#### System safety and learning

The system safety and learning workstream was established to identify and prioritise key lessons from the recall and to translate lessons into future improvements, delivering patient safety across the health system. This workstream also documented the recall process to develop the Operational recall guide: playbook for future responses to large scale serious clinical adverse events that will be used to inform future patient recalls.

An international roundtable was held to identify best practice in colonoscopy. This best practice is published in the proceedings from the roundtable.

# Service delivery and product development

Throughout the recall, several processes and products were developed to support streamlined delivery of patient care. The products were developed with potential future recalls in mind and are designed for future utilisation.

#### Patient management system

Patient information was managed via a secure, electronic customer relationship management system (CRM). The CRM was custom built for the colonoscopy recall using Microsoft Power Apps and was designed to securely store patient information and relevant clinical information. It was also designed to capture each stage of the patient journey and assisted those coordinating the recall to follow the progress of each patient.

Once the patient information was entered into the CRM, the patients moved through the various stages of the recall via a series of modules or apps as detailed below.

- Screening: developed to support initial information collection including whether a clinical assessment was
  required, based on specific criteria. The screening module was accessed by Healthdirect support staff who
  implemented initial patient screening and information provision.
- Clinical assessment: accessed by clinicians when triaging patient care requirements, this module was
  developed to support clinical assessment and triage.
- Hospital allocation: this module coordinated patient allocation for specialist clinical assessment and colonoscopy as required.
- Hospital tracking and outcome: this module ensured the recording of patient hospital allocation, care delivery and patient outcomes.
- Review: accessed by clinical experts, this module was developed to document analysis of results and finalise
  the patient care journey.

The CRM enabled secure data exchange between Safer Care Victoria, the two call centres (the Healthdirect support line and the clinical call centre), each of the participating health services, and VAHI. Access to the CRM and confidential patient information was monitored and restricted to registered users.

While the CRM was built specifically for this recall, a baseline product is now available that can be adapted for future patient recalls including device recalls, medication recalls and clinical recalls.

#### **Healthdirect support line**

A dedicated phone line was established to act as a centralised contact and information point for impacted patients throughout the recall. The support line commenced operation on 12 January 2023 and was run by Healthdirect Australia, who are funded by Australian governments to deliver virtual health services. The support line received inbound calls, including public queries and patient enquires, and made outbound calls to contact all in-scope patients for an initial screening. The screening was used to confirm patient contact details and to establish if referral to a clinical nurse specialist for clinical triage was required. Interpreter services were used for all non-English speaking patients and carers.

#### Clinical call centre

A clinical call centre was established by the patient assessment and recall workstream to facilitate clinical assessment of impacted patients. The clinical call centre was sponsored and delivered by Peter Mac in conjunction with Safer Care Victoria. The clinical call centre employed clinical nurse specialists who contacted each patient to assess their individual care requirements. Using a customised script, patients were asked a series of clinical questions which led to one of the following referral pathways:

- no further care required
- specialist consultation required
- colonoscopy (urgent or non-urgent) required.

#### Operational recall guide

The recall harnessed the opportunity to develop and deliver a 'how to' guide for future recalls. The operational recall guide provides practical guidance to those conducting patient recalls. Whilst every patient recall will require tailoring to suit each unique scenario, the guide provides a suggested overall approach with specific phases for consideration. The aim of capturing the lessons and successes from this recall was to support future recall processes for large scale serious clinical adverse events.

The guide proposes workstreams, roles and responsibilities to ensure a coordinated and comprehensive response is delivered to patients and the community. It also suggests structures and governance, which will create an authoritative environment and reduce duplication of efforts from key stakeholders. The guidance is complemented by tools, templates, and support materials for all workstreams and phases to enable an efficient and effective delivery.

#### Colonoscopy roundtable

In March 2023, the system safety and learning workstream organised and facilitated a colonoscopy roundtable. The aim of the roundtable was to identify best practise in colonoscopy to support the provision of services across Victoria, NSW and Australia. Clinicians from across Australia and New Zealand gathered to discuss topics including training and credentialling, recertification, remuneration, quality, equity of access, and managing professional underperformance. The key messages from this roundtable will be incorporated into a whitepaper with recommendations to improve quality and safety of colonoscopy delivery nationally. The whitepaper is expected to be delivered by December 2023.

# **Patient journey**

The recall was a collaborative response that moved quickly to adapt to a fast-changing environment. The Safer Care Victoria delivery team worked closely with the department and health services to maintain a patient focused recall response.

The recall aimed to identify, contact, and provide follow-up care to all impacted patients. Patients progressed through the recall via the following stages:

- 1. Patient identification and contact
- 2. Patient assessment
- Referral and follow-up care
- 4. Exit from the program.

Ensuring a positive and supportive patient experience was a key priority for the governance group. A dedicated support line was available to provide information for the duration of the program, and patients could access free support and counselling through the Mental Health and Wellbeing Hubs.

Information about the recall was also available on the Safer Care Victoria website, detailing who the recall applied to and what the next steps would be for impacted patients.

#### Patient identification and contact

There were 3 health services identified as health services where Surgeon A had performed or supervised colonoscopies: Albury Wodonga Health, Albury Wodonga Private Hospital and Insight Private Hospital (index health services). These health services reviewed patient records and identified 1934 patients who met the criteria for inclusion into the recall (the index patient list). Deidentified demographic information for these patients is provided in Appendix 1.

On 12 January 2023, Safer Care Victoria sent all impacted patients a letter advising them of the recall and providing information about next steps in the recall process. Impacted patients were also notified of the recall by SMS text messages to ensure they were informed in a timely manner.

The Healthdirect support line was established as the centralised contact and information point for impacted patients throughout the recall. Twenty-five people who were not included in the dataset provided by the index health services contacted the Healthdirect support line to clarify if they were eligible for the recall. Following review, none of these patients met the criteria to be included in the recall. These individuals were referred to alternate care as required.

The Healthdirect support line opened on 12 January 2023 and closed on 24 May 2023. Over the 19 weeks the support line was in operation, 1720 inbound calls were received, and 2626 outbound calls were made. From 24 May 2023, all inbound calls to the Healthdirect support line were diverted to Safer Care Victoria and directly managed by the recall team.

#### **Deceased patients**

The index patient list was cross-checked against the Victorian Deaths Index and the NSW Deaths Index, and 56 patients were identified as deceased. As reporting to jurisdictional death indices is considerably lagged, during the recall a further 18 patients were identified to be deceased. Of the 74 deceased patients, cause of death data and patient files are available for 65 patients. None of these patients were found to have died of causes related to their original colonoscopy. The families of these patients were not contacted out of respect for their privacy.

#### Uncontactable patients

The recall program made best efforts to contact all impacted patients to inform them of the recall. In addition to the media campaign, the following steps were taken before patients were discharged from the program as 'uncontactable':

- letter via Australia Post
- text message
- 3 attempted phone calls
- 3 attempted phone calls to next-of-kin
- registered letter, closing the patient out of the program and inviting them to re-engage.

Of the 1934 patients in-scope for the recall, 13 were unable to be contacted by at least one of the methods outlined above.

#### **Open disclosure**

The governance group considered open disclosure to be an important step to ensure that patients received open and transparent information in a timely and coherent manner. Safer Care Victoria partnered with the index health services to develop an open disclosure letter that could be adapted to the individual patient, as appropriate. The health services sent letters to impacted patients, acknowledging the events and outlining the steps that were being taken in response to the incomplete colonoscopies.

Patients who had significant abnormalities identified on their recall colonoscopy were contacted by staff from the index health service, and provided with an apology and the opportunity to discuss the recall and their care.

#### Patient assessment

The clinical call centre commenced contacting patients for clinical assessment on 18 January 2023. Following the pre-screening undertaken by Healthdirect, patients were clinically assessed by a qualified clinical nurse specialist. A standardised tool was developed and used to assess the care requirements for each patient. The tool was developed in consideration of the 4 critical factors outlined in the Victorian colonoscopy categorisation guidelines<sup>5</sup>:

- urgent colonoscopy to take place within 30 days of the medical review by the health service
- non-urgent colonoscopy to take place within 180 days of the medical review by the health service
- specialist consultation by the health service to determine if colonoscopy is required

<sup>&</sup>lt;sup>5</sup> Available at https://www.health.vic.gov.au/publications/colonoscopy-categorisation-guidelines

- no further action required because:
  - the patient did not require any follow-up care
  - the patient intended to seek care or was already receiving care from another health professional
  - the patient requested not to participate in the program
  - the patient was not in-scope for the recall.

#### Referral and follow-up care

Patients received follow-up care at one of 5 health services: the 3 index health services (Albury Wodonga Health, Insight Private and Albury Wodonga Private hospitals), Austin Health and St Vincent's Health. Patients were allocated to a health service based on a combination of clinical need, service availability and patient preference.

Patients requiring specialist consultation had a clinical review from a specialist (colorectal surgeon or gastroenterologist) to confirm if a repeat colonoscopy was required. The medical review enabled the patient to make an informed decision about proceeding to repeat colonoscopy.

Patients referred directly to colonoscopy (urgent or non-urgent) were referred to a health service for their repeat colonoscopy. Repeat colonoscopies commenced on 4 February 2023. These services were additional to existing colonoscopy services to ensure minimal disruption to other patients on existing waitlists.

Wherever possible, colonoscopies were performed at a location convenient to the patient. A small cohort of patients were willing to travel to Melbourne for care. All out-of-pocket expenses related to care, including travel and accommodation costs, were reimbursed to ensure finances were not a barrier to care provision.

Patients living interstate or overseas had their care coordinated through a collaborative model by Albury Wodonga Health and Ramsay Health. The patients were assessed by the clinical call centre and care arranged at a Ramsay Health facility close to their residential address to minimise disruption to the patient.

#### **Exit from program**

The recall program formally closed on 31 July 2023, by which time all patients had exited the program. Patients received a closure letter from Safer Care Victoria unless they were transitioned into a clinical care pathway following their coloscopy, which was continuing beyond the recall closure date.

## Clinical outcomes

Throughout this process, Safer Care Victoria monitored and assessed patient outcomes. Clinical outcomes were recorded for those who progressed to colonoscopy. All other patients exited the program via alternate means across different stages of the recall.

#### Patient exits from the recall program

#### **Healthdirect support line**

The Healthdirect support line made initial contact with impacted patients to perform preliminary screening of each patient. Several attempts were made to ensure each of the 1934 impacted patients were contacted. Of those, 184 patients exited the recall prior to clinical assessment due to the following reasons:

- 74 patients were identified as deceased
- 51 patients could not be contacted via phone
- 59 patients declined participation in the program.

#### Clinical call centre

Clinical assessment of 1750 patients were through the clinical call centre. Of those, 307 patients exited the recall for the following reasons:

- 137 patients were seeking or had sought care from an alternate source
- 68 patients chose not to continue with the program
- 102 patients were assessed medically and did not meet criteria for further investigation.

#### Follow-up care at a health service

There were 1443 patients referred to one of the 5 participating health services for medical review. Of those, 359 exited the program prior to colonoscopy for the following reasons:

- 211 were assessed by a specialist and did not require a colonoscopy
- 106 chose not to continue with the program
- 42 patients were seeking or had sought care from an alternate source.

#### Colonoscopies completed

Of the 1084 patients who underwent a colonoscopy, 497 were categorised as requiring an urgent colonoscopy within 30 days and 587 were categorised as requiring a non-urgent colonoscopy within 180 days.

Of the 1084 patients who underwent repeat colonoscopies, 727 patients were reported to have one or more abnormal findings. A summary of findings is presented in Table 1. The data represents the most significant finding for each patient.

It is not clear if these abnormalities were or could have been detected at the time of the original colonoscopy. All patients with abnormal findings have received or are receiving treatment with no known complications.

**Table 1: Summary of patient outcomes** 

Findings from repeat colonoscopy	Number of patients
No abnormality detected on colonoscopy	327
Cancer detected	7
Polyps <sup>6</sup> most significant finding	548
Hyperplastic polyps <sup>7</sup> most significant finding	115
Adenomatous polyps <sup>8</sup> <10mm diameter	263
Adenomatous polyps <sup>9</sup> >10mm diameter	66
Other polyps/lesions (mostly serrated <sup>10</sup> )	104
Diverticulosis most significant finding	155
Other <sup>11</sup>	19
Outcome unavailable at time of publication	28
Total patients who underwent repeat colonoscopy	1084

#### Polyps and risk of developing cancer

Polyps vary in size, shape and location within the large bowel (Colorectal Surgical Society of Australia and New Zealand). The presence of polyps increases a person's risk for developing colon cancer over their lifetime (Winawer et al 1993). The varying types and sizes of polyps have a different risk of developing cancer. The significance of hyperplastic polyps to cancer risk is low to non-existent, whereas serrated polyps are associated with a higher risk for cancer development. Adenomatous polyps (adenomas) are commonly associated with bowel cancer. The larger the adenomatous polyp, the greater the risk of it becoming cancerous and the higher the risk of complications associated with surgical resection of the bowel. Removing polyps early substantially reduces the incidence of bowel cancer. All identified polyps were removed at the time of colonoscopy.

#### Patients with cancer diagnosis

Seven patients were diagnosed with colorectal cancer. The clinical outcomes of these individuals were pending at the time of publication and will continue to be monitored by Safer Care Victoria and the treating health services. It is believed that the intent of treatment in each case is curative. Based on available information it is not possible to correlate these outcomes with a potentially incomplete original colonoscopy.

<sup>&</sup>lt;sup>6</sup> Polyp: Abnormal growths in the lining of the bowel

<sup>&</sup>lt;sup>7</sup> Hyperplastic polyp: Small, non-cancerous

<sup>&</sup>lt;sup>8</sup> Adenomatous (<10mm) polyp: Typically non-cancerous

<sup>&</sup>lt;sup>9</sup> Adenomatous (>10mm) polyp: More likely to develop into cancer

<sup>&</sup>lt;sup>10</sup> Serrated polyp/lesion: Higher risk for developing into cancer than a typical adenoma

<sup>&</sup>lt;sup>11</sup> Other: insignificant clinical findings

## **Lessons learned**

Lessons learned are system-level improvement opportunities identified throughout the recall. Safer Care Victoria believes in a continuous improvement methodology and sought to learn and improve throughout this process. Where able, lessons were addressed contemporaneously via the actions outlined.

#### Lesson 1. There was sufficient evidence of risk to patient safety to warrant reassessment of all impacted patients.

Findings from the independent review into the surgeon's clinical practice supported the establishment of the recall.

At the conclusion of the recall, it was confirmed that there were 7 patients diagnosed with colorectal cancers. These individuals are now receiving or have received treatments with a curative prognosis. Additionally, there were 548 patients with abnormalities that were reviewed and treated through the recall process. Of those, 170 had clinically significant or pre-cancerous polyps identified and removed. These individuals may not have otherwise received treatment in such a timely manner and were ensured improved outcomes due to the recall program.

#### Lesson 2. There was no existing documented guidance or electronic management system to support a patient recall of this size.

Safer Care Victoria has been involved in several recalls for significant clinical adverse events in recent years. While each recall has been completed and closed off successfully, prior to the Albury Wodonga region colonoscopy recall, there were limited documented systems and processes to support this type of recall. It was of great benefit for this recall and for future recalls to develop the CRM and structured recall guidance.

The CRM has core base modules that can now be used and adapted for future recalls. It will allow stakeholders to securely manage patient data across multiple organisations and transition the impacted patients through each stage of the recall process whilst being centrally monitored by Safer Care Victoria. The CRM allows clinicians and care providers to communicate with each other whilst coordinating and facilitating care across multiple health services, which improves clinical safety and streamlines care.

During the Albury Wodonga region colonoscopy recall, Safer Care Victoria developed the Operational Recall Guide as baseline guidance for future recalls. The guide provides a structured approach to recall, supports effective communication, and outlines clear roles and responsibilities for a successful patient recall.

#### Lesson 3. A targeted collaborative approach is an effective way to respond to a health emergency or critical event.

It was quickly recognised that no single health service could manage the large number of patients impacted by this recall. Safer Care Victoria and the department requested additional support from across Victoria and NSW to support the response

Safer Care Victoria worked collaboratively with the NSW Ministry for Health, Clinical Excellence Commission NSW, Albury Wodonga Health and Peter Mac during the initial establishment of the recall. Clear governance arrangements from the commencement of the recall meant that effective communication and leadership was

maintained throughout. In addition to the 3 index health services providing follow-up care for impacted patients, St Vincent's Health and Austin Health offered surgical consultations and additional scope lists.

Having the support of additional services meant impacted patients received timely assessment and follow up care, and streamlined care services, all through a flexible and adaptive response. Additionally, collaborative work ensured there was limited impact on delivery of services to other patients in the community. This approach resulted in care delivery that met the clinical, physical, emotional and geographical needs of impacted patients independent of where they lived and their financial status.

#### Lesson 4: Further support and oversight of colonoscopy practices is required to ensure ongoing safety.

Throughout the recall, it was identified that there would be learnings on best practice in colonoscopy. An international roundtable, including representatives from the Gastroenterology Society of Australia, Royal Australasian College of Surgeons, and Royal Australasian College of Physicians, was held to discuss issues and improvement opportunities. The roundtable key members will produce a whitepaper that will outline key recommendations. The whitepaper is expected to be released in September 2023.

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# **Appendices**

## **Appendix 1: Patient demographics**

Demographic	Number of patients	%
Age group		
18-24	39	2.0%
25-34	148	7.7%
35-44	185	9.6%
45-54	275	14.2%
55-64	422	21.8%
65-74	505	26.1%
75+	360	18.6%
Sex at birth		
Female	1392	71.9%
Male	501	25.9%
Not provided	41	2.0%
Indigenous status		
Aboriginal but not Torres Strait Islander origin	40	2.1%
Both Aboriginal and Torres Strait Islander origin	7	0.4%
Neither Aboriginal nor Torres Strait Islander origin	1628	84.2%
Not answered/ not determined	259	18.3%
Total patients in-scope for recall	1934	100%



