Safer Care Victoria

Removal of gallbladder during bariatric surgery

Evidence-based guidance supplement

OFFICIAL

Section 1 - Guidance production process

In March 2020, during the first wave of the coronavirus (COVID-19) pandemic in Victoria, all non-urgent elective surgery was temporarily suspended. This decision was made so that health services could conserve personal protective equipment (PPE), minimise the risk of infection to staff and patients, and ensure intensive care unit capacity for coronavirus (COVID-19) care. This provided an opportunity to improve safety, quality, and equity by aligning services with national and international clinical consensus on care that provides the best outcomes for patients.

In May 2020, Safer Care Victoria partnered with the Victorian Perioperative Consultative Council (VPCC) to review the clinical evidence for surgical procedures – ensuring care was prioritised towards the patients that needed it most. A list of 26 specific surgical procedures was identified as having limited evidence of clinical benefit for patients, except when specific clinical indications exist.

Following consultation and sector engagement, in February 2021, Safer Care Victoria (Best Care) published 26 guidance's for the Victorian health care sector and consumers. The guidance provides advice about the elective surgery procedure, indications when it should be performed and recommendations on alternative health care options which are safe, evidence-based and considered best practice. The guidance also encourages and supports joint decision making between consumers and their health professional.

After successfully completing the first tranche of procedures, Best Care utilised a selection process to identify additional elective procedures for tranche 2 of the project. In August 2021, Best Care worked with an Advisory Group to prioritise these procedures for guidance development. After reviewing literature, collecting data and consulting with subspecialists, 2 additional procedures were selected for guidance development by June 2022.

Safer Care Victoria follows a tiered approach to endorsing, adapting and developing evidence-based guidance, as detailed in our Evidence Based Guidance Operating Framework. This framework details how we apply the principles detailed in the Safer Care Victoria Evidence-based guidance strategy.

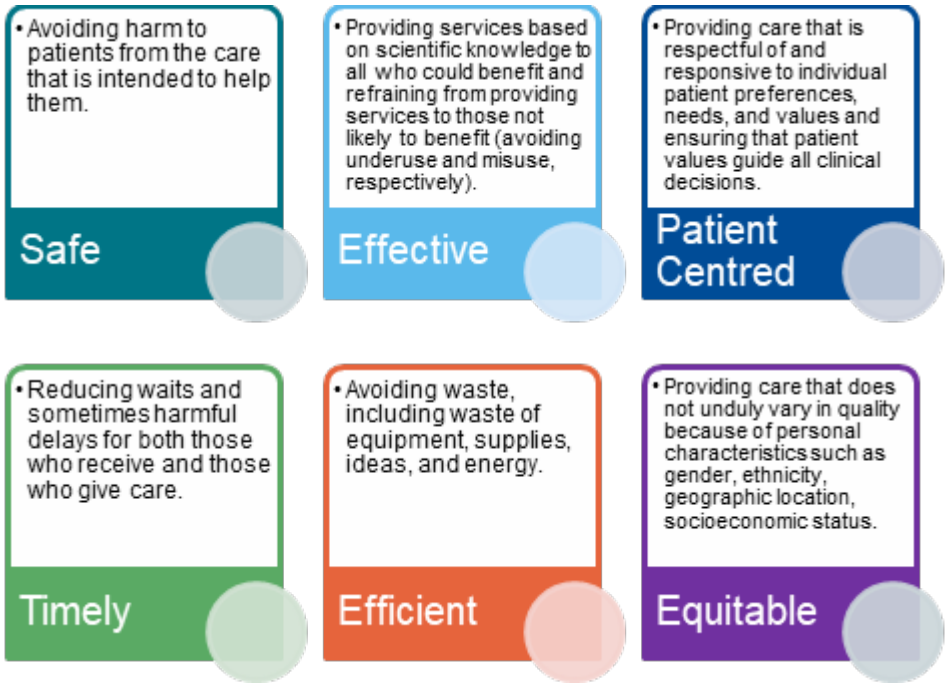
In accordance with SCV's Evidence Based Guidance Operating Framework Tier 2 processes have been followed.

1.1 Topic selection

A multidisciplinary Best Care Advisory Group consisting of clinicians, consumers and health service leaders were responsible for the procedure selection process.

A robust procedure selection framework was developed. The selection of procedures for Best Care was guided by the six domains of health care quality framework as established by the Institute of Medicine (IOM) (Fig 1). The final guidance considered each of these domains in establishing indications, recommendations and alternative pathways of care.

Figure 1 – The six domains of healthcare quality

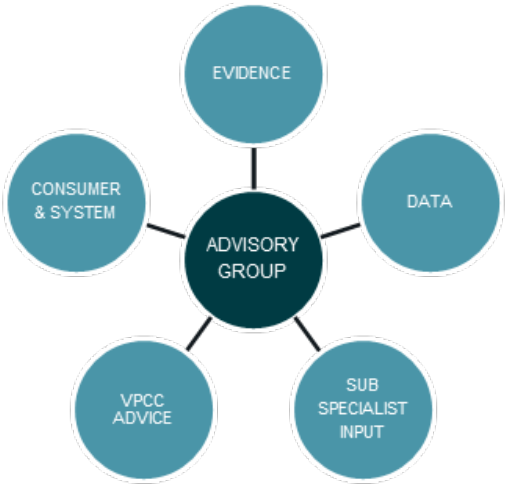


Trance 2 procedures: Six inputs to the procedure selection process

The selection process was informed by six inputs (see Fig 2):

1. Evidence – preliminary independent literature review, coupled with evidence from subspecialty input
1. Data – aggregate data derived from VAHI analysis
2. Subspecialty input – advice on best practice and underlying evidence
3. VPCC advice – dating from initial selection of 17 Tranche 2 procedures
4. Consumer-centred and system level considerations
5. Best Care Advisory Group Consensus

Figure 2: Inputs to guide procedure selection process



The SCV project team synthesised the information from inputs 1 – 5 (outlined below) and presented a summary to the advisory group, to support members to reach a consensus.

Evidence - Preliminary independent literature review

Preliminary Literature Review

The purpose of the preliminary literature review at the procedure selection phase is to determine if there is high-quality evidence relevant to the Victorian context which suggests that:

- There are specific indications for when the procedure is likely to be most beneficial
- The procedure has little to no benefit to patient outcome for specific patient groups.

Procedures that meet at least one of these criteria were prioritised for selection.

Proposed method of preliminary literature review

A preliminary literature review was performed under the follow parameters:

- Search date limited to last 10 years. The search date limits should be expanded in the event that the search returns very few results.
- Publication types limited to NHMRC Level I, II, III-1 and III-2 (systematic reviews, RCTs, pseudorandomised control trials and comparative studies)

The SCV project team then completed the NHMRC body of evidence matrix (Appendix 1) questions 1 and 2 – evidence base and consistency of studies.

After the procedures for Tranche 2 was selected, a more detailed literature review was performed and reviewed by clinical experts and consumers on the Expert Working Groups (EWG).

Detailed Literature Review

The purpose of the detailed literature review at the guidance development phase is to perform a more detailed and nuanced synthesis of evidence on the procedure, in order to refine the indications and recommendations in the guidance. This review was analysed by the EWG who developed the guidance.

Proposed method for detailed literature review

The guidance developed within Tranche 2 aligned with the SCV evidence-based guidance framework. This project produced outputs classified as tier 2. This framework uses an endorse, adapt, develop approach. It is therefore important that a search is conducted for current evidence and pre-existing guidance on the topic for the EWG to consider when producing Tranche 2 guidance. Each procedure had an evidence search summary form completed which clearly outlined:

- Search question
  - Databases searched
- Keywords used
  - Search strategy
  - Search limits
  - Date of search
  - Evidence level for each reference using NHMRC levels of evidence tool
  - Key findings and recommendations from each study

VAHI data

VAHI collected aggregate data on the volume of each procedure at a state-wide level for public and private healthcare systems and at a metropolitan and combined regional and rural level. This guided decision making as the Advisory Group and Expert Working Group were able to understand the differences between procedure completion rates and potential sources of variation at an aggregate level.

Subspecialty society input

Input from subspecialty societies was sought to understand the current Victorian context for each procedure. This was completed separately to the literature review to ensure independence of views and minimise bias within the procedure selection process.

Subspecialty societies were asked to provide:

- Advice on best practice models of care for the procedure, indications, and potential alternative pathways
- Reference to the evidence that underpins best practice
- Reference to any existing guidance that informs clinical practice within Victoria
- Knowledge or evidence that specific population groups will be impacted by guidance on the procedure and if indications should be adjusted for them (e.g. socioeconomic status, geographic location, Aboriginal and Torres Strait Islander peoples, CALD communities, populations with specific diseases/conditions)
- Common referral sources for this procedure (e.g. GPs, outpatient specialists).

Victorian Perioperative Consultative Council advice

In June 2020 the Victorian Perioperative Consultative Council (VPCC) provided advice on the indications and recommendations for the 17 procedures considered for inclusion within Tranche 2. These findings formed part of the procedure selection process with clinical experts determining if the literature aligned with the VPCC advice and the advice collected from subspecialty groups.

Consumer-centred and system-level considerations

Consumers and clinical experts on the advisory board were asked to consider a series of questions focused on the domains of Health Care Quality using the IOM framework. This allowed the Advisory Group's decision to be guided not only by data, evidence, and clinical considerations (addressing the safety and effectiveness domains), but also to understand how the clinical decision-making may be influenced by the other domains of quality healthcare (patient-centred, timely, efficient, and equitable). The questions also enabled the group to understand issues driving procedure completion and unwarranted variation.

The questions asked within the procedure selection were:

- What are the common referral sources for this procedure?
- Should there be variation of indications for specific patients and populations? (e.g. socioeconomic status, geographic location, Aboriginal and Torres Strait Islander peoples, CALD communities, populations with specific diseases/conditions)
- Do alternative pathways exist for this procedure?
- Is there inequity of access or lack of access to alternative pathways?
- Will exploration of alternative pathways or delay in this procedure create harm, instability, or insecurity for the patient?

At the guidance development phase, consumers with specific lived experience were part of the EWGs to provide insights on access to alternative pathways and other considerations that may impact a consumer if access to the procedure was not recommended.

Advisory group procedure selection consensus

The Best Care Advisory Group were presented with a summary of the information relating to the above inputs for each procedure.

There were two specific tools used to help selection of Tranche 2 procedures:

1. Procedure prioritisation matrix – summarises and grades evidence, data, VPCC advice and other key clinical considerations (e.g. pre-existing guidance). Where a score can be placed against an item this was tallied to form a numerical score. This score may be considered as part of a broader discussion within the group to help determine which procedures are included within Tranche 2.
2. Consumer-centred and system-level framework with key questions.

A prioritisation matrix was used to rank procedures based on the quality and consistency of evidence, current guidance for the Victorian context, frequency in which the procedure was performed and VPCC and subspeciality advice.

The final decision was based on whether guidance would improve outcomes for patients and the sector, if the procedure had specific indications, at specific time intervals for specific patient groups and whether potential harm from the procedure would outweigh any benefits.

Scope

The guidance is intended to be used by clinicians and consumers to make informed decisions about the most appropriate pathway of care. The guidance details a specific elective surgery procedure that should now only be done for specific indications.

The guidance aims to:

- Inform clinicians and consumers about what is considered best care pathways in relation to the identified procedures based on current evidence
- Support clinicians and their patients to discuss available options and make informed healthcare decisions together
- Empower Victorians to feel well informed about the best management of their healthcare needs.

Scope of the clinical guidance

Population	Adult patients (>16 years)
Purpose	Inform clinicians and consumers about what is considered best care pathways in relation to the identified procedures based on current evidence
Outcome	Reduce the number of unnecessary surgical procedures defined as low value care, and reduce state-wide variation across public health services, by 1 December 2023
Exclusions/out of scope	Private health services

1.2 Expert working group

Multidisciplinary expert working groups (EWGs) were established by SCV in early 2022 to develop the clinical guidance. Advisory Group members were offered the opportunity to chair an EWG, and all other members were selected through an Expression of Interest (EOI) process. The EOI was open to clinicians, consumers and carers. Applicants were asked to submit a short cover letter outlining the following:

Clinicians:

- Experience and capability working collaboratively with a range of different consumers and clinicians.
- Examples of experience developing guidance or projects aimed at improving health outcomes.

Consumers:

- Interest in sharing their lived experience as part of the Best Care Expert Working group.
- A brief description of their lived experience or other knowledge or skills that would be of value.
- A description of any experience working on projects, committees or other working groups with other consumers and clinicians (desired by not required).
- Any support requirements for participation in the Best Care Expert Working group.

Applications were reviewed by SCV staff and final membership of the group was endorsed by the Chair.

Removal of gallbladder during bariatric surgery EWG membership

Member	Role	Organisation
Wendy Brown	Chair	
Dr Richard Chen	Bariatric Surgeon	The Alfred Cabrini Health
Dr Damien Loh	Bariatric Surgeon	The Alfred Northern Hospital
Dr Salena Ward	Bariatric Surgeon	St Vincent's Hospital Box Hill Hospital
Dr Douraid Abbas	Bariatric Surgeon	Ballarat Bariatrics
Ass Prof Chrys Hensman	Bariatric Surgeon	Monash University LapSurgery Australia St John of God Berwick Hospital
Louise Becroft	Senior Dietitian	The Alfred
Helen Smolka	Perioperative Coordinator	The Alfred
Jacinta Velt	Bariatric Nurse	Melbourne Gastro Oesophageal Surgery
Betsy Palcic	Consumer	
Priya Sumithran	Endocrinologist	Austin Health University of Melbourne
Darrin Goodall-Wilson	Bariatric Surgeon	St Joh of God
Dr Alexander Craven	Bariatric Surgeon	Austin Hospital
Dr Abhishek Verma	General Practitioner	RACGP
Dr Richard Chen	Bariatric Surgeon	The Alfred Cabrini Health
Dr Damien Loh	Bariatric Surgeon	The Alfred The Northern Hospital

Consumer engagement

A consumer is defined as someone who has a personal experience (as a patient or caregiver) of the selected procedure in a Victorian public hospital in the past ten years. All consumers were offered orientation to SCV and the Best Care Project. They were also reimbursed for their time and travel expenses. To support safe participation, consumers were given access to the Department of Health and Human Services (DHHS) employee

assistance program. Consumers were also offered the opportunity to debrief with SCV staff and the working group chair after every meeting.

Conflict of interest

EWG members were required to declare any conflicts of interest in a formal declaration. No relevant conflicts were identified.

1.3 Methodology to develop the guidance

Production timeline

March 2022 – June 2022

Tier of guidance

The following details the tiers of guidance which SCV may endorse, adapt or develop, in accordance with our evidence-based guidance strategy. The need for Tier 2 guidance was identified during scoping.

Tier	Purpose
Tier 1 – Clinical Practice Guidelines	• Developed when system level, outcome focused recommendations are required – broad relevance. • Absence of existing guidance around what is best practice. • Outcome focused and provided graded recommendations informed by high level evidence.
Tier 2 – Clinical Guides	• Detailing how to translate evidence-based recommendations made in Tier 1 guidelines into practice in Victoria, through system level change. • May support implementation of new policy. • Addressing multistage clinical processes. • Informed by existing high-level evidence and national and international guidance. • Formal GRADE system not used - accompanied by guidance supplement including evidence table. • Incorporates local experiential evidence of clinicians and consumers.
Tier 3 – Pathways, flowcharts, fact sheet	• Developed to provide evidence informed expert advice on single interventions, procedures or processes, relevant to the Victorian setting. • Informed by existing high-quality guidelines and evidence synthesis, expert knowledge and local context.

Decision to endorse, adapt or develop

In line with SCV's evidence-based guidance strategy, and the guiding principles of the Best Care project, a procedures selection process was developed to ensure opportunities to endorse existing guidance were explored. In June 2020 the VPCC provided advice on the indications and recommendations for the 17 procedures considered for inclusion within Tranche 2. These findings formed part of the procedure selection process with clinical experts determining if the literature aligns with the VPCC advice.

A preliminary independent literature review was conducted by SCV, supported by evidence from subspecialists and data derived from VAHI. Following appraisal, no suitable guidance was identified for endorsement or adaptation that was appropriate for the Victorian setting. Consequently, this guidance was developed.

Search method to review the evidence

Search question	PICO question for the procedure removal of gallbladder during bariatric surgery Patient/ Population/ Problem Patients requiring bariatric surgery Intervention Removal of gallbladder Comparison No gallbladder remover Outcome Low value care, value based care, complication, mortality, morbidity, efficacy
Databases searched	• EbscoHost: Academic Search Complete; Pubmed • OVID: MEDLINE; EMBASE • Cochrane • Informit (Australian & NZ databases): Health Collection; Australian Policy Observatory (APO) • VGLS Catalogue • Google Advanced
Keywords used	Bariatric surgery, obesity surgery, obesity, removal of gallbladder, cholecystectomy, cholecystitis symptomatic, gallstones symptomatic, bariatric surgery in isolation, cholecystitis asymptomatic, cholecystectomy, gallstones asymptomatic
Search limits	2010 to 2021 Peer reviewed journals articles and reports
Other search comments	The Victorian Government Library Services assisted with the literature search.

Summary of evidence

There are multiple views on the management of the gallbladder at the time of cholecystectomy, however, more recent publications suggest that concurrent cholecystectomy at the time of bariatric surgery is only justified for those with symptomatic gallstone disease prior to the bariatric procedure.

Despite the inconsistencies in study findings, the quality of evidence is level 1.

Level	Intervention	Diagnostic accuracy	Prognosis	Aetiology	Screening intervention
I	A systematic review of level II studies.	A systematic review of level II studies.	A systematic review of level II studies.	A systematic review of level II studies.	A systematic review of level II studies.
II	A Randomised Control Trial	A study of test accuracy with an independent, blinded, comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation.	A prospective cohort study	A prospective cohort study	A Randomised Control Trial
III-1	A pseudorandomised control trial (i.e. alternate allocation or other method)	A study of test accuracy with an independent, blinded, comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation.	All or none	All or none	A pseudorandomised control trial (i.e. alternate allocation or other method)
III-2	A comparative study with concurrent controls				A comparative study with concurrent controls
III-3	A comparative study without concurrent controls			III-3	Non-randomised experimental trial
IV	Case series with either a pre-test/ post-test outcome.	Study of diagnostic yield (no reference standard)	Case series, or cohort study or persons at different stages of disease.	A cross-sectional study or case series	Cohort study
Consensus	Expert opinions based on respected authorities or reports of expert committees in the absence of higher-level evidence.				
NA	Evidence that cannot be graded such as legislation.				

Evidence search summary

Reference (Vancouver style)	Evidence level (see Appendix)	Key findings outcomes or recommendations
Xia, C. et al. **The Safety and Necessity of Concomitant Cholecystectomy During Bariatric Surgery in Patients with Obesity: a Systematic Review and Meta-analysis.** 2021. Obesity Surgery: The Journal of Metabolic Surgery and Allied Care, Vol. 1	I	**Systematic review and meta-analysis** Compared bariatric surgery only and concomitant cholecystectomy Higher post-op complication rate in concomitant cholecystectomy Following bariatric surgery, gallstone patients had a higher subsequent cholecystectomy rate than those with normal gallbladders Recommendation concomitant cholecystectomy for documented gallstones rather than for normal gall bladder
Leyva-Alvizo, A. et al. **Systematic review of management of gallbladder disease in patients undergoing minimally invasive bariatric surgery.** 2020. Surgery for Obesity and Related Diseases, Vol. 16 (1), 158-164	I	**Systematic review** Reviewed the management of gallbladder disease in patients undergoing bariatric surgery Routine prophylactic cholecystectomy at the time of bariatric surgery is not recommended. In symptomatic patients who are undergoing bariatric surgery, concomitant cholecystectomy is acceptable and safe. Ursodeoxycholic acid may be considered for gallstone formation prophylaxis during the period of rapid weight loss. Routine preoperative screening and postoperative surveillance ultrasound is not recommended in asymptomatic patients.
Tustumi F. et al. **Cholecystectomy in Patients Submitted to Bariatric Procedure: A Systematic Review and Meta-analysis**. 2018. Obesity Surgery: The Journal of Metabolic Surgery and Allied Care, Vol. 28 (10), 3312	I	**Systematic Review and Meta-analysis** Prophylactic cholecystectomy may be avoided. Concomitant cholecystectomy increases the risk for postoperative complications and operative time. If cholecystectomy is not indicated, patients should be carefully followed with attention for biliary complications, once cholecystectomy performed post-bariatric surgery is at higher risk for complications and reoperations.
Elgohary, H **Concomitant versus Delayed Cholecystectomy in Bariatric Surgery.** 2021 Journal of Obesity, Vol. 1-9.	II	RCT. Consideration for delay of cholecystectomy in confirmed gallstone patients by 2 months if there is a high level of difficulty
Şen O and Türkçapar. AG **Risk of Asymptomatic Gallstones Becoming Symptomatic After Laparoscopic Sleeve Gastrectomy**. 2021. The American surgeon, Vol. 31348211011107	III	Retrospective study. Do not recommend cholecystectomy in patients with asymptomatic gallstones during the same session with laparoscopic sleeve gastrectomy.

Reference (Vancouver style)	Evidence level (see Appendix)	Key findings outcomes or recommendations
Kızılkaya MC and Yılmaz. S. **The Fate of the Gallbladder in Patients Admitted to Bariatric Surgery.** 2021 Bariatrik Cerrahiye Kabul Edilen Hastalarda Safra Kesesinin Kaderi., Vol. 59 (1), 80-84	III	Patients do not require routine imaging of the gallbladder before bariatric surgery in asymptomatic patients, and we recommend performing concomitant cholecystectomy only in symptomatic patients.
Coskun, M. et al. **Is Concomitant Cholecystectomy Necessary for Asymptomatic Cholelithiasis During Laparoscopic Sleeve Gastrectomy?** 2018 Obesity Surgery, Vol. 28 (2), 469-473	III	Suggest only observation for asymptomatic gallbladder stones in patients who will undergo sleeve gastrectomy
Tan, T. et al **Clinical analysis of prophylactic cholecystectomy during gastrectomy for gastric cancer patients: a retrospective study of 1753 patients.** 2019. BMC Surgery, Vol. 19 (1)	III	The value of prophylactic cholecystectomy performed during gastric cancer surgery is still being debated. Prophylactic cholecystectomy may be necessary in gastric cancer patients without Billroth I gastrectomy and with diabetes mellitus. Simultaneous cholecystectomy during gastric cancer surgery does not increase the postoperative mortality and morbidity rates.
Y. N. Kim et al. **A comparison of short-term postoperative outcomes including nutritional status between gastrectomy with simultaneous cholecystectomy and gastrectomy only in patients with gastric cancer.** 2019 Chinese journal of cancer research. Vol. 31 (3), 443-452	III	In gastric cancer patients with gallbladder disease, simultaneous cholecystectomy is safe and not associated with additional nutritional loss.
Della Penna, A. et al. **Ursodeoxycholic Acid for 6 Months After Bariatric Surgery Is Impacting Gallstone Associated Morbidity in Patients with Preoperative Asymptomatic Gallstones.** 2019 Obesity Surgery: The Journal of Metabolic Surgery and Allied Care, Vol. 29 (4), 1216	III	UDCA for 6 months after bariatric surgery seems to reduce the incidence of gallstone-associated morbidity when compared to the current literature. Thus, our results call the concept of prophylactic concomitant cholecystectomy in patients with asymptomatic gallstones into question while at the same time paving the way for a future clinical trial.

NHMRC Evidence Statement

1. Evidence base (number of studies, level of evidence and risk of bias in the included studies)

☒ A One or more level I studies with a low risk of bias or several level II studies with a low risk of bias

☐ B One or two Level II studies with a low risk of bias or SR/several Level III studies with a low risk of bias

☐ C One or two Level III studies with a low risk of bias or Level I or II studies with a moderate risk of bias

☐ D Level IV studies or Level I to III studies/SRs with a high risk of bias

2. Consistency (if only one study was available, rank this component as 'not applicable')

☐ A All studies consistent

☒ B Most studies consistent and inconsistency can be explained

☐ C Some inconsistency, reflecting genuine uncertainty around question

☐ D Evidence is inconsistent

☐ NA Not applicable (one study only)

1.4 Reaching consensus

Decision making was made on a consensus basis. If consensus could not be reached, a simple majority was used. The chair was responsible for identifying issues that required resolution outside of scheduled meetings. For an out-of-session resolution to be reached there must be a majority in agreement with the proposed resolution.

SCV working group members were responsible for the guidance creation process and preparing the guidance supplement. They did not have casting votes for the purposes of decisions making in this group.

Consultation

Prior to consultation the following process occurred:

1. EWG approved final draft of guidance.
6. The overarching Best Care advisory group was consulted.
7. SCV Executive Leadership Team endorsed the guidance.
8. An open public consultation on the final draft of the guidance occurred over a four-week period (May 2022). The consultation report is attached to the appendix.
9. A targeted consultation occurred concurrently on the final draft of the guidance over a four-week period (May 2022). The EWG identified appropriate professional peak bodies to be consulted. The full list and report is attached to the appendix.

1.6 Consumer health information

One consumer with lived experience was deeply involved in the development of the consumer information. This contains general information about the removal of gallbladder during bariatric surgery. The advice, exceptions and best care recommendations are discussed. The consumer information will be published on the Better Health Channel website.

1.7 Review

At the time of development, the expert working group suggested that guidance review timelines should be two years, or more frequently if required, to reflect any changes in evidence and best practice. Review will be conducted in accordance with the Evidence-based Guidance Operating Framework.

Section 2 - Supporting health services to implement guidance

2.1 Implementation

The use of improvement science, such as the Model for Improvement, is recommended to support local testing and implementation of the guidance.

Best Care implementation activities and resources included:

- Promotion of guidance to health services, peak professional bodies, surgical societies and consumers groups for feedback and endorsement
- Promotion of the introduction of the guidance to relevant health services, peak professional bodies, surgical societies and consumers groups.

2.2 Dissemination

Communication plan

A detailed Best Care communication plan was approved by SCV communication team for the public and targeted consultation phase of guidance review and the publication of the guidance in June 2022.

Engagement strategy

There are two parts to the engagement strategy. First, the consultation phase and second the publication of the guidance and consumer information. In the consultation phase we engaged with the sector to seek consumers' and multidisciplinary clinicians' feedback for the removal of gallbladder during bariatric surgery.

The surgical procedure guidance has two documents to be reviewed:

1. Clinical guidance
2. Consumer information

Targeted and public consultation recommended on May 9 for a period of four weeks.

Guidance was published on the SCV website on 30 June 2022 with a PDF document of consumer information and link to the Better Health Channel, where the consumer information will be held.

Communication objectives

- To build awareness of Best Care and its aim to provide the Victorian healthcare sector and consumers with high quality, evidence-based clinical guidance on a new group of non-urgent elective procedures.
- To promote Safer Care Victoria as a leading agency in healthcare quality and safety.
- To seek targeted consultation for the two surgical procedure guidance.
- To seek public consultation for the two surgical procedure guidance.
- To promote the publication of the Tranche 2 guidance.

Communication activities

The targeted consultation list can be found in Appendix 3.

Communication activities included:

- Safer Care Victoria health service CEO email
- Department of Health, health service CEO email
- Peak professional bodies, surgical societies, and consumers groups
- Safer Care Victoria e-news
- Safer Care Victoria internal communications
- Social media posts (LinkedIn, Facebook, Twitter)

Key messages

Audience	Key messages
General	• All Victorians should be provided with the best care when they are seeking health care advice about non-urgent elective procedures. Some procedures only offer benefits to patients under very specific circumstances. • Best Care guidance provides healthcare clinicians and consumers with evidence-based alternatives to non-urgent elective surgical procedures, so they can make an informed decision on the most appropriate care. • Safer Care Victoria is expanding the existing series of Best Care guidance to include new and improved guidance on additional procedures.
Health sector • Leaders and advisers (Clinical network leads, VPCC) • Health service CEOs, Directors of Surgery, Directors of Nursing, Directors of Allied Health • Clinicians (surgeons and general practitioners, nursing, allied health) • Professional colleges and associations – RACS and surgical speciality societies/associations, ACORN, Victorian perioperative nursing group	• In February 2021, Best Care published guidance on 26 procedures, which provide evidence-based information for Victorian healthcare professionals in relation to elective surgical procedures which can only be performed under certain circumstances or at certain time intervals. • The guidance enables healthcare clinicians and consumers to discuss whether surgical intervention is clinically appropriate or whether alternative treatments would be more beneficial. • Safer Care Victoria has added to this list of guidance and developed two further clinical guidance for additional elective procedures. • We are seeking input from the health sector to improve the guidance development process and ensure the guidance we produce is useful, relevant and based on the best available evidence.

Audience	Key messages
Health consumers • Health service consumer leads • Health Issues Centre	• All Victorians should be provided with the best care when they are seeking health care advice about non-urgent procedures. Some procedures only offer benefits to patients under very specific circumstances or at specific time intervals. • You should also feel empowered to make informed decisions when discussing a non-urgent procedure with your healthcare professional. • Our Best Care guidance will give you some alternative evidence-based options to discuss with your healthcare professionals, so you can decide together on the care that suits you best. • With the help of consumers with lived experience we have developed two additional guidance on elective procedures, and hope this guidance is relevant and easy to understand.
DHHS/SCV Staff	• We are leading the way in delivering expert clinical guidance to Victorian consumers and the healthcare sector. • Two additional Best Care guidance on elective procedures have been added helping guide joint decision-making between consumers and their healthcare professional so that they can choose the most appropriate care.

2.3 Measuring the impact of our guidance

Evaluation strategy

- How will guidance adoption and impact be measured?
- At the time of review the following will be addressed:

Acceptability	• How many times has the guidance been access in the past 12 months? • How does this compare with what is expected? Who is accessing the guidance? E.g., 1 health service/ region?
Satisfaction	• What is the sectors satisfaction with the guidance? (format, content, accessibility, ability to implement in different settings, usability) • Has the endorsement achieved its aim from the sectors perspective?
Effectiveness	• Have the project aims been achieved? • Consider what outcome measures were identified during project planning and development to endorse the guidance.
Need	• Why was the guidance originally endorsed/ adapted/ developed? • What was the problem the guidance aimed to address? Does this still exist?
Cost effectiveness	• Reflect on the effort and costs versus impact to date

Section 3 – Governance

3.1 Approval

This guidance was approved by the SCV Centres of Clinical Excellence Director 5 July 2022.

3.2 Funding

The funding for the Best Care project (tranche 2) was $350,000 derived from the Better Care Victoria fund.

References

1. Adopt, adapt or start from scratch [internet]. Canberra: National Health and Medical research Council; 2018 Nov 22 [cited 2021 July 20]. Available from: https://www.nhmrc.gov.au/guidelinesforguidelines/plan/adopt-adapt-or-start-scratch
2. AGREE Advancing the science of practice guidelines [Internet]. Ontario: The SGREE Research trust; c2014 [cited 2021 Aug 18]. Available from: https://www.agreetrust.org/copyright/

Appendix 1 – NHMRC Body of Evidence Matrix

To assist guideline developers, the NHMRC have developed an approach for assessing the body of evidence and formulating recommendations. This will ensure that while guidelines may differ in their purpose and formulation, their developmental processes are consistent, and their recommendations are formulated in a consistent manner.

The NHMRC sets out the basis for rating five key components of the 'body of evidence' for each recommendation. These components are:

1. The evidence base, in terms of the number of studies, level of evidence and quality of studies (risk of bias).
2. The consistency of the study results.
3. The potential clinical impact of the proposed recommendation.
4. The generalisability of the body of evidence to the target population for the guideline.
5. The applicability of the body of evidence to the Australian healthcare context.

Table 1 Body of evidence matrix

Component	A	B	C	D
	Excellent	Good	Satisfactory	Poor
Evidence base[1]	one or more level I studies with a low risk of bias or several level II studies with a low risk of bias	one or two level II studies with a low risk of bias or a SR/several level III studies with a low risk of bias	one or two level III studies with a low risk of bias, or level I or II studies with a moderate risk of bias	level IV studies, or level I to III studies/SRs with a high risk of bias
Consistency[2]	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	evidence is inconsistent
Clinical impact	very large	substantial	moderate	slight or restricted
Generalisability	population/s studied in body of evidence are the same as the target population for the guideline	population/s studied in the body of evidence are similar to the target population for the guideline	population/s studied in body of evidence differ to target population for guideline but it is clinically sensible to apply this evidence to target population[3]	population/s studied in body of evidence differ to target population and hard to judge whether it is sensible to generalise to target population
Applicability	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

SR = systematic review; several = more than two studies

[1] Level of evidence determined from the NHMRC evidence hierarchy – Table 3, Part B

[2] If there is only one study, rank this component as 'not applicable'.

[3] For example, results in adults that are clinically sensible to apply to children OR psychosocial outcomes for one cancer that may be applicable to patients with another cancer

Appendix 2 – Public and target consultation report

Purpose

The purpose of this document is to detail feedback received during the public and targeted consultation phase of guidance review.

How we engaged

In the consultation phase we engaged with the sector to seek consumers and multidisciplinary clinicians' feedback for the removal of gallbladder during bariatric surgery.

The surgical procedure guidance has two documents to be reviewed:

1. Clinical guidance
2. Consumer information

Targeted and public consultation commended on 9 May for a period of four weeks.

Objectives of the consultation:

- To build awareness of Best Care and its aim to provide the Victorian healthcare sector and consumers with high quality, evidence-based clinical guidance on a new group of non-urgent elective procedures.
- To promote Safer Care Victoria as a leading agency in healthcare quality and safety
- To seek targeted consultation for the two surgical procedure guidance
- To seek public consultation for the two surgical procedure guidance
- To promote the publication of the Tranche 2 guidance

Who provided feedback

The targeted consultation list can be found in Appendix 3.

Communication activities included public communications to:

- Safer Care Victoria health service CEO email
- Department of Health health service CEO email
- Peak professional bodies, surgical societies and consumers groups
- Safer Care Victoria e-news
- Safer Care Victoria internal communications
- Social media posts (LinkedIn, Facebook, Twitter)

Appendix 3 – Targeted consultation contact list

The following organisations were approached for feedback, and support promoting the guidance through their networks:

- North Western Melbourne Primary Health Network
- Australian & New Zealand Metabolic and Obesity Surgery Society
- Royal Australasian College of Surgeons
- The Australian and Aotearoa New Zealand Gastric and Oesophageal Surgery Association
- Weight Issues Network
- Obesity Action Coalition
- General Surgeons Australia

Guidelines developed by Safer Care Victoria are reviewed every two years or earlier if new evidence emerges.

Table 1. Provides a summary of changes made to the guidelines since original publication.

Publication date	Approved by	Summary of major changes