

Postoperative radiotherapy after radical prostatectomy – evidence-based guidance supplement

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Section 1.0 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.

2. 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](#).

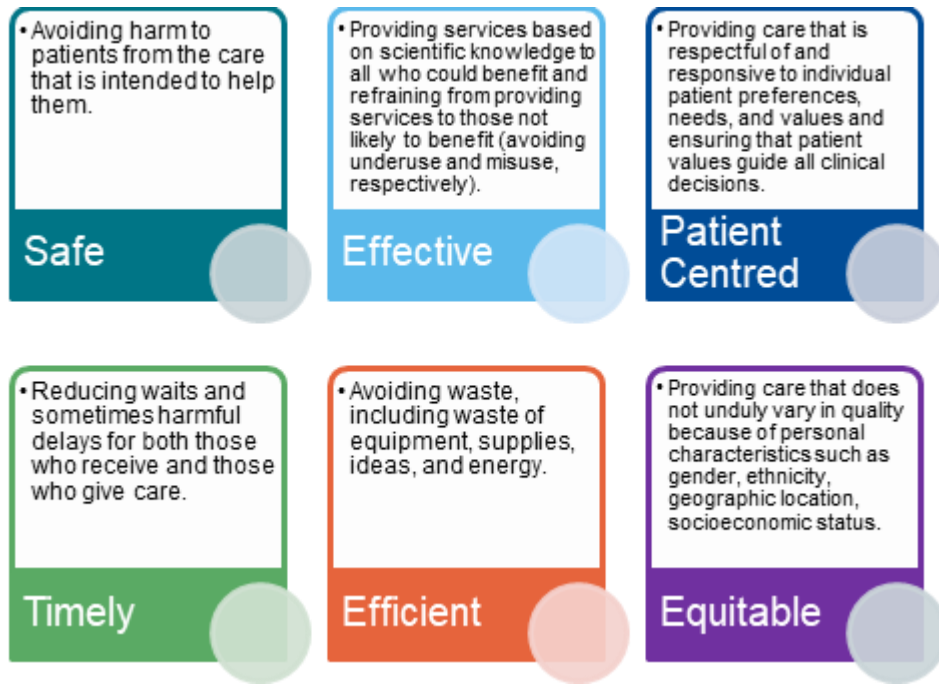
3. In accordance with SCV's Evidence Based Guidance Operating Framework Tier 2 processes have been followed.

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.

Fig 1. The six domains of healthcare quality

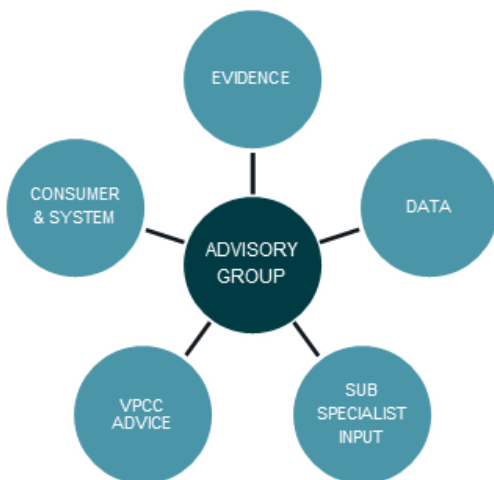


Tranche 2 procedures, 6 inputs to the procedure selection process:

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

1. EVIDENCE – preliminary independent literature review, coupled with evidence from subspecialty input
4. DATA – aggregate data derived from VAHI analysis
3. SUBSPECIALTY INPUT – advice on best practice and underlying evidence
4. VPCC ADVICE – dating from initial selection of 17 Tranche 2 procedures
5. CONSUMER-CENTRED AND SYSTEM LEVEL CONSIDERATIONS
6. BEST CARE ADVISORY GROUP CONSENSUS

Fig 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

1.1 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:

1. There are specific indications for when the procedure is likely to be most beneficial
2. 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).

1.2 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 EWG 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)

VPCC advice

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 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:

1. What are the common referral sources for this procedure?
2. 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)
3. Do alternative pathways exist for this procedure?
4. Is there inequity of access or lack of access to alternative pathways?
5. 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. The guidance aims to:

- Inform clinicians 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

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.

Table 1: Scope of the clinical guidance

Population	5. 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 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, or 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.

Table 2: Postoperative radiotherapy after radical prostatectomy EWG membership

Member	Role	Organisation
Conrad Bishop	Urologist/Oncologist	Epworth
Melissa Caruso	Prostate Cancer Nurse Specialist	Eastern Health
Stephen Chin	Radiation Oncologist	Austin Health
Ken Freestone	Consumer	Consumer with lived experience
Amelia Johnston	Acute Manager	SCV
Aaron Kent	Radiation Oncologist	Alfred Health
Robyn Lindsay	Chief Executive Officer	Echuca Health Services
Jeremy Miller	Radiation Oncologist	Alfred Health
Declan Murphy	Urologist/Oncologist	Peter MacCallum Cancer Centre
Wee Loon Ong	Radiation Oncologist	Alfred Health
Glen Osborne	Radiation therapist	Peter MacCallum Cancer Centre
Max Shub	Consumer	Consumer with lived experience
Jonathan Tomaszewski	Radiation Oncologist	Ballarat/Austin
Raymond Wen	GP	PHN Rep/GP

Emma McKeown	Senior Project Officer, Clinical Fellow	SCV
Monique Parker	Senior Project Officer	SCV

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 PRODUCE THE GUIDANCE

Production timeline

Jan 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	<ul style="list-style-type: none"> Developed when system level, outcome focused recommendations are required – broad relevance Absence of existing guidance around what is best practice. Outcome focused and provide graded recommendations informed by high level evidence
Tier 2 – Clinical Guides	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 post-operative radiotherapy after radical prostatectomy Patient/ Population/ Problem Prostate cancer, radical prostatectomy Intervention Radiotherapy post operatively, early salvage radiation Comparison No radiotherapy, PSA undetectable, adjuvant radiation Outcome Low value care , value based care , complication, mortality, morbidity ,efficacy
Data base/s searched	<ul style="list-style-type: none"> • 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	Post-operative radiotherapy, Adjuvant radiotherapy, early salvage radiotherapy, radical prostatectomy, low value care, value-based care
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

The use of adjuvant radiotherapy to the prostate bed after radical prostatectomy had been shown to halve the risk of biochemical progression when compared with observation for men with prostate cancer with high-risk features. Results of three randomised trials initiated between 1988 and 1996 supported the use of adjuvant radiotherapy (ARO 96-02/AUO AP 09/95; EORTC trial 2291; SWOG8794), with one of these studies also showing improved metastasis-free survival and overall survival. Despite this evidence, adjuvant radiotherapy has not been widely adopted due to concerns over perceived toxicity. A potential limitation of these three randomised trials is that there was no standard management for patients on observation who developed relapse. Salvage radiotherapy was given intermittently and at varying lengths of time after relapse, with some patients having documented locoregional progression before treatment. The results of the three studies were used to generate American and European guidelines, which recommend that such men be referred for consideration of adjuvant radiotherapy. This recommendation to routinely administer adjuvant radiotherapy comes at the potential cost of increased morbidity. A very recent local multi-centred RCT (RAVES trial) shows that observing these patients and delivering salvage radiation when PSA first starts to rise has similar efficacy. This spares approx. 50% of men from pelvic radiation and is associated with significantly lower genitourinary toxicity.

Two other international RCTs the RADICALS and GETUG-17 trials also have concordant results suggesting that adjuvant radiotherapy does not improve event-free survival in men with high-risk features following radical prostatectomy. It now appears preferable to wait until the cancer recurs, heralded by a PSA rising to 0.20 ng/mL, before commencing radiotherapy, which would spare many men from potential radiotherapy-related

side-effects. A meta-analysis of all three trials (ARTISTIC) concluded adjuvant radiotherapy does not improve event-free survival in men with localised or locally advanced prostate cancer. Until data on long-term outcomes are available, early salvage treatment would seem the preferable treatment policy as it offers the opportunity to spare many men radiotherapy and its associated side-effects.

The following levels of evidence has been used, based upon the National Health and Medical Research Council's (NHMRC) 2009 levels of evidence and grades for recommendations for developers of guidelines.³ Note that consensus and NA have been added to reflect the importance of consensus statements from respected authorities.

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 Non-randomised experimental trial Cohort study Case control study Interrupted time series with a control group	A comparison with reference standard that does not meet the criteria for level II and level III-1 evidence.	Analysis of prognostic factors amongst persons in a single arm of a randomised control trial.	A retrospective cohort study	A comparative study with concurrent controls Non-randomised experimental trial Cohort study Case control study
III-3	A comparative study without concurrent controls Historical control study Two or more single arm study Interrupted time series without a parallel control group	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls Historical control study Two or more single arm study
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	Case series
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.
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Evidence Search Summary

Reference (Vancouver style)	Evidence level (see Appendix)	Key findings outcomes or recommendations
ARTISTIC Vale, Claire L et al. Adjuvant or early salvage radiotherapy for the treatment of localised and locally advanced prostate cancer: a prospectively planned systematic review and meta-analysis of aggregate data. 2020. <i>The Lancet</i> , Volume 396, Issue 10260, 1422 – 1431	I	3 RCTs, 2153 patients. Eligible if compared immediate adjuvant radiotherapy versus early salvage radiotherapy, following radical prostatectomy in men (age ≥18 years) with intermediate-risk or high-risk, localised or locally advanced prostate cancer. Conclusion: Adjuvant radiotherapy does not improve event-free survival in men with localised or locally advanced prostate cancer. Until data on long-term outcomes are available, early salvage treatment would seem the preferable treatment policy as it offers the opportunity to spare many men radiotherapy and its associated side-effects.
Daly, Tiffany et al. Adjuvant radiotherapy following radical prostatectomy for prostate cancer. 2011. Cochrane Database of Systematic Reviews.	I	Adjuvant RT after RP improves overall survival and reduces the rate of distant metastases, but these effects are only evident with longer follow up. At 5 and 10 years it improves local control and reduces the risk of biochemical failure, although the latter is not a clinical endpoint. Moderate or severe acute and late toxicity is minimal. There is an increased risk of urinary stricture and incontinence, but no detriment to quality of life, based on limited data. Given that the majority of men who have undergone a RP have a longer life expectancy, radiotherapy should be considered for those with high-risk features following radical prostatectomy. The optimal timing is unclear.
RCT RAVES TRIAL Kneebone, Fraser-Browne et al. Adjuvant radiotherapy versus early salvage radiotherapy following radical prostatectomy (TROG 08.03/ANZUP RAVES): a randomised, controlled, phase 3, non-inferiority trial. 2020. <i>The Lancet Oncology.</i> , 21(10), 1331–1340.	II	Multicentre RCT Salvage radiotherapy yields similar results to adjuvant radiotherapy following radical prostatectomy. This spares approx... 50% of men from pelvic radiation and is associated with significantly lower genitourinary toxicity.
RADICALS TRIAL Parker CC et al. Timing of radiotherapy after radical prostatectomy (RADICALS RT): a randomised, controlled phase 3 trial. 2020. <i>Lancet</i> .	II	Multi-centre (International) RCT 1396 patients. Two arms salvage radiotherapy and adjuvant radiotherapy. Results showed routine administration of adjuvant radiotherapy after radical prostatectomy is not supported. Adjuvant radiotherapy increases the risk of urinary morbidity. An observation policy with salvage radiotherapy for PSA biochemical progression should be the current standard after radical prostatectomy.
GETUG-17 TRIAL Sargos Pet et al. Adjuvant radiotherapy versus early salvage radiotherapy plus short-term androgen deprivation therapy in men with localised prostate cancer after radical prostatectomy (GETUG-AFU 17): a randomised, phase 3 trial. 2020. <i>Lancet Oncol</i> 2020; 21: 1341–52	II	Multi-centre (national-France) RCT-424 patients, 2 arms immediate adjuvant radiotherapy or delayed salvage radiotherapy at the time of biochemical relapse. All patients received short-term hormonal therapy. Findings lacked statistical power, however found no benefit for event -free survival in patients assigned to adjuvant radiotherapy compared with patients assigned to salvage radiotherapy. Adjuvant radiotherapy increased the risk of genitourinary toxicity and erectile dysfunction. A policy of early salvage radiotherapy could spare men from overtreatment with radiotherapy and the associated adverse events.
SWOG (RCT-1987) TRIAL Thompson IM, Jr, Tangen CM, Paradelo J, et al. Adjuvant	II	RCT (National-US) multi-centre trial, 425 patients. 2 arms: usual care and observation, or adjuvant radiotherapy.

radiotherapy for pathologically advanced prostate cancer: a randomized clinical trial. 2006. <i>JAMA</i> .296:2329-35.		Overall survival significantly improved with adjuvant radiotherapy
EORTC (RCT) Bolla, Michel et al. Postoperative radiotherapy after radical prostatectomy for high-risk prostate cancer: long-term results of a randomised controlled trial (EORTC trial 22911) 2012. <i>The Lancet</i> , Volume 380, Issue 9858.	II	International (Europe) multi-centre RCT, 1005 patients. Two arms: adjuvant therapy or Observation until biochemical progression. Adjuvant radiotherapy improved progression but 10 year follow-up progression was not maintained and there was no effect on distant metastases or overall survival
ARO (RCT) Wiegel T, et al. Phase III postoperative adjuvant radiotherapy after radical prostatectomy compared with radical prostatectomy alone in pT3 prostate cancer with postoperative undetectable prostate-specific antigen: ARO 96-02/AUO AP 09/95. 2009. <i>J Clin Oncol</i> . 2009 Jun 20;27(18):2924-30.	II	Two arms: Radical prostatectomy alone or Radical Prostatectomy and adjuvant radiation with those with detectable PSA. Adjuvant RT for prostate cancer with postoperatively undetectable PSA significantly reduces the risk of biochemical progression. Further follow-up is needed to assess the effect on metastases-free and overall survival.
Mizuno, T. et al. Impact of Early Salvage Radiotherapy in Patients with Biochemical Recurrence after Radical Prostatectomy: Results of a Multi-institutional Retrospective Study. 2019 <i>International Journal of Radiation Oncology, Biology, Physics</i> , Volume 105, Issue 1, E295 – E296	III	402 patients. Multi-centred. Early salvage radiotherapy is beneficial only for selected high-risk subgroups of patients affected by biochemical recurrence.

NHMRC Evidence Statement

1. Evidence base (number of studies, level of evidence and risk of bias in the included studies)		
	<input checked="" type="checkbox"/> A	One or more level I studies with a low risk of bias or several level II studies with a low risk of bias
	<input type="checkbox"/> 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
	<input type="checkbox"/> 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
	<input type="checkbox"/> 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')		
	<input type="checkbox"/> A	All studies consistent
	<input checked="" type="checkbox"/> B	Most studies consistent and inconsistency can be explained
	<input type="checkbox"/> C	Some inconsistency, reflecting genuine uncertainty around question
	<input type="checkbox"/> D	Evidence is inconsistent
	<input type="checkbox"/> 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.

1.5 CONSULTATION

Prior to consultation the following process occurred:

- EWG approved final draft of guidance
- The overarching Best Care advisory group were consulted
- SCV Executive Leadership Team endorsed the guidance.
- Public consultation – An open public consultation on the final draft of the guidance occurred over a 4 week period (May 2022). The consultation report is attached to the appendix.
- A targeted consultation occurred concurrently on the final draft of the guidance over a 4 week period (May 2022). The EWG identified appropriate professional peak bodies to be consulted. The full list and report is attached to the appendix.

Endorsement

- Endorsement from key stakeholders included:
 - Urological Society Australia and New Zealand (USANZ)
 - Royal Australian and New Zealand College of Radiologists (RANZCR)
 - Australian and NZ urological Nurses society (ANZUNS)

1.6 CONSUMER INFORMATION

Two consumers with lived experience were deeply involved in the development of the consumer information. This information contains general information about prostate cancer and radiation treatments following a radical prostatectomy. The advice, exceptions and best care recommendations are discussed along with support groups and useful resource available.

This information will be published on the SCV and Better Health Channel websites.

1.7 REVIEW

At the time of development, the EWG 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 2.0 Supporting health services to implement guidance

2.1 IMPLEMENTATION

The use of improvement science, such as the [Model for Improvement](#) is recommend 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. The purpose of this document is to detail the communication plan 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 communication strategy. First, the consultation phase and secondly 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 commenced on April 26th for a period of 4 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 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)

Key messages

Audience	Key messages
<p>General</p>	<p>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,</p> <p>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.</p> <p>Safer Care Victoria is expanding the existing series of Best Care guidance to include new and improved guidance on additional procedures.</p>
<p>Health sector</p> <ul style="list-style-type: none"> • Leaders and advisers (Clinical network leads, VPCC) • Health service CEO's, 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 	<p>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.</p> <p>The guidance enables healthcare clinicians and consumers to discuss whether surgical intervention is clinically appropriate or whether alternative treatments would be more beneficial.</p> <p>Safer Care Victoria has added to this list of guidance and developed two further clinical guidance for additional elective procedures.</p> <p>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.</p>
<p>Health consumers</p> <ul style="list-style-type: none"> • Health service consumer leads • Health Issues Centre 	<p>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.</p> <p>You should also feel empowered to make informed decisions when discussing a non-urgent procedure with your healthcare professional.</p> <p>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.</p>

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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• What is the sectors satisfaction with the guidance? (format, content, accessibility, ability to implement in different settings, usability)• Has the endorsement achieved it's aim from the sectors perspective?
Effectiveness	<ul style="list-style-type: none">• Have the project aims been achieved?• Consider what outcome measures were identified during project planning and development to endorse the guidance.
Need	<ul style="list-style-type: none">• Why was the guidance originally endorsed/ adapted/ developed?• What was the problem the guidance aimed to address? Does this still exist?
Cost effectiveness	<ul style="list-style-type: none">• 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 in XXX 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 base¹	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
Consistency²	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.

- Clinical guidance
- Consumer information

Targeted and public consultation commenced on May 9th for a period of 4 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)

WHAT YOU TOLD US

Feedback: Clinical Guidance	<ul style="list-style-type: none"> • Consider more emphasis on patients who are not suitable for salvage radiation due to the risk of metastatic disease. • Emphasise potential complications following salvage radiation. • Messaging around the threshold PSA figure of 0.2 as a trigger for delayed salvage RT is confused
Feedback: Consumer Information	<ul style="list-style-type: none"> • Include nurse in discussion of side effects. • Add Continence Foundation of Australia to Further Help and Support section

Appendix 3 – targeted consultation contact list

The following organisations were approached for feedback, and to promote the guidance through their networks:

- Prostate Cancer Foundation
- Health Information Centre
- Australian and NZ urological nurses society
- Urological society of Australia and New Zealand
- Royal Australian and New Zealand College of Radiologists
- North Western Melbourne Primary Health Network

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