RADIATION ONCOLOGY—GUIDELINES

Guidelines for safe practice of stereotactic body (ablative) radiation therapy: RANZCR 2023 update

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Introduction

Purpose and scope

The aim of this guideline is to provide an educational resource for radiation therapy service providers to ensure appropriate care of patients receiving stereotactic ablative radiation therapy (SABR)/stereotactic body radiation therapy (SBRT). As the practice of SABR continues to evolve and advance with new technologies, techniques and clinical evidence, a revision to this guideline was necessary to build upon the principles of the initial publication in 2015.[1] The principles applied within this document refer to the delivery of SABR to extra-cranial sites for malignant conditions. These guidelines are not meant to be a set of inflexible rules, or to be used for litigious purposes. They do not replace the clinical judgement or decisions made by the treating team. The definitions used in these guidelines may be broader than the descriptors published by Medicare/Medicare Benefits Scheme. The definitions used in these guidelines may not be consistent with these descriptors.

A Radiation Oncology Alliance Working Group was established with representation from the Faculty of Radiation Oncology (FRO) of the Royal Australian and New Zealand College of Radiologists (RANZCR), Australian Society of Medical Imaging and Radiation Therapy (ASMIRT), Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) and the Cancer Nurses Society of Australia (CNSA). Given the complex geography and provision of radiation therapy services in Australia and New Zealand these guidelines provide a framework with key recommendations from the Radiation Oncology Alliance Working Group for service providers. Feedback has been sought from the memberships of the RANZCR FRO, ASMIRT, ACPSEM and the CNSA.

Guidance has been outlined in two clear sections. The first deals with provision of services on a departmental level covering aspects of departmental staffing, equipment for patient simulation, contrast administration, planning, peer review, treatment and quality assurance (QA) measures. The second deals with services on an organisation level covering aspects of credentialing, trials, protocols and data collection, research, education and the establishment of networks.

Definitions

In this guideline document:

SABR means stereotactic ablative radiation therapy.

SBRT means stereotactic body radiation therapy.

College means The Royal Australian and New Zealand College of Radiologists.

Member means a member of the College.

For the purposes of this document *SABR* and *SBRT* are interchangeable and defined (as compared with conventional radiation therapy) by the following:

- High-precision, image-guided dose delivery to well-defined target/s
- Highly conformal dose with steep dose gradients
- Larger doses per fraction (typically ≥5 Gy per fraction)
- Fewer treatment fractions (typically ≤8 fractions)
- Intra-fraction motion management where applicable.

Introduction

SABR refers to an external beam radiation therapy treatment that delivers a high biological dose of radiation therapy with high geometric precision to an extra-cranial target. As this is done with only one or few fractions and involves steep dose gradients, specialised planning and treatment delivery techniques are needed, with associated specific QA requirements.

The uptake of this treatment technique worldwide has been rapid,[2] particularly for lung,[3] spine[4] and liver treatments.[5] In Australia and New Zealand, SABR is available in all states, major cities and some rural centres.

Although there is no universal consensus on the definition of what constitutes SABR, published guidelines from international bodies including the American Society of Therapeutic Radiation Oncology (ASTRO),[6,7] the SABR UK Consortium[8] and the Canadian Society of Radiation Oncology (CARO),[9] commonly describe high doses per fraction, small number of fractions and the requirement of specialised planning, treatment delivery and QA when defining this treatment.

The practice of SABR is evolving and indications are expanding as developments in clinical evidence, technologies and techniques emerge. Randomised studies of SABR compared to conventional radiation therapy have shown improved local control and overall survival benefit in early stage lung cancer,[10] and improved complete pain response in spinal metastases with SABR.[11] In the oligometastatic setting, phase 2 randomised data have shown improved overall survival with the addition of SABR to standard of care therapy.[12] Indications for SABR has also expanded to include non-malignant conditions such as for cardiac arrhythmias,[13] which are beyond the focus and scope of these guidelines.

As the biological radiation therapy dose, the dose per fraction, and the requirements of treatment precision and accuracy for SABR are more demanding than conventionally fractionated radiation therapy, specific guidelines are required to ensure safe practice.

Key to delivering these treatments safely and accurately is strict SABR procedures and protocols administered by a coordinated team between Radiation Oncologists (RO), Radiation Oncology Medical Physicists (ROMP), Radiation Therapists (RT) and Radiation Oncology Nurses (RON).

This document is intended to serve as a guideline to ensure best practice in the establishment of SABR programs and the planning and delivery of these treatments. This revised guideline builds upon the principles

established in the initial publication in 2015. Comprehensive departmental protocols should be used for each clinical site and this document should be used in conjunction with these protocols.

Departmental considerations for delivery of SABR treatments

Departmental staffing and responsibilities

Departmental – general staffing

It is recognised that SABR is a technically complex treatment delivery technique, and adequate multidisciplinary expertise is necessary for delivery of safe treatment. Members of all four disciplines (RO, RT, ROMP, RON) are required for the adequate delivery of SABR. Each discipline has both distinct and overlapping roles in the treatment planning process, treatment QA, and treatment delivery. It is recommended that ongoing training and maintenance of technical skills of the relevant stakeholders should comprise a core component of an institution's SABR program. A clearly communicated and documented staff reporting structure within the department is also recommended to allow clinical concerns to be raised in the process of providing a SABR service. Ultimately, the department has the responsibility of ensuring the safe practice and delivery of SABR and that associated care is provided to patients receiving this treatment.

Best practice guidance for this treatment technique is to be carried out in an organised program with demonstrated expertise or external support providing expertise. 'One-off' treatments by radiation multidisciplinary teams who do not specialise in the area should not be undertaken. International bodies have recommended that minimum SABR procedures ranging from 10 to 25 per year should be met to maintain expertise in the delivery of this technique.[8,14,15] Increased institutional experience has been identified as a factor associated with improved clinical outcomes.[16] The establishment of networks between departments is recommended to maximise consistency in clinical outcomes and has been described on a national level.[17]

Participation in an external, independent review process of the SABR service is highly encouraged. This can be acquired through participation in multi-institutional clinical trials and their associated QA procedures, and/or undertaking review by external auditing providers such as the Australian Clinical Dosimetry Service and International Stereotactic Radiosurgery Society. Staffing levels and staffing workloads should enable these activities.

Departmental – Staffing for treatment delivery

Adequate staffing is essential for complex treatment delivery, and a high level of oversight is required for SABR.

When introducing SABR into clinical practice or a new technique in an established service, it is recommended that RO and ROMP are also present (or readily contactable) at the patient's first SABR treatment to help facilitate safe and accurate treatment by providing expertise and support if required and to directly manage any clinical issues and/or treatment-related toxicities.

The roles and responsibilities of the treating team can be reviewed once a service has been established, an appropriate number of patients have been treated and staff training/competency assessment has been implemented. Once these are attained and as clinical skills and expertise are developed by the clinical professionals, it may be appropriate to reduce the requirement of physical presence of RO and/or ROMP during treatment but have them immediately available to attend or readily contactable when required.

Staff roles and responsibilities

Radiation Oncologists (RO). Treating RO are expected to have oversight on the overall treatment regimen in terms of treatment simulation, planning and delivery. RO are responsible for:

- Ensuring communication between and providing leadership for the treating team.
- Appropriate patient selection, participation in multidisciplinary decision making and peer review.
- Risk assessment of patients.
- Prescription of dose and fractionation of the treatment regimen, and defining dose and volumetric limits to normal tissues.
- Oversight of the simulation technique and immobilisation procedures.
- Supervision of the administration of intravenous contrast or the appropriate delegation to a suitably qualified health practitioner.
- Verifying image fusion, defining the target volumes and defining the critical organs at risk.
- Decision making regarding image-guidance and motion management strategies.
- Decision making regarding suitability of proceeding with treatment.
- General oversight of all QA processes.
- Conducting clinical audits of patient outcomes.

For RO, specific training in SABR prior to performing any stereotactic procedures is required.[7,8,15,18] This training should be assessed during the credentialing process determined by the service provider at the organisational level. (See Section 'Credentialing of Expertise') RO undertaking SABR should demonstrate expertise is maintained, (See Section 'Maintenance of Expertise') and commitment to conducting clinical audits of patient outcomes aimed at improving patient care.

Radiation Therapists (RT). RT must maintain constant communication with RO and ROMP throughout the following procedures, for which they are responsible.

- Pre-simulation consultation and assessment of patient to elicit information from the patient regarding anxiety levels, current pain status, analgesic use and other fears or concerns the patient may have and escalate to the Radiation Oncologist if appropriate.
- Positioning and immobilisation.
- Evaluation, recommendation and implementation of motion management strategies.
- Acquisition and registration of images.
- Cannulate and administer intravenous contrast following appropriate training.
- Construction and evaluation of plan dosimetry.
- Participation, consultation in and documentation of plan QA in conjunction with ROMP.
- Perform image guidance procedures.
- Assist or lead decision making based on imaging as per department protocol and skill level.
- Treatment delivery.
- Training and credentialing of RT aligned with competency based assessments.
- Contribution to regular and ongoing protocol development and enhancement.
- Provide education and support for the patient and significant others throughout the treatment phase.

While the involvement of RT in the SABR process is not limited to individual independent practitioners, specialised RT roles may be appropriate within suitably large departments treating a high volume of SABR. Oversight of RT within the multi-disciplinary team and management of aspects of the SABR program using clinical leadership, evidence-based judgement and clinical expertise may align with ASMIRT dimensions for extended scope of practice. Institutions treating multiple sites with SABR and significant patient loads may consider specialist RT for each site if practical.

SABR treatment should be performed by a minimum of two RT trained in stereotactic treatment and that meet a specified competence level.

Specific training for RT may be undertaken at a dedicated teaching course and/or in-house training with mentoring by other members of the multi-disciplinary team who have established specialist knowledge and expertise in SABR.

Radiation Oncology Medical Physicists (ROMP). - Certified ROMP, as defined by the ACPSEM, must be involved in supporting the SABR program and should have specific training in SABR. In establishing and supporting a SABR program, additional physics resources (personnel, hardware and software) will be required for development, implementation and ongoing management of quality and safety of treatments.

ROMP are responsible for:

- Technical aspects of the development of SABR techniques and departmental implementation.
- QA and safety of the entire SABR treatment process (imaging, treatment planning and delivery).
- Involvement in the consultation process and discussion throughout the entire SABR procedure.
- Acceptance testing, commissioning and QA of all equipment and software, as well as end-to-end tests to meet SABR specific requirements,[19] including but not limited to
  - Multimodality imaging volume definitions and treatment planning.
  - Imaging for patient positioning and treatment verification.
  - Immobilisation equipment.
  - Dose calculation and optimisation algorithms used by the treatment planning system.
  - The treatment delivery system.
  - Small field dosimetry.
- Develop and manage an appropriate patient specific QA program.
- Undertake available external audits such as that provided by the Australian Clinical Dosimetry Service.
- SABR technical QA program.
- Accuracy and deliverability of the treatment plan.
- Demonstrated participation in continued professional development by the certified ROMP (ACPSEM CPD System) is mandatory.

Joint RO/RT/ROMP Responsibilities. It is recognised that SABR requires strong multi-disciplinary collaboration therefore the following are joint and inter-linked responsibilities of RO/RT/ROMP involved in the program.

- Development of a clearly documented comprehensive, multidisciplinary risk assessment of the clinical implementation of SABR at the service to form the basis for the development of the QA program and patient pathway.
- Effective immobilisation and motion management.
- Appropriate imaging for treatment planning and image-guided treatment delivery.
- Treatment plan QA (dosimetry, accuracy and deliverability).
- Contribution to an incident learning system.
- Training and mentoring of staff.
- Participation in SABR research and clinical trial activities.
- Attendance and contribution to regular multi-disciplinary SABR QA rounds.
- Review of the SABR service implementations at predetermined time frames to ensure responsibilities are met.

Radiation Oncology Nurses (RON). RON involved in the care of the patient receiving SABR should have a sufficiently thorough knowledge of the planning and delivery techniques used and the associated treatment side-effects that can be expected, in order to provide accurate and comprehensive care.

RON are involved in but are not limited to:

- Assessment of patients prior to planning to provide education and support, to elicit information from the patient regarding anxiety levels, current pain status, analgesic use and other fears or concerns the patient may have and escalate to the Radiation Oncologist if appropriate.
- Administration of medications (e.g. for anxiety, analgesia) prior to simulation and during treatment. Suitably qualified RON may also cannulate and administer IV contrast for planning purposes and provide care for the patient following contrast administration depending on departmental protocol.
- Provide education and support for the patient and significant others throughout the treatment phase. RON are involved in providing support to patients and are positioned to escalate patient issues to the Radiation Oncologist/Radiation Therapist.
- Provide follow-up in the short-term post completion of treatment to assess management of patients' acute side effects and to identify issues that require management in consultation with the Radiation Oncologist.

Departmental procedures and equipment

Procedures prior to radiation therapy planning

Given the highly conformal nature of these treatments it is imperative that a patient being considered for SABR has the most appropriate imaging to enable accuracy in target delineation. This may include but is not limited to high-resolution magnetic resonance imaging (MRI) or CT scans and/or CT/positron emission tomography (PET). If specific imaging sequences are required, the imaging team should be instructed directly. If fiducial marker implantation is part of the department's motion management procedure or to act as a surrogate marker for image matching, they should be implanted into or near the target prior to simulation either by an interventional radiologist or in the case of lung, gastrointestinal or genitourinary tumours, an interventional endoscopist. Placement location of fiducial markers should be chosen following consultation with the multidisciplinary team. Given the various types of fiducial markers available for use it is important that there is appropriate engagement of specialists to provide this service. Any anatomical/functional imaging should be performed at a similar time to radiation therapy planning with the patient immobilised in the simulation/treatment position if possible.

Given the longer simulation and treatment times that may be involved with SABR, patient symptoms and co-morbidities should warrant particular consideration prior to planning. Any pain or discomfort should be managed with analgesia and/or corticosteroids prior to simulation and consideration given to methods of relaxation or anxiolytics in patients who find maintaining the required planning/treatment position difficult and/or experience anxiety. If tumour and organ motion are thought to be a significant factor then consideration should also be given to the type of immobilisation to be used, to the patient's respiratory stability and whether this is likely to deteriorate during the planning and treatment process. The use of anxiolytics to assist motion management should be prescribed consistently before planning/treatment to maximise the beneficial effect.[20]

As the planning procedures for SABR are different to other forms of radiation therapy treatment it is recommended that patients have access to specific written and/or multi-media delivered information regarding the nature of the treatment. A pre-planning checklist may be useful on the day at the time of simulation to ensure these key issues are addressed prior to commencing the patient positioning.

Simulation procedures

Patient stability for stereotactic planning and treatment is paramount. It is recommended that the entire length of the patient be supported comfortably and effectively and that indexed equipment is used.

Due to the possible extended treatment times patient comfort is most important. Therefore, in some circumstances arm positioning and support needs to be considered with reference to potential beam or arc placement.

Stabilisation and immobilisation options should be considered at the time of simulation and will vary depending on the site of the treatment (neck, thorax, abdomen or pelvis). Customised supports such as vacuum bags should be available and are recommended in the treatment of all thoracic and abdominal targets including spine SABR.[21–23] Other specialised immobilisation systems may also be considered including but are not limited to evacuated drapes and abdominal compression. Commercially available 'standard' head and neck, knee and foot supports may also be used in conjunction with vacuum bags.

Due to the generally smaller targets with SABR techniques, CT planning slice thickness of ≤2 mm through the tumour site is recommended.[22] Particularly for lung and upper abdominal SABR, tumour motion must be assessed and accounted for through a specified triage system. To provide robust, individualised care, departments should have at least two motion management

options available. This may include free breathing, respiratory gating or breath hold techniques. Simulation imaging must be appropriate for the motion management technique used for treatment. When tumour motion is expected during treatment delivery, four dimensional computed tomography (4DCT) simulation at a minimum should be available to facilitate assessment of the range, nature and definition of tumour motion. Breath hold, abdominal compression or gating techniques can and should be applied where appropriate to minimise patient specific setup margins.

It is important to note that image quality in 4DCT will depend on the patient's ability to maintain a steady and consistent respiratory pattern. The 4DCT acquired for treatment planning in SABR should be reviewed to ensure they are appropriate representations of tumour motion.[24,25] Respiratory coaching methods for free breathing or breath hold techniques can be utilised to enable patients to achieve stable breathing or to achieve familiarity with dedicated equipment.

Motion management is beyond the scope of this document; however, it is an essential part of the simulation and treatment of SABR. Motion management, including methods to minimise respiratory motion and real-time monitoring of and adaptation to respiratory motion should be assessed on a per-patient basis. This should be done in a multi-disciplinary context taking into account patient comfort, potential gains to patient outcomes and technical feasibility. For any department undertaking SABR, a motion management plan is essential and guidance is provided by the American Association of Physicists in Medicine (AAPM) Task Group Report 76.[26]

Contrast administration

Intravenous (IV) contrast use should be considered during simulation CT when tumours or adjacent critical organs are poorly visualised on non-contrast CTs such as liver and pancreas. Large anatomical variations exist between diagnostic imaging and CT simulation due to patient position, respiratory conditions and organ motion. It is recommended that IV contrast imaging is acquired as part of the CT simulation procedure using immobilisation and motion management techniques to minimise geometric uncertainty when co-registering diagnostic contrast images to simulation CTs. For tumours near gastrointestinal structures, it may also be advantageous to use oral contrast for CT simulation to assist with organ at risk delineation.

The RANZCR Iodinated Contrast Media Guideline provides practical guidance on risk assessment and management of patients prior to IV contrast administration and general safety considerations.[27] Adequately trained staff must be available within the SABR treating team to facilitate the safe and appropriate use of IV contrast.

Planning procedures

The planning for SABR often requires multimodality image fusion. Therefore, image registration and fusion capabilities are essential to be able to link the various data sets used in planning. Accurate multi-modality image registration is critical given the tight geometric tolerance in SABR, and a clearly defined registration request and QA process should be followed such as that defined in AAPM TG132 Report.[28] This report addresses the 'use of image registration and data fusion algorithms and techniques in radiation therapy treatment planning', providing practical recommendations for performing and documenting multi-modality image fusion.

The treatment planning system (TPS) should enable a range of planning options that include static beams, dynamic arcs and intensity modulated beams or arcs and combination techniques. For treatment planning, the dose calculation should be performed on a maximum grid resolution of 2 mm. The TPS should include dose calculation algorithms of at least a superposition/convolution type or Monte Carlo/linear Boltzmann equation, that take into account the impact of density heterogeneities on secondary electrons. This is particularly important where beams will traverse interfaces between tissues of significant variation in their electron densities (including lung and bone).[29] Dose calculation algorithm accuracy should be verified for small fields.[30] Care should be given to minimise treatment plan complexity including modulation, due to long treatment times, use of respiratory gating/breath hold and potential interplay effects in single fraction treatments.

Flattening Filter Free (FFF) beams which accelerate the speed of treatment delivery should be considered to limit patient time on treatment, however, consideration of the motion management technique used, number of treatment fractions and the modulation technique is also necessary.

Dose distributions in SABR are characterised by tight conformance of the prescription isodose to the PTV, sharp fall off outside of the target and hot spots within the centre of the target, as long as there is no spillage into normal tissue. The use of non-coplanar beams or arcs may help achieve plan goals; however, this should take into consideration the available image guidance options and extended treatment times.

Peer review

A robust peer-review process performed prospectively and prior to SABR treatments should be established. Prospective peer-review processes can lead to changes in nearly one-quarter of patients, as demonstrated at a high-volume centre.[31] In a multicentre study of lung SBRT, the peer-review process led to major contour changes in nearly one-quarter of patients.[32] Variations in target and organ-at-risk delineation have been shown to

significantly impact dose coverage of the PTV, at a greater degree than variations in planning and delivery techniques.[33]

Changes recommended through the peer-review process have been shown to reduce with increasing volume of patients treated for a particular body site and SABR experience of the clinician.[17,31] Low-volume centres are therefore encouraged to implement a robust peer-review process through partnership with high-volume centres. The implementation of a nationwide SABR peer-review process has been described in the Australian setting through the use of video-conferencing.[17]

Treatment

Within Australia and New Zealand, treatment systems used to deliver SABR include linear accelerators with C-arm, rotational/enclosed or robotic configurations. Advantages and disadvantages of each type of delivery system are well described in UK SABR consortium guidelines,[8] Canadian Association of Radiation Oncology (CARO) guidelines[9] and TG101-SBRT AAPM guidelines.[34]

Image guidance is fundamental to the delivery of stereotactic treatment. Online correction and intrafraction imaging provide the required geometric precision and accuracy necessary in delivering SABR treatments. Therefore, an effective image guidance system will have capabilities for volumetric or stereoscopic imaging that provides 3D information on target and Organ At Risk (OAR) positions, real-time or near real-time imaging capability to enable on-line correction and the ability to image intra-fractionally due to long treatment times. Imaging technology is evolving rapidly. Standard IGRT includes planar and stereoscopic kV and MV x-ray images and MV and kV cone beam CT (CBCT) which can be gated or binned using a respiratory trace. To ensure a safe SABR program, well-defined imaging protocols should be adhered to that include consideration of tolerances, action levels and frequency of imaging for both intra and inter fractional evaluation. In the decision-making process of selecting appropriate image guidance, consideration should be given to projection angles selected for planar imaging, marker/fiducial definition, surrogacy errors and any metal artefacts caused by these (or incidental nearby surgical clips, etc.).

Surface-guided radiation therapy systems may be used as a surrogate for the respiratory state, and assist in the monitoring and assessment of patient position during treatment.[35] The frequency of imaging required during a patient's treatment may be influenced by the patient's stability.

Contemporary treatment delivery also includes the ability to perform online adaptive treatment planning immediately prior to treatment delivery, based on volumetric CT, PET or MRI acquired at time of treatment. The use of online adaptive treatment planning requires consideration of additional resource and training requirements that are beyond the scope of these guidelines.

Treatment delivery units should meet the AAPM TG101 tolerances on linear accelerator performance including the following: high degree of accuracy of mechanical rotation around the isocentre (<2 mm diameter), ability to deliver high dose rates, and an effective means of monitoring patient position during treatment.[34] Many clinical sites will also benefit from beam modulation, 6 degrees of freedom couch correction and patient respiration monitoring equipment. Patient specific setup margins require consideration of the equipment used and precision and accuracies achieved within each departmental setting.[36] As most SABR applications use multileaf collimator (MLC) collimation, a carefully characterised MLC model in the TPS is required.[34]

Contingency plans should provide treatment delivery redundancy, such that in the event of catastrophic machine breakdown SABR treatment courses can be completed. This should be incorporated into risk management at the planning stages of the SABR program implementation.

Departmental QA measures

General

It is recommended that any department undertaking SABR utilises peer-reviewed and evidence-based protocols that are regularly reviewed and date tracked. SABR treatments may be more error prone compared to conventional techniques,[37] and strategies should be employed to mitigate these risks, in order to improve patient outcomes.

Key factors to reduce the risk of serious adverse events include, but are not limited to[38]:

- Appropriate patient selection for SABR treatment as per the clinical site;
- Appropriate dose and fractionation schedule specific for the clinical site and location or the tumour;
- Accuracy in target delineation;
- Extensive OAR delineation with dose constraints based on evidence-based practice;
- Consideration given to any previous treatment with radiation therapy at that site;
- Peer review and stringent QA at every stage of planning and treatment.
- Effective communication in preparation for and during treatment delivery.

These factors are best discussed for each individual patient in a peer-review forum prior to the commencement of treatment, with appropriate documentation of any important recommendations or changes. Databases linking patient treatment parameters, dosimetry and outcome and clinical audits are encouraged to ensure ongoing QA.

Dose reporting recommendations

The International Commission on Radiation Units and Measurements (ICRU) Report 91 provides recommendations for SABR reporting.[39] The following metrics were recommended and should be reported.

- Planning Target Volume (PTV): D50, $D_{near\text{-}max}$ reported by D2%, $D_{near\text{-}min}$ reported by D98%;
- Gross Tumour Volume (GTV)/Clinical Target Volume (CTV): D50;
- Organ At Risk/Planning Organ At Risk (OAR/PRV): $D_{near\text{-}max}$ reported by $D_{2\%}$ or D_{35mm3}, clinically relevant dose and volume constraints

As the practice of SABR continues to evolve, clinical trial protocol metrics following patient enrolment are considered reasonable alternatives for reporting.

Plan delivery and equipment QA measures

As for all complex radiation therapy treatments, individual patient QA should occur prior to treatment. At a minimum this should include a relative and absolute dose measurement and calculation performed prior to treatment with adequate time to amend the plan if required. This may be reviewed after a local risk assessment and sufficient clinical experience has been achieved such that a process-based QA program may be established as an alternative.

QA procedures at the treatment machine should include all routine procedures, as well as (but not limited to) the following:

- Fluence measurement to check the MLC delivery pattern;
- Clearance on the treatment unit for planned treatment fields (arc or static) should be checked, particularly where couch angles off 0 degrees are used or the isocentre is significantly offset from midplane, or patient body habitus/position is of concern.

External audits

An on-site external audit and review of processes prior to commencing a SABR program per clinical site is strongly recommended. The scope of this includes:

- Review of imaging, treatment planning and treatment processes per clinical site.
- Review of equipment used, QA program and tolerances.
- Observation of end-to-end (Level 1, 2, 3) dosimetry performed with phantom geometry conditions approaching reality as close as possible (i.e. moving targets, small fields, inhomogeneity).

There are external auditing services evaluating SABR delivery such as that provided by the Australian Clinical Dosimetry Service and International Stereotactic Radiosurgery Society, which is recommended for centres delivering SABR, and these should be repeated with any major change of SABR software or equipment. There may also be audits undertaken as credentialing for a particular study by a clinical trials organisation. However, they are likely to be clinical site specific and not comprehensive to cover all aspects of SABR QA for all of the clinical sites.

Organisational considerations for delivery of SABR treatments

Delivery of SABR services and networks

In this section of the guidelines, we address issues particular to Australian and New Zealand centres wishing to implement and maintain a SABR service.

In comparison with many international centres, Australian and New Zealand centres tend to be smaller with the majority having between 2 and 5 linear accelerators. This can pose particular issues in terms of the development of specialist expertise in SABR. The treatment requires intensive efforts by a multidisciplinary team to develop the technical infrastructure and protocols required for safe planning and delivery, particularly during the early implementation phase.

As the interest in and the implementation of a SABR service increases throughout Australia and New Zealand, it is important that this highly resource intensive treatment is delivered through adequate processes that minimise the variation in expertise despite variable caseloads amongst departments.

Australian and New Zealand centres require innovative approaches to streamline the education and training of radiation therapy staff delivering SABR, and to make the complex QA required feasible. Obtaining expertise through mentorship and partnerships at a national level have been described through the use of video-conferencing.[17] Maintenance of expertise by meeting minimum caseloads for body site specific treatment should be achieved and recommendations are made in Section 'Maintenance of Expertise'. Therefore, it is recommended that centres implementing a new SABR service or technique actively seek partnerships with more experienced centres. This process of collaboration may be enabled by the development of clinical trials and formal networks to support the clinical, technical and data collection needs for SABR departments.

Processes which may help to facilitate the safe implementation of SABR include:

- Standardisation of technical and clinical protocols at a state or national level.
- Formal processes to audit technical QA.
- State or nationally based data collection through the development of registries to formally document disease control and toxicity outcomes.

- Participation in multicentre clinical trials with centralised QA and peer-review and/or credentialing mechanisms.
- Implementation of a dedicated SABR credentialing process.

Credentialing of expertise

Centres that deliver a SABR service should consider implementing a dedicated credentialing process for RO to demonstrate competency in SABR prior to active clinical involvement in the delivery of treatments. This training should be body site specific that involves similar clinical and technical proficiencies.

Recommendations for inclusion in the credentialing process include:

- Demonstrated SABR training through fellowship or mentorship in partnership with experienced centres.
- Body site specific experience with a minimum caseload of 10 treatments per site demonstrated in the past 12 months. Recommendations for defining body sites with similar clinical and technical proficiencies include thorax, abdomen, pelvis and spine/non-spine bone.
- For RO that are unable to demonstrate experience through a minimum caseload, the availability of mentorship either through the credentialing centre or in partnership with an external centre should be demonstrated.
- Involvement in a dedicated SABR peer-review process.
- Attendance at SABR courses.
- Involvement in the credentialing process of multi-centre trials through benchmark cases.

The credentialing process of RO in the Australian setting of variable volume centres delivering a SABR service has been previously described.[15] Workplace practices for the credentialing process should be reviewed regularly to ensure staff competency meets current minimum standards.

Maintenance of expertise

Maintenance of expertise should be demonstrated through minimum caseload of body site specific experience, continued professional development and regular participation in the peer-review process. Higher volume caseloads have been shown to reduce changes recommended in peer-review chart rounds.[31,40] Recommendations for minimum caseloads to maintain expertise in SABR have ranged from 10 to 25 procedures per year.[8,14,15] In the Australian setting, a minimum caseload of 12 procedures per body site per year has been described to maintain credentialing of individual RO.[15] It is recommended that RO demonstrate a minimum caseload of 10 procedures per body site or have mentorship available either through the credentialing centre or in partnership with an external centre to ensure competency is maintained. Centres may consider caseloads as part of a unit for uncommonly treated body sites; however, the availability of mentorship should be demonstrated if minimum caseloads are not met. Centres should review body site specific caseloads at pre-determined time intervals to ensure clinical and technical proficiencies can be demonstrated for each body site.

The RT/ROMP workforce will maintain expertise through participation in planning, motion management and treatment of patient cases, peer review of cases, audit and development of the service.

Innovative approaches in maintaining skills in SABR and meeting minimum caseloads should be a priority, particularly for uncommonly treated body sites. At a national, state or regional level, lower volume centres should form partnerships with higher volume centres to maintain staff expertise. Ongoing case review with individual case discussion and documentation, which could usefully be performed at a network level, would support clinicians responsible for SABR treatment and provide an avenue for mentorship.

As the practice of SABR continues to evolve, enrolment in clinical trials is recommended to ensure that the adaptation of new technologies and techniques is done safely. It is recognised that clinical trials are associated with significant costs and additional administration. The additional imposts associated with collaborative trials may prevent many individual centres from trial participation. However, the rigorous QA and auditing processes proposed above, coupled with network level support for trial participation may help to overcome this problem. Therefore, departmental participation in trials, where available, is strongly encouraged. The development of network level trial coordination centres to streamline the processes of ethical approval and data collection may reduce the onerous administrative burden on small radiation therapy centres. Participation in collaborative trials should be considered an additional criterion in demonstrating the maintenance of expertise.

Key recommendations

1. Departmental staffing recognises that SABR is an advanced radiation therapy planning and delivery technique that requires multidisciplinary input from RO, RT, ROMP and RON. These team members require high-level expertise with defined roles and responsibilities to ensure high-quality treatment. It is strongly recommended that all individuals involved in SABR treatments receive SABR specific training.
2. Comprehensive, multidisciplinary risk assessment and reporting structure should be developed and clearly documented as the basis for the SABR QA program.
3. Departments must have clearly documented procedures and protocols for simulation, planning and treatment for SABR techniques. It is strongly recommended that clinical site specific protocols be developed prior to starting an SABR program.
4. Robust peer-review process should be undertaken prospectively and prior to the delivery of SABR treatments.

Partnerships between centres are encouraged to draw upon and maintain clinical site specific expertise.

5 Image guidance that facilitates online matching of the target is a fundamental component of safe and effective SABR. Specialised equipment for immobilisation is required as is the ability to manage motion for targets affected by respiratory excursion. Strict requirements should be met to deliver these treatments as outlined in the document.

6 Departmental QA procedures and protocols should be documented and meet existing national and international guidelines.

7 Implementation of a dedicated SABR credentialing processes should be considered to evaluate clinical competency and maintenance of expertise.

8 Networks should be established with an emphasis on maintenance of expertise, providing guidance through mentorship, QA, collection of data and trial participation to ensure the safe adaptation of new technologies and techniques in the delivery of SABR treatments.

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Data availability statement

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