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A Quality Initiative of the Program in Evidence-Based Care (PEBC), Ontario Health (Cancer Care Ontario)

Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

A. Sahgal, S. Kellett, T. Nguyen, P. Maralani, J. Greenspoon, K. Linden, A. Pearce, F. Siddiqi, M. Ruschin and the SBRT for Spine Expert Panel

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PUBLICATIONS RELATED TO THIS REPORT

Sahgal A, Kellett S, Ruschin M, Greenspoon J, Follwell M, Sinclair J, Perry J, Islam O and the Stereotactic Radiosurgery for Brain Metastasis Guideline Development Group. Organizational Guideline for the Delivery of Stereotactic Radiosurgery for Brain Metastasis in Ontario. Toronto (ON): Cancer Care Ontario; 2019 August 27. Program in Evidence-Based Care Guideline No.: 21-4.

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Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

Section 1: Recommendations

This section is a quick reference guide and provides the guideline recommendations only. For key evidence associated with each recommendation and implementation considerations, see Section 2.

GUIDELINE OBJECTIVES

The objective of this organizational guideline is to ensure that cancer centres across Ontario have guidance as to how spine stereotactic body radiotherapy (SBRT) should be administered with the intent to minimize side effects and maximize patient safety. The administration of spine SBRT also includes the surveillance of SBRT patients post-SBRT, with both clinical and imaging follow-up practices as an essential practice for patient safety.

TARGET POPULATION

All cancer adult patients (>18) with spinal metastasis who are eligible to receive treatment with SBRT.

INTENDED USERS

Stakeholders include all Ontario Regional Cancer Programs that currently deliver, or planning spine SBRT. Specifically, in these Cancer Programs this guideline is intended for:

1. Clinicians involved in the organization and delivery of spine SBRT in Ontario.
2. Administrators involved in the organization and delivery of care of patients with spinal metastasis who are eligible for spine SBRT in Ontario.

RECOMMENDATIONS

Recommendation 1

The following medical professionals are recommended to be part of the multidisciplinary team evaluating patient eligibility and performing spine SBRT

- Radiation oncologist
- Spine surgeon
- Neuroradiologist
- Medical physicist
- Medical dosimetrist
- Radiation therapist

Qualifying Statements for Recommendation 1

- The clinical and imaging details of each spine SBRT case must be discussed in a multidisciplinary case conference (MCC) and local quality assurance (QA) procedures followed such that each plan is reviewed
- The MCC should ideally be comprised of a radiation oncologist, spine surgeon, medical oncologist, radiation therapist and neuroradiologist. It is recognized that not all centres have access to a spine surgeon and, in this situation, having a spine SBRT fellowship-trained radiation oncologist lead the MCC and/or participate in a partner's institution MCC with access to the full composition of MCC members is strongly advised

- The members of the MCC listed above are in addition to the nurses and administrative staff who provide general support for all patients in the radiation oncology department.
- More information about MCCs is available from the Ontario Health (Cancer Care Ontario) (OH [CCO]) website included an MCC standards document and several guideline-based clinical tools (1)
- Treatment plan QA should be performed by the medical physicist in accordance with local procedures
- Contours and treatment plan reviewed in a QA rounds with radiation oncology, medical physics and radiation therapy present, and ideally prior to treatment delivery

Recommendation 2
The following training and/or certification requirements and responsibilities for members of the multidisciplinary team performing spine SBRT are recommended:

Radiation oncologist

- Qualifications
    - The radiation oncologist is accredited by a nationally or internationally recognized program or licensing board
    - Participation in a dedicated fellowship or course that provides technology-specific spine SBRT training is strongly recommended
    - Mentoring or training in a supervised setting within a spine SBRT program is strongly recommended
- Responsibilities:
    - Team leader, responsible for the selection of members of the spine SBRT team
    - Most responsible physician (MRP)
        - MRP refers to the physician who has overall responsibility for directing and coordinating the spine SBRT treatment and management of an individual patient at a specific point in time. The MRP will be responsible for the handover of care during periods of absence or transition of care to a different MRP and/or between treatment modalities. They will be the primary patient contact person during the duration of the treatment and will be responsible for communicating the harms and benefits of the spine SBRT treatment to patients
    - Oversee treatment of patient and sign off on treatment plan
    - Verification of target volume and normal tissues
    - Oversee patient positioning and immobilization
    - Participate in the monitoring and follow-up of patients post-SBRT procedure

Spine surgeon

- Qualifications
    - The spine surgeon is accredited by a nationally or internationally recognized program or licensing board
    - Participation in a training course that provides spine SBRT training is strongly recommended
- Responsibilities:
    - It is recognized that a spine surgeon may not be present at each spine SBRT centre within Ontario; however, participation in the treatment decision-making team through an MCC is strongly recommended

- In the case where surgical input on clinical decision making is not routinely possible at least one radiation oncologist must have subspecialty fellowship training in spine SBRT and lead that team

Neuroradiologist

- Qualifications
  - The neuroradiologist is accredited by a nationally or internationally recognized program or board
- Responsibilities:
  - Participation in the MCC
  - Participation in developing imaging protocols required for spine SBRT cases
  - Reviewing pre- and post-procedure imaging

Medical physicist

- Qualifications
  - The qualified medical physicist is certified by the Canadian College of Physicists in Medicine or an equivalent national or international certification agency
  - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
  - Highly beneficial to have dedicated magnetic resonance (MR) training for sequence optimization and QA procedures
- Responsibilities:
  - Being knowledgeable of all technical aspects of a spine SBRT program, which includes simulation, imaging, planning, equipment, treatment delivery, and verification of output calibration
  - Development of the technical QA program including continual monitoring and associated documentation
  - Working with the radiation oncologists, radiation therapists, and medical dosimetrists to develop the optimal application of spine SBRT and treatment plan for a given patient
  - Being available for consultation for patient set-up and treatment delivery on the day(s) of the treatment
  - Participating in the peer review QA process
  - Being knowledgeable of the radiation safety procedures
  - Ensure members of the spine SBRT team have the necessary training to ensure the safe operation of the spine SBRT program
  - Working with the information technology staff to ensure network connectivity and data backup procedures are in place
  - Being aware of all sources of uncertainty in spine SBRT, including mechanical and dosimetric, and be able to provide mitigation strategies
  - Participating in continuing education activities to maintain expertise and awareness of best practices and guidelines
  - Note: In some centres, the medical physicist may also be responsible for spine SBRT planning

Medical dosimetrist

- Qualifications:
  - Medical Radiation Technologist - Radiation Therapist [MRT(T)] graduate of a recognized radiation therapy program with registration with the appropriate provincial college

    - Considered beneficial if trained in an SBRT-specific setting (within an SBRT program or by a supervised vendor)
    - Considered beneficial if experienced in treatment planning
- Responsibilities of the medical dosimetrist must be clearly defined and may include the following:
    - Working with the radiation oncologist and medical physicist in developing an effective SBRT treatment plan for the patient
    - Ensuring all relevant volumetric patient image data are included in the treatment planning system (TPS)
    - Generate all appropriate technical documentation required to implement the treatment plan
    - Be available for the first treatment and assist with verification for subsequent treatments as necessary

Radiation therapist

- Qualifications
    - [MRT(T)] graduate of a recognized radiation therapy program with registration with the appropriate provincial college
    - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
- Responsibilities of the radiation therapist must be clearly defined and may include the following:
    - Appropriate fabrication of effective patient immobilization devices
    - Patient treatment preparation for the spine SBRT procedure that includes patient positioning/immobilization
    - Performing and assessing pre-treatment imaging for treatment verification
    - Monitoring the patient during treatment
    - Delivering accurate spine SBRT treatment after appropriate approvals
    - Patient care and side effect management
    - Organizing daily workflow of patients and staff
    - Performing daily QA and ensuring safe operation of the technology unit
    - Performing emergency procedures adhering to protocols if necessary
    - Note: In some spine SBRT procedure centers, RTs would be engaging with diagnostic imaging at the time of MRI to ensure proper imaging techniques

Qualifying Statements for Recommendation 2

- Responsibilities may be reassigned where appropriate provided all qualifications and training standards are met
- Support for continuing education for personnel may also be beneficial it is possible that one individual could fulfil both the responsibilities of the radiation therapist and medical dosimetrist, if the appropriate qualifications are obtained

Recommendation 3

The following are recommended for minimum applicable equipment and imaging requirements for simulation and delivery of spine SBRT. Predominant technologies that are employed in Ontario for the delivery of spine SBRT include:

- Image-Guided Linear Accelerator (Linac) with a sub-centimetre multileaf collimator (MLC)
- CyberKnife

Qualifying Statements for Recommendation 3

- Other units may be available; however, in Ontario these are the most common delivery apparatus used for spine SBRT delivery within the province
- Only image-guided technologies should be used for spine SBRT
- While a sub-centimetre MLC is sufficient and safe for the delivery of spine SBRT, a Linac with a ≤5 mm MLC is ideal
- In addition, the recommendations and guidelines presented apply to any technology that a centre would use for spine SBRT

Recommendation 4

The following are recommended as the appropriate level of Simulation and Immobilization for patients undergoing spine SBRT in Ontario

Simulation

- Simulation (includes the mandatory acquisition of volumetric axial MR imaging [MRI]) treatment should be performed as close as possible to the treatment delivery date and optimally no longer than seven and certainly no more than 14 days (including weekend days and statutory holidays) from the treatment delivery date. In the case of epidural disease, treatment should be completed no more than seven days (including weekend days and statutory holidays) from the date of simulation

MRI parameters

- MR axial T1 and T2 sequences of no more than 1-2 mm in slice thickness that include one to two vertebral segments above and below the SBRT target vertebral segments
- MR axial T1 and T2 sequences should be acquired without gadolinium; if a post gadolinium axial is requested then it represents a third sequence to be fused
- Multiple simulation MRI sequences may be required based on the number and location of the spinal segments to be treated to ensure accurate fusion to the treatment planning computed tomography (CT). For example, when treating a T12 and a L5 metastasis, then the simulation MRI should include as a minimum acquisition from T11 to L1 and from L4 to S1 and not one imaging set from T11 to S1
- Contouring of the clinical target volume (CTV) is based on the fusion of the MRI to the planning CT. Several guidelines, review articles and the Canadian Cancer Trials Group (CCTG)-led Symptom Control-24 (CCTG SC24) randomized controlled protocol are recommended to guide practice (2-8)

CT parameters

- CT simulation slice thickness should not exceed 2 mm. Intravenous contrast is optional
- If a treatment-planning CT myelogram is performed then the intrathecal contrast should be injected just prior to the treatment-planning CT, such that the CT is acquired in the simulation suite with the patient immobilized in the treatment position and contrast in place. The acquisition of a diagnostic CT myelogram, which is not acquired with the patient immobilized and in the treatment position, is discouraged as fusion to the treatment-planning CT is an additional potential source of error. It is important to note that this procedure does not replace the process of acquiring treatment planning MR images for fusions

Immobilization

- For lesions that are at the region of T4 and above, the SBRT for Spine Working Group recommends a thermoplastic head and neck mask
- For lesions below the region of T4, the Working Group recommends near-rigid body immobilization. If less robust immobilization is applied, the image guidance procedures should be modified to ensure an overall planning target volume (PTV) margin of no more than 2-3 mm and spinal cord planning organ at risk volume (PRV) of no more than 2 mm. Typically the modifications can include intra-fraction cone-beam CT (CBCT) imaging and/or stereoscopic intra-fraction x-ray-based imaging. In these scenarios full six degrees of freedom positional corrections must be applied

Qualifying Statements for Recommendation 4

- The Working Group members recognize that the MRI acquisitions are dependent on the scanner on which the imaging is performed at the spine SBRT centre
- Involvement of medical physics and radiation therapy to review the entire MRI procedure (from image acquisition to fusion) with end-to-end testing is strongly recommended to minimize the risks associated with geometric distortion especially if using a 3T scanner
- In some instances, images may come from diagnostic departments that are not within the dedicated spine SBRT centre. In these cases, special QA considerations should be given to those images, as they may not meet the minimum recommendation parameters for simulation
- For CT, sufficiently high spatial resolution and signal must be used in accordance with guidelines and recommendations

Recommendation 5

The following are recommended for the appropriate level of QA for: (a) treatment-delivery unit/machine quality control (QC); (b) imaging; and (c) treatment planning:

- The responsible medical physicist should determine that the appropriate testing procedure is used, and documentation is maintained
- Online Image Guidance: Image guidance is essential for accurate spine SBRT treatment delivery regardless of what system or accessories are being used. CBCT is a volumetric imaging technique that is available on most modern linacs and strict adherence to QA guidelines covering geometric fidelity, kV-to-MV coincidence, and image quality is essential. Stereoscopic imaging may also be used with adherence to the relevant guidelines. Since treatment delivery time could be lengthy, some consideration of real-time imaging or imaging mid-treatment during treatment should be considered
- Spatial and dosimetric accuracy: Sub-millimetre accuracy of all delivery components (including MLC position/motion accuracy, isocentricity, couch motions, etc.) should be strictly maintained via the QA program. When considering QA recommendations, it is recommended to use “stereotactic radiation (SRS)/SBRT” tolerances as appropriate, which are more stringent than conventional external beam radiotherapy (cEBRT) techniques. For example, in TG-142, the “SRS/SBRT” specifications should be applied as needed for all machine and imaging-related procedural tests. A positional end-to-end test for delivery accuracy is recommended that encompasses as much of the workflow as possible, from MRI, through to target delineation and treatment delivery. For reference dosimetry in linacs, standard protocols TG-51 (9) and IAEA TRS-398 (10) apply as well as recommendations as per TRS-483 using MSR fields if using CK (11). It is recommended that a medical physicist on the SBRT team have some dedicated small-

field dosimetry training, whether through a certified medical physics training program, or by experienced physicists with small-field dosimetry expertise
- Every spine SBRT treatment plan should be subject to recommended patient-specific QC checks. In the case of linac-based spine SBRT, guidelines for patient-specific QC are listed below under Qualifying Statements

Qualifying Statements for Recommendation 5
- These recommendations are specific to spine SBRT and are in addition to existing guidance documents made available by the treatment unit manufacturer and international and national guidelines
- It is recommended that a medical physicist on the spine SBRT team have dedicated small-field dosimetry training, whether through a certified medical physics training program, or by a combination of continuing education courses and direct training by experienced physicists with small-field dosimetry expertise
- An audit/credentialing procedure (example: IROC) would be highly beneficial in establishing new spine SBRT programs or for credentialing for clinical trials. Several reports have indicated that systematic variability among clinics can be reduced via such independent dose-audits (12-14)
- The patient-specific QC program should follow established guidelines:
    - NCS (Netherlands) Report 28 (2018: QA Audit IMRT and VMAT) (15)
    - AAPM TG 218 (2018: IMRT Tolerances and Methodology) (16)
    - ICRU 83 (2010: IMRT Plan Evaluation) (17)

Recommendation 6
The following are the minimum recommended requirements for patient follow-up after spine SBRT treatment (i.e., MRI timing and frequency):
- Follow-up of SBRT patients should consist of routine clinical visits for the first year (every 3 months); second and third year (every 3-6 months); and every four to six months thereafter, as determined by the MCC

Qualifying Statements for Recommendation 6
- Spinal MRI and not CT or x-ray is the appropriate imaging modality for treatment response monitoring
- A routine clinical visit incorporates a standard full spine MRI, or at a minimum an MRI of the involved spinal region (cervical, thoracic, or lumbar depending on the anatomic location of the treated spinal segment). Gadolinium is not required
- The details of the follow-up plan may be clarified at the discretion of the MCC based on the histology of the spine metastases and the clinical context (for example, a patient with hormone sensitive metastatic prostate cancer treated with spinal SBRT and an undetectable prostate-specific antigen may continue on six-monthly MRI follow-up after the third year of follow-up or delayed to every nine to 12 months if the MCC recommends a more protracted schedule)

Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

Section 2: Guideline – Recommendations and Key Evidence

GUIDELINE OBJECTIVES

The objective of this organizational guideline is to ensure that cancer centres across Ontario have guidance as to how spine stereotactic body radiotherapy (SBRT) should be administered with the intent to minimize side effects and maximize patient safety. The administration of spine SBRT also includes the surveillance of SBRT patients post-SBRT, with both clinical and imaging follow-up practices as an essential practice for patient safety.

TARGET POPULATION

All cancer adult patients (>18) with spinal metastasis who are eligible to receive treatment with SBRT.

INTENDED USERS

Stakeholders include all Ontario Regional Cancer Programs that deliver spine SBRT. Specifically, in these Cancer Programs this guideline is intended for:

1. Clinicians involved in the organization and delivery of spine SBRT in Ontario
2. Administrators involved in the organization and delivery of care of patients with spinal metastasis who are eligible for spine SBRT in Ontario

RECOMMENDATIONS, KEY EVIDENCE, AND JUSTIFICATION

Recommendation 1

The following medical professionals are recommended to be part of the multidisciplinary team evaluating patient eligibility and performing spine SBRT

- Radiation oncologist
- Spine surgeon
- Neuroradiologist
- Medical physicist
- Medical dosimetrist
- Radiation therapist

Qualifying Statements for Recommendation 1

- The clinical and imaging details of each spine SBRT case must be discussed in a multidisciplinary case conference (MCC) and local quality assurance (QA) procedures followed such that each plan is reviewed
- The MCC should ideally be comprised of a radiation oncologist, spine surgeon, medical oncologist, radiation therapist and neuroradiologist. It is recognized that not all centres have access to a spine surgeon and, in this situation, having a spine SBRT fellowship-trained radiation oncologist lead the MCC and/or participate in a partner's institution MCC with access to the full composition of MCC members is strongly advised
- The members of the MCC listed above are in addition to the nurses and administrative staff who provide general support for all patients in the radiation oncology department.

- More information about MCCs is available from the Ontario Health (Cancer Care Ontario) (OH [CCO]) website included an MCC standards document and several guideline-based clinical tools (1)
- Treatment plan QA should be performed by the medical physicist in accordance with local procedures
- Contours and treatment plan reviewed in a QA rounds with radiation oncology, medical physics and radiation therapy present, and ideally prior to treatment delivery

Key Evidence and Justification for Recommendation 1
The requirements for human resources are the expert opinion of the SBRT for Spine Working Group, based on the resources that the group determined would be necessary to support the safe delivery of spine SBRT in patients at Ontario oncology centres

The application of spine SBRT requires the coordinated effort of an MCC of professionals who assume roles during patient selection and treatment. The MCC performing spine SBRT should include the individuals above for the proper patient selection and safe delivery of spine SBRT in Ontario oncology centers

Recommendation 2
The following training and/or certification requirements and responsibilities for members of the multidisciplinary team performing spine SBRT are recommended:

Radiation oncologist
- Qualifications
    - The radiation oncologist is accredited by a nationally or internationally recognized program or licensing board
    - Participation in a dedicated fellowship or course that provides technology-specific spine SBRT training is strongly recommended
    - Mentoring or training in a supervised setting within a spine SBRT program is strongly recommended
- Responsibilities:
    - Team leader, responsible for the selection of members of the spine SBRT team
    - Most responsible physician (MRP)
        - MRP refers to the physician who has overall responsibility for directing and coordinating the spine SBRT treatment and management of an individual patient at a specific point in time. The MRP will be responsible for the handover of care during periods of absence or transition of care to a different MRP and/or between treatment modalities. They will be the primary patient contact person during the duration of the treatment and will be responsible for communicating the harms and benefits of the spine SBRT treatment to patients
    - Oversee treatment of patient and sign off on treatment plan
    - Verification of target volume and normal tissues
    - Oversee patient positioning and immobilization
    - Participate in the monitoring and follow-up of patients post-SBRT procedure

Spine surgeon
- Qualifications
    - The spine surgeon is accredited by a nationally or internationally recognized program or licensing board

    - Participation in a training course that provides spine SBRT training is strongly recommended
- Responsibilities:
    - It is recognized that a spine surgeon may not be present at each spine SBRT centre within Ontario; however, participation in the treatment decision-making team through an MCC is strongly recommended
    - In the case where surgical input on clinical decision making is not routinely possible at least one radiation oncologist must have subspecialty fellowship training in spine SBRT and lead that team

Neuroradiologist

- Qualifications
    - The neuroradiologist is accredited by a nationally or internationally recognized program or board
- Responsibilities:
    - Participation in the MCC
    - Participation in developing imaging protocols required for spine SBRT cases
    - Reviewing pre- and post-procedure imaging

Medical physicist

- Qualifications
    - The qualified medical physicist is certified by the Canadian College of Physicists in Medicine or an equivalent national or international certification agency
    - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
    - Highly beneficial to have dedicated magnetic resonance (MR) training for sequence optimization and QA procedures
- Responsibilities:
    - Being knowledgeable of all technical aspects of a spine SBRT program, which includes simulation, imaging, planning, equipment, treatment delivery, and verification of output calibration
    - Development of the technical QA program including continual monitoring and associated documentation
    - Working with the radiation oncologists, radiation therapists, and medical dosimetrists to develop the optimal application of spine SBRT and treatment plan for a given patient
    - Being available for consultation for patient set-up and treatment delivery on the day(s) of the treatment
    - Participating in the peer review QA process
    - Being knowledgeable of the radiation safety procedures
    - Ensure members of the spine SBRT team have the necessary training to ensure the safe operation of the spine SBRT program
    - Working with the information technology staff to ensure network connectivity and data backup procedures are in place
    - Being aware of all sources of uncertainty in spine SBRT, including mechanical and dosimetric, and be able to provide mitigation strategies
    - Participating in continuing education activities to maintain expertise and awareness of best practices and guidelines
    - Note: In some centres, the medical physicist may also be responsible for spine SBRT planning

Medical dosimetrist

- Qualifications:
    - Medical Radiation Technologist - Radiation Therapist [MRT(T)] graduate of a recognized radiation therapy program with registration with the appropriate provincial college
    - Considered beneficial if trained in an SBRT-specific setting (within an SBRT program or by a supervised vendor)
    - Considered beneficial if experienced in treatment planning
- Responsibilities of the medical dosimetrist must be clearly defined and may include the following:
    - Working with the radiation oncologist and medical physicist in developing an effective SBRT treatment plan for the patient
    - Ensuring all relevant volumetric patient image data are included in the treatment planning system (TPS)
    - Generate all appropriate technical documentation required to implement the treatment plan
    - Be available for the first treatment and assist with verification for subsequent treatments as necessary

Radiation therapist

- Qualifications
    - [MRT(T)] graduate of a recognized radiation therapy program with registration with the appropriate provincial college
    - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
- Responsibilities of the radiation therapist must be clearly defined and may include the following:
    - Appropriate fabrication of effective patient immobilization devices
    - Patient treatment preparation for the spine SBRT procedure that includes patient positioning/immobilization
    - Performing and assessing pre-treatment imaging for treatment verification
    - Monitoring the patient during treatment
    - Delivering accurate spine SBRT treatment after appropriate approvals
    - Patient care and side effect management
    - Organizing daily workflow of patients and staff
    - Performing daily QA and ensuring safe operation of the technology unit
    - Performing emergency procedures adhering to protocols if necessary
    - Note: In some spine SBRT procedure centers, RTs would be engaging with diagnostic imaging at the time of MRI to ensure proper imaging techniques

Qualifying Statements for Recommendation 2

- Responsibilities may be reassigned where appropriate provided all qualifications and training standards are met
- Support for continuing education for personnel may also be beneficial it is possible that one individual could fulfil both the responsibilities of the radiation therapist and medical dosimetrist, if the appropriate qualifications are obtained

Key Evidence and Justificaiton for Recommendation 2

Recommendations for the minimum skill set and experience for spine SBRT team members that perform spine SBRT in Ontario are the consensus of the SBRT for Spine Working Group, based on currently accepted definitions for these specialties in Ontario. These recommendations are also in keeping with other North American standards for SBRT facilities

Recommendation 3
The following are recommended for minimum applicable equipment and imaging requirements for simulation and delivery of spine SBRT. Predominant technologies that are employed in Ontario for the delivery of spine SBRT include:

- Image-Guided Linear Accelerator (Linac) with a sub-centimetre multileaf collimator (MLC)
- CyberKnife

Qualifying Statements for Recommendation 3

- Other units may be available; however, in Ontario these are the most common delivery apparatus used for spine SBRT delivery within the province
- Only image-guided technologies should be used for spine SBRT
- While a sub-centimetre MLC is sufficient and safe for the delivery of spine SBRT, a Linac with a ≤5 mm MLC is ideal
- In addition, the recommendations and guidelines presented apply to any technology that a centre would use for spine SBRT

Key Evidence and Justification for Recommendation 3
These recommendations are the consensus of the Working Group members based on the current technologies that are available in Ontario

Recommendation 4
The following are recommended as the appropriate level of Simulation and Immobilization for patients undergoing spine SBRT in Ontario

Simulation

- Simulation (includes the mandatory acquisition of volumetric axial MR imaging [MRI]) treatment should be performed as close as possible to the treatment delivery date and optimally no longer than seven and certainly no more than 14 days (including weekend days and statutory holidays) from the treatment delivery date. In the case of epidural disease, treatment should be completed no more than seven days (including weekend days and statutory holidays) from the date of simulation

MRI parameters

- MR axial T1 and T2 sequences of no more than 1-2 mm in slice thickness that include one to two vertebral segments above and below the SBRT target vertebral segments
- MR axial T1 and T2 sequences should be acquired without gadolinium; if a post gadolinium axial is requested then it represents a third sequence to be fused
- Multiple simulation MRI sequences may be required based on the number and location of the spinal segments to be treated to ensure accurate fusion to the treatment planning computed tomography (CT). For example, when treating a T12 and a L5 metastasis, then the simulation MRI should include as a minimum acquisition from T11 to L1 and from L4 to S1 and not one imaging set from T11 to S1

- Contouring of the clinical target volume (CTV) is based on the fusion of the MRI to the planning CT. Several guidelines, review articles and the Canadian Cancer Trials Group (CCTG)-led Symptom Control-24 (CCTG SC24) randomized controlled protocol are recommended to guide practice (2-8)

CT parameters

- CT simulation slice thickness should not exceed 2 mm. Intravenous contrast is optional
- If a treatment-planning CT myelogram is performed then the intrathecal contrast should be injected just prior to the treatment-planning CT, such that the CT is acquired in the simulation suite with the patient immobilized in the treatment position and contrast in place. The acquisition of a diagnostic CT myelogram, which is not acquired with the patient immobilized and in the treatment position, is discouraged as fusion to the treatment-planning CT is an additional potential source of error. It is important to note that this procedure does not replace the process of acquiring treatment planning MR images for fusions

Immobilization

- For lesions that are at the region of T4 and above, the SBRT for Spine Working Group recommends a thermoplastic head and neck mask
- For lesions below the region of T4, the Working Group recommends near-rigid body immobilization. If less robust immobilization is applied, the image guidance procedures should be modified to ensure an overall planning target volume (PTV) margin of no more than 2-3 mm and spinal cord planning organ at risk volume (PRV) of no more than 2 mm. Typically the modifications can include intra-fraction cone-beam CT (CBCT) imaging and/or stereoscopic intra-fraction x-ray-based imaging. In these scenarios full six degrees of freedom positional corrections must be applied

Qualifying Statements for Recommendation 4

- The Working Group members recognize that the MRI acquisitions are dependent on the scanner on which the imaging is performed at the spine SBRT centre
- Involvement of medical physics and radiation therapy to review the entire MRI procedure (from image acquisition to fusion) with end-to-end testing is strongly recommended to minimize the risks associated with geometric distortion especially if using a 3T scanner
- In some instances, images may come from diagnostic departments that are not within the dedicated spine SBRT centre. In these cases, special QA considerations should be given to those images, as they may not meet the minimum recommendation parameters for simulation
- For CT, sufficiently high spatial resolution and signal must be used in accordance with guidelines and recommendations

Key Evidence and Justification for Recommendation 4

This recommendation was based on the combined experience of the Working Group members as well as accepted practice within the spine SBRT community

Recommendation 5

The following are recommended for the appropriate level of QA for: (a) treatment-delivery unit/machine quality control (QC); (b) imaging; and (c) treatment planning:

- The responsible medical physicist should determine that the appropriate testing procedure is used, and documentation is maintained
- Online Image Guidance: Image guidance is essential for accurate spine SBRT treatment delivery regardless of what system or accessories are being used. CBCT is a volumetric imaging technique that is available on most modern linacs and strict adherence to QA guidelines covering geometric fidelity, kV-to-MV coincidence, and image quality is essential. Stereoscopic imaging may also be used with adherence to the relevant guidelines. Since treatment delivery time could be lengthy, some consideration of real-time imaging or imaging mid-treatment during treatment should be considered
- Spatial and dosimetric accuracy: Sub-millimetre accuracy of all delivery components (including MLC position/motion accuracy, isocentricity, couch motions, etc.) should be strictly maintained via the QA program. When considering QA recommendations, it is recommended to use "stereotactic radiation (SRS)/SBRT" tolerances as appropriate, which are more stringent than conventional external beam radiotherapy (cEBRT) techniques. For example, in TG-142, the "SRS/SBRT" specifications should be applied as needed for all machine and imaging-related procedural tests. A positional end-to-end test for delivery accuracy is recommended that encompasses as much of the workflow as possible, from MRI, through to target delineation and treatment delivery. For reference dosimetry in linacs, standard protocols TG-51 (9) and IAEA TRS-398 (10) apply as well as recommendations as per TRS-483 using MSR fields if using CK (11). It is recommended that a medical physicist on the SBRT team have some dedicated small-field dosimetry training, whether through a certified medical physics training program, or by experienced physicists with small-field dosimetry expertise
- Every spine SBRT treatment plan should be subject to recommended patient-specific QC checks. In the case of linac-based spine SBRT, guidelines for patient-specific QC are listed below under Qualifying Statements

Qualifying Statements for Recommendation 5

- These recommendations are specific to spine SBRT and are in addition to existing guidance documents made available by the treatment unit manufacturer and international and national guidelines
- It is recommended that a medical physicist on the spine SBRT team have dedicated small-field dosimetry training, whether through a certified medical physics training program, or by a combination of continuing education courses and direct training by experienced physicists with small-field dosimetry expertise
- An audit/credentialing procedure (example: IROC) would be highly beneficial in establishing new spine SBRT programs or for credentialing for clinical trials. Several reports have indicated that systematic variability among clinics can be reduced via such independent dose-audits (12-14)
- The patient-specific QC program should follow established guidelines:
    - NCS (Netherlands) Report 28 (2018: QA Audit IMRT and VMAT) (15)
    - AAPM TG 218 (2018: IMRT Tolerances and Methodology) (16)
    - ICRU 83 (2010: IMRT Plan Evaluation) (17)

Key Evidence and Justification for Recommendation 5

These recommendations are the consensus of the Working Group and are specific to SBRT centres in Ontario. Regardless of technology, the success of a SBRT program hinges on a thorough and ongoing QA program to ensure that the treatment unit is in compliance with the recommendations of the treatment unit manufacturer and within specified clinical tolerances based on international and national guidelines and recommendations (12-17)

Recommendation 6
The following are the minimum recommended requirements for patient follow-up after spine SBRT treatment (i.e., MRI timing and frequency):

- Follow-up of SBRT patients should consist of routine clinical visits for the first year (every 3 months); second and third year (every 3-6 months); and every four to six months thereafter, as determined by the MCC

Qualifying Statements for Recommendation 6

- Spinal MRI and not CT or x-ray is the appropriate imaging modality for treatment response monitoring
- A routine clinical visit incorporates a standard full spine MRI, or at a minimum an MRI of the involved spinal region (cervical, thoracic, or lumbar depending on the anatomic location of the treated spinal segment). Gadolinium is not required
- The details of the follow-up plan may be clarified at the discretion of the MCC based on the histology of the spine metastases and the clinical context (for example, a patient with hormone sensitive metastatic prostate cancer treated with spinal SBRT and an undetectable prostate-specific antigen may continue on six-monthly MRI follow-up after the third year of follow-up or delayed to every nine to 12 months if the MCC recommends a more protracted schedule)

Key Evidence and Justificaton for Recommendation 6
This recommendation is primarily based on the consensus of the Working Group based on their in-field expertise and clinical experiences. It was also supported by a review of published literature detailing the incidence and onset of vertebral compression fracture (VCF) as well as the timing of local failure in spine SBRT patients. The data showed the median time to VCF ranged from 1.5 months to 25 months, with most studies reporting the median time to VCF to be w**ithin** the one to five months interval. When the individual studies in the systematic review were evaluated, the range of time to VCF was between 1-57.2 months post-SBRT. The median time to local recurrence ranged from 3.5 months to 21.0 months post-SBRT.
The Working Group members considered the literature-reported values as well as their clinical experience and determined that patients should be followed with routine clinical visits every three months for the first year; every three to six months during years 2 and 3; and every four to six months thereafter. This recommendation is also in agreement with the follow-up schedule suggested by the SPine response assessment In Neuro-Oncology (SPINO) group (18).

IMPLEMENTATION CONSIDERATIONS
The working group considers the above recommendations to be the minimum standard of care for the safe delivery of spine SBRT in Ontario. It is of the opinion of the working group that recommendations 1 to 5 will not pose any undue stress on the healthcare system, and will provide patients with a side effect profile that respects a reasonable risk of side effects and overall patient safety. The implementation of recommendation 6 has the potential to add approximately 10 to 20 new cases per year in smaller and or larger centres establishing programs and approximately 50-100 new cases per year once programs are well established given the typical volumes currently observed in large high volume centres. A gradual increase in volumes is likely to occur as the technique becomes more widely adopted and integrated into routine practice. While the working group recognises the already high demand for MRI diagnostic imaging in Ontario, the early detection of VCF may lead to improved care for patients with a reduction in emergency room visits for uncontrolled pain or major surgical procedures, as typically early detected VCF can be treated with a minimally invasive cement augmentation

procedure. In addition, early detection of failure may prevent the complication of uncontrolled growth and malignant epidural spinal cord compression that typically requires urgent management.

RELATED GUIDELINES

- Sahgal A, Kellett S, Ruschin M, Greenspoon J, Follwell M, Sinclair J, Perry J, Islam O and the Stereotactic Radiosurgery for Brain Metastasis Guideline Development Group. Organizational Guideline for the Delivery of Stereotactic Radiosurgery for Brain Metastasis in Ontario. Toronto (ON): Cancer Care Ontario; 2019 August 27. Program in Evidence-Based Care Guideline No.: 21-4.

Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

Section 3: Guideline Methods Overview

This section summarizes the methods used to create the guideline. For the evidence review, see Section 4.

THE PROGRAM IN EVIDENCE-BASED CARE

The Program in Evidence-Based Care (PEBC) is an initiative of the Ontario provincial cancer system, Ontario Health (Cancer Care Ontario). The PEBC mandate is to improve the lives of Ontarians affected by cancer through the development, dissemination, and evaluation of evidence-based products designed to facilitate clinical, planning, and policy decisions about cancer control.

The PEBC supports the work of Guideline Development Groups (GDGs) in the development of various PEBC products. The GDGs are composed of clinicians, other healthcare providers and decision makers, methodologists, and community representatives from across the province.

The PEBC is a provincial initiative of OH (CCO) supported by the Ontario Ministry of Health (OMH). All work produced by the PEBC is editorially independent from the OMH.

JUSTIFICATION FOR GUIDELINE

This initiative was raised because the clinical community requested guidance and standardization in the approach to SBRT treatment for spinal metastasis in Ontario. The landscape and technology associated with spinal SBRT has changed significantly over the past five years and practice varies across the province. Guidance is needed to ensure the safe delivery of spine SBRT and coordination of this service across sites in Ontario. If treatment is not done correctly there is a significant risk of spinal cord damage. A small number of patients will likely develop VCFs as a consequence of the treatment and a consistent follow-up program needs to be established for spine SBRT patients.

GUIDELINE DEVELOPERS

This guideline was developed by the Spine SBRT GDG (Appendix 1), which was convened at the request of the Radiation Treatment Program.

The project was led by a small Working Group of the Spine SBRT GDG, which was responsible for reviewing the evidence base, drafting the guideline recommendations and responding to comments received during the document review process. The Working Group had expertise in radiation oncology, surgical oncology and health research methodology. Other members of the Spine SBRT GDG served as the Expert Panel and were responsible for the review and approval of the draft document produced by the Working Group. Conflict of interest declarations for all GDG members are summarized in Appendix 1, and were managed in accordance with the *PEBC Conflict of Interest Policy*.

GUIDELINE DEVELOPMENT METHODS

The PEBC produces evidence-based and evidence-informed guidance documents using the methods of the Practice Guidelines Development Cycle (19, 20). This process includes a systematic review, interpretation of the evidence and draft recommendations by the Working

Group, internal review by content and methodology experts and external review by Ontario clinicians and other stakeholders.

The PEBC uses the AGREE II framework (21) as a methodological strategy for guideline development. AGREE II is a 23-item validated tool that is designed to assess the methodological rigour and transparency of guideline development and to improve the completeness and transparency of reporting in practice guidelines.

The currency of each document is ensured through periodic review and evaluation of the scientific literature and, where appropriate, the addition of newer literature to the original evidence-base. This is described in the *PEBC Document Assessment and Review Protocol*. PEBC guideline recommendations are based on evidence of the magnitude of the desirable and undesirable effects of an intervention or accuracy of a test, and take into account the certainty of the evidence, the values of key stakeholders (e.g., patients, clinicians, policy makers, etc.), and the potential impact on equity, acceptability and feasibility of implementation. A list of any implementation considerations (e.g., costs, human resources, and unique requirements for special or disadvantaged populations, dissemination issues, etc.) is provided along with the recommendations for information purposes. PEBC guideline development methods are described in more detail in the *PEBC Handbook* and the *PEBC Methods Handbook*.

Search for Guidelines

As a first step in developing this guideline, a search for existing guidelines was undertaken to determine whether any guideline could be endorsed. Evidence-based guidelines with systematic reviews that addressed at least one research question were included; guidelines older than three years (published before 2018) were excluded; guidelines based on consensus/expert opinion or methods other than a reproducible transparent systematic review were excluded

The following sources were searched for guidelines in September, 2021 with the search term(s) "Stereotactic Body Radiotherapy" AND "Spine": Canadian Association of Radiation Oncology (CARO), Canadian Partnership for Quality Radiation Therapy (CPQR), American College of Radiology/ASTRO Practice Parameters, The Royal Australian and New Zealand College of Radiologists, National Institute for Health and Care Excellence Evidence Search, Canadian Medical Association Journal Infobase, Scottish Intercollegiate Guidelines Network, American Society of Clinical Oncology, National Health and Medical Research Council – Australia Clinical Practice Guidelines Portal, and Cancer Council Australia – Cancer Guidelines Wiki.

Assessment of Guideline(s)

A guideline from the American College of Radiology (ACR) practice parameter for the performance of SBRT (22) was found during the search for guidelines. While the ACR practice parameter contained information on a number of relevant domains, it could not be endorsed because it was not specific to the use of SBRT for spinal metastasis as well as geographical differences between the American and Canadian SBRT centres. In addition to the ACR Practice Parameter, the Canadian Association of Radiation Oncology (CARO) Practice Guidelines for Lung, Liver and Spine Stereotactic Body Radiotherapy was also found (23). As this guideline was published in 2012 it did not meet our guideline inclusion criteria

GUIDELINE REVIEW AND APPROVAL

Internal Review

For the guideline document to be approved, 75% of the content experts who comprise the GDG Expert Panel must cast a vote indicating whether or not they approve the document, or abstain from voting for a specified reason, and of those that vote, 75% must approve the

document. In addition, the PEBC Report Approval Panel (RAP), a three-person panel with methodology expertise, must unanimously approve the document. The Expert Panel and RAP members may specify that approval is conditional, and that changes to the document are required. If substantial changes are subsequently made to the recommendations during external review, then the revised draft must be resubmitted for approval by RAP and the GDG Expert Panel.

Patient and Caregiver-Specific Consultation Group

Four patients/survivors/caregivers participated as Consultation Group members for the Spine SBRT Working Group. They reviewed copies of the project plan/draft recommendations and provided feedback on its/their comprehensibility, appropriateness, and feasibility to the Working Group's Health Research Methodologist. The Health Research Methodologist relayed the feedback to the Working Group for consideration.

External Review

Feedback on the approved draft guideline is obtained from content experts and the target users through two processes. Through the Targeted Peer Review, several individuals with content expertise are identified by the GDG and asked to review and provide feedback on the guideline document. Through Professional Consultation, relevant care providers and other potential users of the guideline are contacted and asked to provide feedback on the guideline recommendations through a brief online survey.

DISSEMINATION AND IMPLEMENTATION

The guideline will be published on the OH (CCO) website and may be submitted for publication to a peer-reviewed journal. The Professional Consultation of the External Review is intended to facilitate the dissemination of the guideline to Ontario practitioners. Section 1 of this guideline is a summary document to support the implementation of the guideline in practice. OH (CCO)-PEBC guidelines are routinely included in several international guideline databases including the CPAC Cancer Guidelines Database, the CMA/Joule CPG Infobase database, NICE Evidence Search (UK), and the Guidelines International Network (GIN) Library.

IMPLEMENTATION CONSIDERATIONS.

Implementation of guidelines developed by the PEBC may be undertaken by Radiation Treatment Program. At the time of publication, planned activities include the use of this document as a guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario.

ACKNOWLEDGEMENTS

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- Faith Maelzer for data auditing
- Sara Miller for copy editing.

Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

Section 4: Recommendation Development

INTRODUCTION

Spinal metastases represent a significant complication of metastatic cancer. They can cause significant pain and put the patient at risk of malignant epidural spinal cord compression, cauda equina syndrome, and mechanical instability. Treatment of spinal metastases has been traditionally based on delivering a short course of palliative conventional external beam radiotherapy (cEBRT). Surgery is selectively reserved for patients with frank mechanical instability and/or symptomatic malignant epidural spinal cord compression/cauda equina syndrome. Although the complete response rates for pain have been disappointing at approximately 10%, and a lack of dose-response observed to improve outcomes within cEBRT schedules evaluated in several randomized controlled trials (RCTs), patients had limited therapeutic options for pain relief and local control.

With the advent of image-guided radiation therapy with technical advances allowing for millimetric precision in delivery, the treatment of metastases with stereotactic body radiotherapy (SBRT) emerged (23). Spinal metastases were one of the earlier indications under investigation with the intent to optimize pain control and local control. Due to the technical demands associated with spine SBRT, only few centres in Ontario could adopt this technique early in its development, despite high rates of local and pain control suggested in uncontrolled trials. There were also safety concerns as only with time did recommendations for spinal cord tolerance and dosing become available to guide the community for safe practice (8, 24).

In 2021, the Canadian Cancer Trials Group (CCTG)-led Symptom Control-24 (CCTG SC24) RCT evaluating 20 Gy in five cEBRT fractions, vs. 24 Gy in two SBRT fractions, for patients presenting with painful spinal metastases was reported (8). The primary endpoint was the radiation-site-specific complete pain response rate at three months, and a 21% absolute increase in complete pain relief was observed favouring the SBRT vs. the cEBRT arm (35% vs. 14%, respectively). The benefit was sustained at the six-month and final secondary endpoint (32% vs. 16%, respectively). A secondary analyses of the Sunnybrook Odette Cancer Center sub-cohort with mature follow-up was recently reported focused on rates of local control and re-irradiation. The results indicate that long-term local control is significantly better with 24 Gy in two SBRT fractions vs. 20 Gy in five cEBRT fractions with one- and two-year rates of local failure of 6.1% vs. 28.4% and 14.8% vs. 35.6%, respectively. Re-irradiation rates were also significantly better with 24 Gy in two SBRT fractions vs. 20 Gy in five cEBRT fractions with one- and two-year rates of re-irradiation of 2.2% vs. 15.8% and 8.2% vs. 22.4%, respectively (24). As a result, there has been increasing demand from the oncologic community within Ontario and globally to offer spine SBRT to selected patients. As a point of caution, although the adverse event profiles were generally similar with respect to iatrogenic VCF rates, the severity of the VCF requiring an intervention was greater in those treated with SBRT with mature follow-up (23).

Spine SBRT requires considerable resources as a specialized MRI-based technique (8). Sophisticated immobilization technologies, acquisition of treatment planning MRI sequences for fusion, image-guided delivery and specialization on behalf of the radiation oncologist is required (24). The QA program must also adjust to ensure millimetric precision and adherence to SBRT specific processes to ensure safe delivery given the inherent proximity of the spinal

cord and other dose-limiting organs at risk. Spine SBRT requires a team to be created within the local radiation treatment program that involves radiation oncology, medical physics, radiation therapy, spine surgery, and neuroradiology. Lastly, centres have to also adopt follow-up programs with spinal MRI to ensure VCFs are diagnosed, and to verify that treatment was delivered appropriately with respect to tumour control(18). Although the cost of SBRT is greater than conventional palliative radiation (25), there was less financial toxicity for patients in delivering two SBRT fractions vs. five conventional fractions in the CCTG SC24 RCT (8), and as SBRT for patients with oligometastases increasingly becomes a standard of care, the demand for spine SBRT will only increase (26).

The purpose of this document is to establish considerations for safe spine SBRT practice as a framework to guide Cancer Centers in Ontario who want to offer this treatment for their patients.

GUIDELINE REVIEW

This Organizational Guideline was developed by the Spine SBRT GDG, a collaboration of OH (CCO)'s PEBC and the Radiation Treatment Program. The standards were written in accordance with a methodology adapted from the PEBCs practice guideline development process and reporting format. The report was designed to address professional and organizational standards around the delivery of spine SBRT in Ontario.

RESEARCH QUESTION(S)

What are the optimal organizational standards for the safe delivery of spine SBRT to adult cancer patients with spinal metastases in Ontario with respect to:

1. Multidisciplinary teams responsible for the delivery of spine SBRT
2. Equipment/imaging requirements for simulation and delivery of spine SBRT
3. QA of the treatment and treatment unit
4. Post-spine SBRT imaging follow-up.

METHODS

As with all PEBC guidelines, a search for existing guidelines was completed. The Methods and Results of the search for existing guidelines are presented above in Section 3 of this document. The authors determined that for Questions 1-3 it was unlikely that research studies addressing these issues had been published (or were not the best evidence to inform recommendations) and therefore a search of the literature was not required for these questions and they would not be part of the data review. A search for published data was conducted for Question 4. The standards presented below embody recommendations for the organization of the delivery of spine SBRT in Ontario. With the exception of Research Question 4, the recommendations are based on the consensus opinion of the Spine SBRT GDG. Research Question 4 was also primarily based on the consensus opinion of the Working Group; however, for this research question a review of published data detailing the timing of adverse events was also undertaken to inform this research question. Primary consideration was given to the perceived benefits for patients and the small likelihood of harm arising from recommendation implementation.

Search for Data on Timing of Adverse Events and Local Failure

For Research Question 4, a search was conducted to find published literature with data on MRI follow-up programs, frequency of adverse events and local failure, and onset of adverse events and local failure after spine SBRT treatment. The optimal study design would be a RCT comparing follow-up MRI to clinical observation only, or comparing difference imaging examinations with various frequencies, and its effect on patient management and survival;

however, it was hypothesized in the review planning stage that there would be no studies that evaluated this and, therefore, data on the incidence and timing of VCFs, myelopathy and radiculopathy and adverse events after spine SBRT in the study population were prioritized as this would provide valuable information as to the frequency and the need for a specialized MRI follow-up program. Studies were included if they met the following criteria:

- RCTs or comparative studies that controlled for confounders.
- If the above studies are unavailable, single-arm studies evaluating SBRT in patients with spinal metastasis where outcomes include timing and frequency of post-SBRT adverse events, and timing of local failure with a *minimum* follow-up period of three months (for acute toxicity) and six months (for late toxicity), with minimum sample size of 30 can be included.

Literature Search Strategy

A review of published data was conducted using the MEDLINE and Embase databases up to December 1, 2022, with search terms directly pertaining to SBRT and timing of adverse events and local failure (see Appendix 2 for the full search strategy). Reference lists and data tables from included published articles were also consulted.

Study Selection Criteria

A review of the titles and abstracts was conducted by SK. For studies that warranted full-text review, SK reviewed each study independently. Due to the retrospective, non-comparative nature of the studies required for this guideline a quality assessment of included studies was not performed.

Data Extraction

All included primary studies underwent data extraction by SK with all extracted data and information audited subsequently by a Working Group member (TN) and an independent data auditor (FM).

Recommendation Development Process

Due to the lack of relevant guidelines and high-quality primary evidence to support the recommendations, the Spine SBRT Working Group relied on their combined expertise to develop recommendations that would be acceptable for use within Ontario SBRT treatment centres. The Working Group drafted and confirmed a preliminary set of recommendations related to the organizational requirements for programs performing spine SBRT within Ontario. Discussions were conducted through videoconferences and e-mail communication and were informed by the clinical experience of the members and existing technical guidance documents. In the case of Research Question 4, evidence from the literature was used to support the expert opinions and clinical experience of the Working Group members.

KEY EVIDENCE FOR RECOMMENDATIONS

1. **Multidisciplinary teams responsible for the delivery of spine SBRT**
   a. ***Who are the medical professionals who ideally should be part of the multidisciplinary team evaluating patient eligibility and performing spine SBRT?***
   b. ***What are the training and/or certification requirements for members of the multidisciplinary team performing spine SBRT?***

The application of spine SBRT requires the coordinated effort of an MCC of professionals who assume roles during the patient selection and treatment procedure. MCCs ensure that each

patient case is discussed in a multidisciplinary forum with appropriate expertise to generate an appropriate treatment plan. The MCC performing spine SBRT should include the following individuals who have the credentials and responsibilities listed below. The MCC should be comprised ideally of a radiation oncologist, spine surgeon, medical oncologist, and a neuroradiologist. It is recognized that not all centers have access to a spine surgeon and, in this situation, having a spine SBRT fellowship trained radiation oncologist lead the MCC is strongly advised and/or participate in a partner's institution MCC with access to the full composition of MCC members. The members of the MCC are in addition to the nurses and administrative staff who provide general support for all patients in the radiology department. The evidence for this research question is indirect and, are the expert consensus of the SBRT for Spine Working Group, based on the resources that the group determined would be necessary to support the safe delivery of spine SBRT in patients at Ontario oncology centers. More information about MCCs is available from the OH (CCO) website included an MCC standards document and several guideline-based clinical tools (1)

Radiation oncologist

- Qualifications
    - The radiation oncologist is accredited by a nationally or internationally recognized program or licensing board
    - Participation in a dedicated fellowship or course that provides technology-specific spine SBRT training is strongly recommended
    - Mentoring or training in a supervised setting within a spine SBRT program is strongly recommended
- Responsibilities:
    - Team leader, responsible for the selection of members of the spine SBRT team
    - MRP
        - MRP refers to the physician who has overall responsibility for directing and coordinating the spine SBRT treatment and management of an individual patient at a specific point in time. The MRP will be responsible for the handover of care during periods of absence or transition of care to a different MRP and/or between treatment modalities. They will be the primary patient contact person during the duration of the treatment.
    - Core member of the MCC
    - Oversee treatment of patient and sign off on treatment plan
    - Verification of target volume and normal tissues
    - Oversee patient positioning and immobilization
    - Participate in the monitoring and follow-up of patients post-SBRT procedure

Spine surgeon

- Qualifications
    - The spine surgeon is accredited by a nationally or internationally recognized program or licensing board
    - Participation in a training course that provides spine SBRT training is strongly recommended
- Responsibilities:
    - It is recognized that a spine surgeon may not be present at each spine SBRT centre within Ontario; however, participation in the treatment decision-making team through a MCC is strongly recommended

- In the case where surgical input on clinical decision making is not routinely possible, at least one radiation oncologist must have subspecialty fellowship training in spine SBRT and lead that team.

Neuroradiologist

- Qualifications
  - The neuroradiologist is accredited by a nationally or internationally recognized program or board
- Responsibilities:
  - Participation in the MCC
  - Participation in developing imaging protocols required for spine SBRT cases
  - Reviewing pre- and post-procedure imaging

Medical physicist

- Qualifications
  - The qualified medical physicist is certified by the Canadian College of Physicists in Medicine or an equivalent national or international certification agency
  - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
  - Highly beneficial to have dedicated MR training for sequence optimization and QA procedures.
- Responsibilities:
  - Being knowledgeable of all technical aspects of a spine SBRT program, which includes simulation, imaging, planning, equipment, treatment delivery, and verification of output calibration
  - Development of the technical QA program including continual monitoring and associated documentation
  - Working with the radiation oncologists, radiation therapists, and medical dosimetrists to develop the optimal application of spine SBRT and optimal patient-specific treatment plan
  - Being available for consultation for patient set-up and treatment delivery on the day of the treatment
  - Participating in the peer review process
  - Being knowledgeable of the radiation safety procedures
  - Ensure members of the spine SBRT team have the necessary training to ensure the safe operation of the spine SBRT program
  - Working with the information technology staff to ensure network connectivity and data backup procedures are in place
  - Being aware of all sources of uncertainty in spine SBRT, including mechanical and dosimetric, and be able to provide mitigation strategies
  - Participating in continuing education activities to maintain expertise and awareness of best practices and guidelines
  - Note: In some centres, the medical physicist may also be responsible for spine SBRT planning

Medical dosimetrist

- Qualifications:
  - Medical Radiation Technologist - Radiation Therapist [MRT(T)] graduate of a recognized radiation therapy program with registration with the appropriate provincial college

    - Considered beneficial if trained in an SBRT-specific setting (within an SBRT program or by a supervised vendor)
    - Considered beneficial if experienced in treatment planning
- Responsibilities of the medical dosimetrist must be clearly defined and may include the following:
    - Working with the radiation oncologist and medical physicist in developing an effective SBRT treatment plan for the patient
    - Ensuring all relevant volumetric patient image data are included in the treatment planning system (TPS)
    - Generate all appropriate technical documentation required to implement the treatment plan
    - Be available for the first treatment and assist with verification for subsequent treatments as necessary
    - Note: It is possible that one individual could fulfil both the responsibilities of the radiation therapist and medical dosimetrist, if the appropriate qualifications are obtained
    -

Radiation therapist

- Qualifications
    - MRT(T) graduate of a recognized radiation therapy program with registration with the appropriate provincial college
    - Considered beneficial if trained in a spine SBRT-specific setting (within an SBRT program or by a supervised vendor)
- Responsibilities of the radiation therapist must be clearly defined and may include the following:
    - Appropriate fabrication of effective patient immobilization devices
    - Patient treatment preparation for the SBRT procedure that includes patient positioning/immobilization
    - Performing and assessing pre-treatment imaging for treatment verification
    - Monitoring the patient during treatment
    - Delivering accurate SBRT treatment after appropriate approvals
    - Patient care and side effect management
    - Organizing daily workflow of patients and staff
    - Performing daily QA and ensuring safe operation of the technology unit
    - Performing emergency procedures adhering to protocols if necessary
    - Notes:
        - In some SBRT procedure centres radiation therapists would be engaging with diagnostic imaging at the time of MRI to ensure proper imaging techniques
        - It is possible that one individual could fulfil both the responsibilities of the radiation therapist and medical dosimetrist, if the appropriate qualifications are obtained

In addition to the members listed above an administrative team is required to support the spine SBRT program. These duties may include ensuring there are adequate resources, time, and personnel required for performing spine SBRT. Support for continuing education for personnel should also be considered.

These recommendations for team members and their minimum skill set and experience for SBRT team members that perform spine SBRT in Ontario was the consensus of the GDG, based on currently accepted definitions for these specialities in Ontario.

2. Equipment/imaging requirements for simulation and delivery of spine SBRT. What are the minimum applicable equipment and imaging requirements for simulation and delivery of spine SBRT

a. Delivery of spine SBRT

i. Minimum applicable technologies of treatment delivery units

Spine SBRT is a technologically intensive program that requires the use of resources that are above what would be considered typical for palliative radiotherapy treatment, and even some curative indications. There is potential for treatment-related adverse events due to the highly conformal nature of spine SBRT dose distributions, steep dose gradients adjacent to dose-limiting critical organs at risk such as the spinal cord/cauda equina, esophagus and bowel, high dose per fraction radiation delivery, and a small PTV margin typically on the order of 1-2 mm.

Linear accelerators (linac) are isocentric devices that have been adapted to incorporate tertiary collimators (MLCs) to finely shape the radiation beams, image guidance and positional corrections in all six degrees of freedom. In Canada, the most common delivery unit for SBRT for spinal metastasis is Linac-based. Intensity-modulated radiotherapy and volumetric arc therapy can be used as a means of creating inversely planned complex dose distributions and delivery time shortened with the use of flattening-filter-free technology. When using SBRT for the treatment of spinal metastasis, the Working Group recommends a linac with a sub-centimetre or less MLC, and image guidance capability with CBCT and/or stereoscopic imaging. Although six degrees of freedom positional corrections is strongly recommended, it is not an absolute requirement. QA recommendations for linacs include AAPM Task Group Reports 142 (27) and 101 (28) and COMP technical QC guidelines (29). Specifically, linacs that are designated for spine SBRT should be carefully tested for: (1) targeting accuracy at all combinations of couch, gantry, and collimator angles used clinically; and (2) dosimetric accuracy for small (<2 cm) MLC-defined fields at the location of the target, which includes off-axis locations.

CyberKnife is a robotically mounted linac that sequentially delivers large numbers of non-isocentric beams through the target. Cyberknife is a unique technology with its own specifications for spine SBRT (30).

b. Immobilization

Immobilization of the patient undergoing the SBRT procedure is dependant on the location of the spinal metastases. For lesions that at the T4 region and above, the SBRT for Spine Working Group recommends a standard thermoplastic head and neck mask. For lesions below the T4 region, the Working Group recommends near-rigid body immobilization (31). If less robust immobilization is applied, the image guidance procedures should be modified to ensure an overall PTV margin of no more than 2-3 mm and a spinal cord PRV of no more than 2 mm and, ideally, full six degrees of freedom positional corrections applied. Multiple simulations and imaging sequences may be required based on the location of the spinal segments to be treated and based on the site-specific qualities of the metastases.

c. Simulation

Spinal SBRT requires on both CT or MRI for complete target and organs at risk delineation and localization.

Simulation with MRI

The treatment planning MRI sequences should be acquired no more than 14 days from the date of treatment. In the case of epidural disease, simulation MRI should be completed no more than seven days from the date of treatment. MR axial T1 and T2 sequences should be

acquired with a 1- 2mm slice thickness and include one to two vertebral segments above and below the SBRT target spinal segment(s). MR axial T1 and T2 sequences should be acquired without gadolinium; if a post gadolinium axial is requested then it represents a third sequence to be fused. For example, for cases with paraspinal disease some centres may prefer additional contrast-specific imaging. Contouring of the clinical target volume (CTV) is based on the fusion of the MRI to the planning CT. Several guidelines, review articles and the Canadian Cancer Trials Group (CCTG)-led Symptom Control-24 (CCTG SC24) randomized controlled protocol are available to guide practice (2-8).

Simulation with CT

CT simulation requires fine resolution scans with a recommended slice thickness of 1-2 mm. In situations where a CT myelogram is required for spinal cord delineation, this should be done as a treatment planning myelogram with the patient immobilized in their SBRT-specific device. If a diagnostic CT myelogram is fused to the treatment planning CT, appropriate QA procedure should be undertaken to ensure fusion. A myelogram does not replace the need for treatment planning MRI sequences.

3. What is the appropriate level of QA for:

a. Treatment-delivery unit/machine QC

Regardless of technology, the success of a SBRT program hinges on a thorough and ongoing QA program to ensure that the treatment unit complies with the recommendations of the treatment unit manufacturer, and within specified clinical tolerances based on the international and national guidelines and recommendations listed below. The responsible medical physicist should determine that the appropriate testing procedure is used, and documentation is maintained.

Specific to SBRT, the most essential elements of treatment delivery QA include:

- On-line Image Guidance: Image guidance is essential for accurate spine SBRT treatment delivery regardless of what system or accessories are being used. CBCT is a volumetric imaging technique that is available on most modern linacs and strict adherence to QA guidelines covering geometric fidelity, kV-to-MV coincidence, and image quality are essential. Stereoscopic imaging may also be used with adherence to the relevant guidelines. Since treatment delivery time could be lengthy, some consideration of real-time imaging during treatment, or a mid-treatment verification CBCT, should be considered. The evidence from Hyde et al. (32) recommends a time interval of approximately 20 minutes as a threshold to re-image based on CBCT image-guidance.

- Spatial and dosimetric accuracy: Sub-millimetre accuracy of all delivery components (including MLC position/motion accuracy, isocentrecity, couch motions, etc.) should be strictly maintained via the QA program. When considering QA recommendations, it is recommended to use “SRS/SBRT” tolerances as appropriate, which are more stringent than cEBRT techniques. For example, in TG-142, the “SRS/SBRT” specifications should be applied as needed for all machine and imaging-related procedural tests. A positional end-to-end test for delivery accuracy is recommended that encompasses as much of the workflow as possible from the time of simulation MRI, to target delineation and treatment delivery. For linac reference dosimetry, standard protocols include TG-51 (9), IAEA TRS-398 (10), and those recommendations from TRS-483 using MSR fields if using CK (11). It is recommended that a medical physicist on the SBRT team have some dedicated small-field dosimetry training, whether through a certified

medical physics training program or by experienced physicists with small-field dosimetry expertise.

4. What are the minimum requirements for patient follow-up after spine SBRT treatment (i.e. MRI timing and frequency).

For this recommendation, a review of published data was conducted (methods described above). A total of 3284 studies were brought in by the search. Of these, one systematic review (33) and 21 (8, 24, 34-52) primary studies published after the systematic review were included.

The review evaluated studies containing data on VCFs following SBRT for spine statistics (Table 4-1). Abbouchie et al included 15 studies that evaluated 3394 spinal segments in 2147 patients. The rate of VCF following SBRT ranged from 4.2% to 39% (33). For all studies, the median time to VCF ranged from 1.5 months to 25 months, with most studies reported the median time to VCF to be within one to five months. When the individual studies in the systematic review were evaluated, time to VCF ranged between 1-57.2 months post-SBRT (Table 4-2). In the studies published after the included systematic review, the rate of VCF ranged between 0-22%. Time-to-VCF ranged from 1-45 months, and the median time to VCF remained between six to eight months post-SBRT (Table 4-3).

Time-to-local failure was a secondary outcome of the studies included, of which three reported the median time to local recurrence (34, 53, 54). The reported medians ranged from 3.7 months to 21.0 months post-SBRT. Ling et al reported the widest range of recurrences, with recurrences observed from two months to 137 months post-SBRT (54). Details of these studies are summarized in Tables 4-2 and 4-3.

a. Recommended Clinical Follow-up

Based primarily on the clinical expertise of the SBRT for Spine Working Group and informed by published data summarizing time-to-VCF and time-to-local failure, the following clinical follow-up plan is recommended. Patients should be followed with routine clinical visits every three months for the first year; every three to six months during years 2 and 3; and every four to six months thereafter. It should be noted that a routine clinical visit incorporates a standard full spine MRI, or at a minimum an MRI of the involved spinal region (cervical, thoracic or lumbar depending on the anatomic location of the treated spinal segment), and gadolinium is not required. The follow-up treatment plan may be changed at the discretion of the MCC and modifications based on the primary tumour type may be appropriate.

Imaging interpretation has been recommended to be performed by a neuroradiologist (18). It is important to consider that we are still in the infancy of understanding signal change characteristic following SBRT in the bone and, at present, there are no quantitative criteria to accurately determine response. Furthermore, both fracture and pseudoprogression can confound interpretation. Pseudoprogression has been defined by SPINO as an imaging-based transient increase in apparent tumour size following SBRT, similar to what is observed in some cases of brain glioma following radiotherapy (18). The incidence of pseudoprogression in the literature varies from 14-18% (55) to as high as 37% (56), and may be observed as early as three weeks (57) to even up to three years (58) following SBRT.

Table 4-1. Included Systematic Reviews with Relevant Published Data

Study Name	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Adverse Events and Timing	Time to Adverse Event
Abbouchie et al, 2020 (33)	Systematic Review (Up to 2019)	2147 patients/ 3394 spinal segments	16-27 Gy in 1-3 fractions	Varied by study	*See Table 4.2*	-VCF events: range 4.2%-39.0% -Median time to VCF: ranged 1.5–25.0 mo -VCF reported within initial 1–5 mo in most studies. The exceptions were Ling et al. (10.2 mo) and Rose et al. (25.0 mo)	

Abbreviations: mo, months; SBRT, Stereotactic body radiotherapy; VCF, vertebral compression fracture;

Table 4-2. Breakdown of Studies Included in Abbouchi et al

Study Name	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Tseng et al, 2018 (53)	Retrospective	145 patients/ 279 spinal segments	24 Gy in 2 fractions	MRI spine and clinical assessment every 2 to 3 mo	Median time to LF: 9.2 mo LF rate: 1 yr: 9.7% 2 yr: 17.6%	Isolated vertebral segmental bone failures were observed in 10 of 40 patients (25.0%)	Cumulative risk of VCF: 1 year: 8.5% 2 years:13.8%
Mehta et al, 2018 (59)	Retrospective	83 patients/ 98 spinal segments	Median: 24 Gy (range, 14-44) in 3 fractions (range, 2-5)	MRI and clinical assessment every 3 mo for first year then every 6 mo thereafter	LC: 6 mo: 93% 1 yr: 84%	Radiculopathy: n=1 VCF rate: n=4 spinal segments (4.2%)	Median time to VCF: 5.8 mo
Ling et al, 2018 (54)	Retrospective	43 patients/ 84 spinal segments	12-24 Gy in one fraction	MRI spine and clinical assessment 3 mo after spine SBRT then as per physician preference	LC: 1 yr: 82.7% 5 yr: 57.7% 10 yr: 54.3% Median time to LF: 21.0 mo (range, 2.0-137.4)	VCF rate: n=9 spinal segments (10.7%) De novo: n=7 Progressive: n=2 Other toxicities Grade >2: 20.9%	Median time to VCF: 10.2 mo (range, 3.2-57.2) Time to other toxicities: median 12.8 mo (range, 4.2-59.0)
Yoo et al, 2017 (60)	Retrospective	29 patients/ 42 spinal segments	16-20 Gy in 1 fraction, 18-45 Gy in 3 fractions	CT, MRI or PET/CT and clinical assessment every 1-3 mo	LC: 6 mo: 74.5% 1 yr: 68.3% LC (including salvage re-irradiation): 1 yr: 87.2%	VCF rate: n=12 spinal segments (28.6%) De novo VCF: n=6 Progressive VCF: n=6	Not stated

Study Name	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Thibault et al, 2017 (61)	Retrospective	55 patients/ 100 spinal segments	Median: 24 Gy in 2 fractions	MRI spine and clinical assessment every 2 to 3 mo	LR: 6 mo: 5.1% 12 mo: 12.3%	VCF rate: n=17 spinal segments (17%)	Median time to VCF: 1.7 mo (range, 0.8-7.8)
Boyce-Fappiano et al, 2017 (62)	Retrospective	448 patients/ 1070 spinal segments	10 Gy in 1 fraction to 60 Gy in 5 fractions	Median spine MRI and clinical assessment frequency of every 2 mo	Not reported	VCF rate: n=90 spinal segments (8.4%)	Median time to VCF: 2.7 mo (range, 5 days-54.9) 66% of VCFs occurred within the first 6 mo
Lee et al, 2016 (63)	Retrospective	79 patients/ 100 spinal segments	Median: 18 Gy in 1 fraction and 27 Gy in 3 fractions	MRI spine and clinical assessment every 3 mo during the 1st year, then every 6 mo thereafter	Not reported	VCF rate: n=32 patients (40.5%) De novo: n=19 Progressive: n=13	Median time to VCF: 3.3 mo (range, 0.4 – 34.1) Mean time to VCF: 5.7 mo
Jawad et al, 2016 (64)	Retrospective	541 patients/ 594 spinal segments	Median: 20 Gy (range 8–40 Gy) in 1 fraction (range 1–5)	Imaging (MRI, CT and/or PET-CT) and clinical assessment every 3 mo	Crude LC: 80%	VCF rate: n=34 patients (5.7%)	Median time to VCF: 3 mo (range, 1.0-36.0)
Germano et al, 2016 (65)	Retrospective	95 patients/ 143 spinal segments	10-18 Gy in 1 fraction	MRI spine and clinical assessment every 3 mo during initial year, then every 6 mo thereafter.	Crude LC: 94%	VCF rate: n=30 spinal segments (21%) 1 year Fracture-Free Probability = 76% Risk of facture at: 6 mo: 22.0%	VCF occurred within the first 6 mo in 92 % of cases Mean time to VCF: 5 mo (range, 3–24)

Study Name	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
						12mo : 24.0%	
Thibault et al, 2014 (66)	Retrospective	37 patients/ 71 spinal segments	Median: 24 Gy (range 18–30) and 2 (range 1–5)	MRI spine and clinical assessment every 2 to 3 mo	LC: 1 yr: 83.4% 2 yr: 66.2%	VCF rate: n=10 spinal segments (14.1%) De novo: n=3 Progressive: n=7	Median time to VCF: 1.6 mo (range, 1 day to 7.8 mo)
Sung et al, 2014 (67)	Retrospective	72 patients/Not reported	18-45 Gy in 1-5 fractions	X-rays every mo for initial 3 mo, then regular clinical assessment and MRI (interval not stated)	Not reported	VCF rate: n=26 patients (36%)	Mean time to VCF: 1.5 mo (range: 0.3-3.5 mo)
Sahgal et al, 2013 (68)	Retrospective	252 patients/ 410 spinal segments	8-26 Gy in 1 fraction, 18-26 Gy in 2 fractions, 18-35 Gy in 3 fractions, 25-35 Gy in 4 fractions, 25-35 Gy in 5 fractions	MRI spine and clinical assessment every 2 to 4 mo	Not reported	VCF rate: n=57 spinal segments (13.9%)	Median time to VCF: 2.5 mo Mean time to VCF: 6.3 mo (range, 0.03-43.0)
Cunha et al, 2012 (69)	Retrospective	90 patients/ 167 spinal segments	8-24 Gy in 1 fraction, 18-24 Gy in 2 fractions, 20-27 Gy in 3 fractions, 30 Gy in 4 fractions, 25-35 Gy in 5 fractions	MRI spine and clinical assessment every 2 mo	Not reported	VCF rate: n=19 spinal segments (11%)	Mean time to VCF: 3.3 mo Median time to VCF: 2 mo (range, 0.5-21.6)
Boehling et al, 2012 (70)	Prospective	93 patients/123 spinal segments	18 Gy in 1 fraction, 27 Gy in	MRI spine MRI every 3 mo for initial year, then every 6 mo thereafter	Crude LF: 26%	VCF rate: n=39 spinal segments (31.7%)	Median time to VCF: 3 mo

Study Name	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
			3 fractions, 30 Gy in 5 fractions.			Progressive VCF: n=25 spinal segments De novo VCF: n=14 spinal segments	Median time to VCF: 14 mo
Rose et al, 2009 (71)	Retrospective	62 patients/ 71 spinal segments	Median: 24 Gy in 1 fraction	MRI spine and clinical assessment at 2 mo after treatment then every 3 to 4 mo thereafter	Crude LF: 11%	VCF rate: n=27 spinal segments (39.0%)	Median time to VCF: 25 mo

Abbreviations: CT, computed tomography; LC, local control; LF, local failure; mo, month(s); MRI, magnetic resonance imaging; PET, positron emission tomography; SBRT, stereotactic body radiotherapy; VCF, vertebral compression fractures; yr, year(s)

Table 4-3. Primary Studies with Relevant Data Published after Included Systematic Reviews

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Zeng et al, 2022 (50)	Retrospective	159 patients/301 (28 Gy in 2 fractions) 323 patients/646 segments (24 Gy in 2 fractions)	28 Gy/24 Gy in 2 daily fractions	All patients were followed with a full spine MRI every 2 to 3 months and clinical assessment	LF 35/301; 11.6% (28 Gy cohort) 140/646; 21.7% (24 Gy cohort) The median time to LF was longer in the 28 Gy (13.0 mo; range, 2.0-61.4 mo) compared with the 24 Gy (9.9 mo; range, 0.3-100.5 mo) cohort	No cases of radiation myelopathy VCF: 28 Gy: 37/301 (12.3%) 24 Gy: 75/646 (11.6%)	24 Gy: 6 mo: 5.2% 12 mo: 7.0% 24 mo: 10.7% 28 Gy: 6 mo: 6.2% 12 mo: 8.8% 24 mo: 10.8%
Singh et al, 2022 (48)	Retrospective	436 patients/514 spine segments	Median 27 Gy (range 12-50 Gy) in 3 fractions (range 1-5)	Not reported	LC: 1 yr: 79.9% 2 yr: 73.6%	Not reported	Not reported
Zeng et al, 2021 (51)	Retrospective	Radioresistant histologies: 173 patients/395 spinal segments Prostate cancer: 94 patients/185 spinal segments	24 Gy in 1 fraction, 24-28 Gy in 2 fractions, 24-27 Gy in 3 fractions, 25-35 Gy in 4-5 fractions	MRI spine and clinical assessment every 2-3 mo	LF: 1-yr : 19.2% 2-yr : 22.4% 3-yr : 36.3%	Overall VCF rate: n=75 spinal segments (12.9%) 1-yr: 8.2% 2-yr 13.3%	Median time to VCF: 9 mo (range, 0.4 to 43.4 mo)

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Zeng et al, 2022 (24)	Retrospective	137 patients SBRT: 66 (48.2%) cEBRT: 71 (51.8%)	24 Gy in 2 fractions	Median follow-up of 11 mo (IQR, 5.3-28.5 mo)	LF SBRT: n=13 (10.9%) cEBRT: n=57 (33.7%)	12 mo VCF: 8.2% 24 mo VCF: 11%	No radiation myelopathy or radiation plexopathy events.
Kowalchuk et al, 2021 (72)	Retrospective	331 patients/ 464 treatments	1 fraction 16-24 Gy (median, 20 Gy; range, 16-30 Gy)	Median 21 mo	-	VCF: De novo: n=64 (76%) Progression: n=29 (23%)	VCF timing: median 9 mo (IQR, 3-21 mo)
Abugharib et al, 2022 (35)	Prospective review of database	93 patients/183 spine segments	24-28 Gy in 2 fractions, 30 Gy in 4 fractions	MRI spine and clinical assessment every 2 to 3 mo	LC: 1-yr: 96% 2-yr: 86%	VCF crude rate: n=15 patients (16.1%), 24 spinal segments (13.1%)	VCF (estimate) 1 yr: 4% 2 yr: 10%
Zeng et al, 2021 (52)	Retrospective	79 patients/ 135 spine segments	18-24 Gy in 1 fraction, 20-28 Gy in 2 fractions, 24 Gy in 3 fractions, 30 Gy in 4-5 fractions	MRI spine and clinical assessment every 2 to 3mo	LF: 3 yr: 12.5% 5 yr:14.4%	VCF rate (in patients living >3 years): De novo: n=13 patients (9.6%) Progression: n=6 patients (4.4%) Plexopathy: n=6 (1 brachial and 5 lumbosacral plexopathy)	Incidence of VCF: 1 yr: 2.2% 2 yr: 7.4% 3 yr: 10.4% 5 yr: 14.4% Median time to plexopathy: 35.7 mo (range, 10.9-41.9)

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Sahgal et al, 2021 (8)	Randomized Controlled Trial	SBRT: 114 patients/ 185 spinal segments	24 Gy in 2 fractions	MRI spine and clinical assessment at 3 mo then at 6 mo	LF: 24.3%	VCF rate: n=12 patients (11%)	No timing of VCF reported; however, all adverse events happened within the 6 months of patient follow-up
Kim et al, 2021 (40)	Retrospective	163 patients/ 179 spinal segments	Median: 20 Gy in 1 fraction	Spine MRI or CT and clinical assessment every 1-3 mo for first two years, then every 6mo for years 3-5, then yearly thereafter	Crude LF: 25.2% 2-year Local Progression-Free Survival: 71.1%	1-year VCF rate: 12.1% 2-year VCF rate: 13.2% VCF rate: n=21 (12.9%) De novo: n=16 (9.8%) Progression n=5 (3.1%)	Median time to VCF: 6 mo (range, 1–45) 60% of VCF developed within 8 months post-SBRT
Hussain et al, 2021 (39)	Retrospective	41 patients/ 48 spinal segments	24 Gy in one fraction, 24–27 Gy in three fractions, 30–35 Gy in five fractions	Clinical assessment 6 weeks after SBRT. Spine imaging (ideally MRI) and clinical assessment every 3 mo for 1st year, then frequency as per treating physician	Not reported	VCFs: n=2 patients (4.9%)	Time to VCF: 3-14 mo

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Guckenbergeret al, 2021 (38)	Follow-up of RCT	57 patients/ 63 spinal segments	30 Gy in 10 fractions with SIB to 48.5Gy, 20 Gy in 5 fractions with SIB to 35 Gy	MRI spine and clinical assessment every 3 mo in initial year, then every 6 mo thereafter	Crude LC: 82%	VCF: n=20 patients (35%) De novo: n=12 patients Progressive: n=8 patients	Timing not reported
Vargas et al, 2020 (49)	Retrospective propensity matched analysis	45 patients/ 71 spinal segments	Not reported	Not reported	5-yr LC: SBRT: 86.7%	5-year VCF rate: n=10 patients (22.2%)	Timing not reported
Sasamura et al, 2020 (47)	Retrospective	43 patients/ 45 spinal segments	25 Gy in 5 fractions	CT or MRI spine every few mo	LC: 1 yr: 67.0% 2 yr: 51.0%	Grade 3 VCF: n=1	Timing not reported
Sandhu et al, 2020 (46)	Retrospective	74 patients/ 114 spinal segments	Median: 20 Gy (IQR 20–24) in 1 fraction (IQR 1–3)	At least one follow-up imaging scan which included CT, PET/CT, and/or MRI spine	LF: 1 yr: 24.0% 2 yr: 32.0%	VCF rate: n=15 patients (13.2%)	Incidence of VCF 1 yr: 7.0% 2 yr: 8.0%
Park et al, 2020 (45)	Retrospective	156 patients/ Not reported	Median 17 Gy in 1 fraction, 21 Gy in 3 fractions	All patients had follow-up at 3 mo. Schedule beyond that was not reported.	Crude LF: 11.5%	VCF: n=0 (within the 3 mo of follow-up reported)	N/A
Chen et al, 2020 (36)	Retrospective	193 patients/ 302 spinal segments	Median: 24 Gy in 3 fractions	Not reported	LF: 1 yr: 10.7% 2 yr: 15.2%	VCF rate: n=26 spinal segments (8.6%) 1 year: 4.6% 2 years: 6.7%	Median time to VCF: 4.2 mo

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Abbouchie et al, 2020 (34)	Retrospective	84 patients/ 113 spinal segments	Median: 30 Gy in 3 fractions	Imaging (MRI, PET/CT, CT, and/or bone scan) and clinical assessment every 3 months within first year and then "as required" thereafter	Time to local progression: 8.5 mo (range 3.7-27.0) LC: 1 year: 78.8% 2 year: 72.4%	VCF rate: n=5 spinal segments (4.4%) De novo: n=2 spinal segments Progressive: n=3 spinal segments	Median time to VCF: 9.2 mo
Ozdemir et al, 2019 (44)	Retrospective	120 patients/ 180 spinal segments	16 Gy or 18 Gy in 1 fraction	Imaging (PET/CT or MRI) and clinical assessment every 3 mo for first two years, then every 6 mo for years 3-5, then annually thereafter	Crude LF: 12%	Grade 3 VCF rate: n=5 patients (4%) Fracture-Free Survival: 1 year: 67.2% 2 year: 40.9%	Median time to VCF: 16 mo
Mantel et al, 2019 (43)	Prospective	56 patients/ 61 spinal segments	35 Gy in 5 fractions, 48.5 in 10 fractions	Imaging (spine MRI and CT) and clinical assessment completed at 6 weeks and 3 mo after treatment, then every 3 mo for first year and every 3 mo thereafter.	Crude LC: 82%	VCF: n=21 spinal segments (34.4%) De novo: n=11 spinal segments Progressive: n=10 spinal segments	Median time to VCF: De novo: 1.9 mo Progressive: 1.6 mo
Lockney et al, 2019 (42)	Retrospective	206 patients/ 239 spinal segments	24 Gy in 1 fraction	Follow-up schedule not reported.	No outcome data	Adjacent level VCF rate: 10.8%	Median time to VCF: 13.5 mo

Study Citation	Type of Study	Patients/Spinal Segments	SBRT Total Dose and Fractions	Follow-up Schedule	Local Failure Outcomes	Serious Adverse Events	Timing of Adverse Events
Giaj-Levra et al, 2019 (37)	Retrospective	32 patients/ 54 spinal segments	12 Gy in 1 fraction, 12 Gy in 3 fractions, 18 Gy in 3 fractions, 21 Gy in 3 fractions, 24 Gy in 3 fractions	PET/CT and/or MRI and clinical assessment ~2 months after SBRT. Then every 2-3 mo for first year.	LC: 6 mo: 86.0% 9 mo: 86.0%	VCF rate: n=0	N/A

Abbreviations: cEBRT, conventional external beam radiotherapy; CT, computed tomography; IQR, interquartile range; LC, local control; LF, local failure; mo, month(s); MRI, magnetic resonance imaging; N/A, not applicable; PET, positron emission tomography; RCT, randomized controlled trial; SBRT, stereotactic body radiotherapy; SIB, simultaneous integrated boost; VCF, vertebral compression fractures; yr, year(s)

DISCUSSION

At present the practice of spine SBRT is increasing globally due to benefits not only in complete response rates for pain (8, 24), but long-term local control and fewer retreatment events. Moreover, the paradigm shift in the management of patients with oligometastases to treat with curative intent (73, 74), also drives the increasing practice of spine SBRT. Given that spine SBRT is one of the most technically intensive practices in radiation oncology with the potential to cause significant harm in the form of radiation myelopathy, VCF and plexopathy, the purpose of this document was to establish considerations for safe spine SBRT practice as a framework to guide cancer centres in Ontario who want to offer this treatment for their patients.

This organizational care guideline defines the basic requirements for safe practice. It is recommended that a multidisciplinary team, led by a radiation oncologist with appropriate training in spine SBRT, discuss each patient in an MCC to ensure appropriateness of the indication. This process ensures that additional interventions in the form of surgery or interventional procedures such as cement augmentation, before or after spine SBRT, be considered to maximize the therapeutic intent. The clinical indications for spine SBRT are beyond the scope of this document, as the intention was to ensure appropriate delivery of treatment and post-delivery follow-up practice.

The minimum technical requirements are outlined in this guideline and reflect current practice in Ontario. At present, we recommend patients be simulated with a near-rigid body immobilization device. Less rigid immobilization may be appropriate if treatment delivery is coupled with near-real-time stereoscopic imaging intra-fraction image guidance. Otherwise, there is potential for unrecognized patient motion to increase the risk of overdosing critical organs at risk. Strict QA procedure must also be adopted both with respect to delivery of treatment and the imaging acquired for treatment planning. As radiation technology continues to evolve to afford delivery with millimetric precision, these requirements are subject to change.

It is well recognized that the treatment planning of spine SBRT is based on both CT and MRI. Resources for volumetric planning MRI sequences must be provided for a centre to perform spine SBRT, as both imaging modalities allow for accurate delineation of the target volume and organs-at-risk. Should a patient have contraindications to MRI, then spine SBRT should not be performed. In particular, the follow-up procedure is based on regular clinical assessments coupled with spinal MRI.

It is noteworthy to consider that at present, with adherence to recommended spinal cord dose thresholds, radiation myelopathy is considered to be an unlikely adverse event (75, 76). Should this devastating late toxicity be observed then a technical and clinical investigation should be performed. However, VCF is not infrequent and can be observed in approximately 10% of vertebral segments treated with 24 Gy in two spine SBRT fractions (8), and the risk may increase depending on factors such as baseline fracture, lytic disease, spinal malalignment, and dose-per-fraction (68). To qualify the recommended interval of patient follow-up practice, a review of the literature was performed specific to local control and the incidence of VCF. Given that the incidence of fracture and local failure events were observed to be widely ranging, it is recommended that patients should be followed with routine clinical visits every three months for the first year; every three to six months during years 2 and 3; and every four to six months thereafter. It should be noted that a routine clinical visit incorporates a standard full spine MRI, or at a minimum an MRI of the involved spinal region (cervical, thoracic, or lumbar depending on the anatomic location of the treated spinal segment) and gadolinium is not required. This recommendation recognizes the change in radiation oncology practice from conventional palliative treatment with no follow-up, to a strict program that is designed to

manage the complications of treatment failure and VCF given the exposure to high-dose radiation. Appropriate resources must be afforded to centres to allow for MRI-based follow-up to perform spine SBRT.

CONCLUSIONS

This organizational guideline for the planning and delivery of spine SBRT in Ontario was designed to ensure safe practice. The recommendations for follow-up were based on the consensus of the Working Group members and supported by a review of the published data defining the incidence of local control and VCF.

Consensus-based organizational guideline for the planning and delivery of spine stereotactic body radiotherapy treatment in Ontario

Section 5: Internal and External Review

INTERNAL REVIEW

The guideline was evaluated by the GDG Expert Panel and the PEBC Report Approval Panel (RAP) (Appendix 1). The results of these evaluations and the Working Group's responses are described below.

Expert Panel Review and Approval

Of the eight members of the GDG Expert Panel, seven members voted and none abstained, for a total of 87.5% response in January 2023. Of those who voted, six approved the document (85.7%). The main comments from the Expert Panel and the Working Group's responses are summarized in Table 5-1.

Table 5-1. Summary of the Working Group's responses to comments from the Expert Panel.

Comments	Responses
1. For Recommendation 2 - consider adding medical dosimetrist (similar qualifications and responsibilities to the SRS guideline). This role is already referenced as a collaborator within the medical physicist responsibilities, so it should be listed as a role for this recommendation as well. For the medical dosimetrist consider responsibility of: perform multi-modality image fusion, as required (this is a key and enabling competency within radiation therapy entry-to-practice national competency profile) a. For medical dosimetrist role, consider qualification (similar to the medical physicist): Beneficial to have MR training for MRI interpretation and development of effective spine SBRT treatment plan for the patient i. Can consider a similar statement for the radiation therapist role: Beneficial to have MR training for MR image formation and interpretation (this will also support your note regarding engaging with diagnostic imaging at the time of MRI) ii. This will be aligned with the current addendum to the entry-to-practice national competency profile (specifically the clinical expert role) for radiation therapy	Thank you. We have included medical dosimetrist as part of our SBRT team recommendation.

Comments	Responses
b. For both the medical dosimetrist role and radiation therapist role consider responsibility (similar to the medical physicist): Participating in continuing education activities to maintain expertise and awareness of best practices and guidelines	
2. *Recommendation 1:* The roles people in MCC and QA are mixed. Not all cases of spine SBRT need MCC discussion. I do not see the need of neurosurgeon having taken a course on spine SBRT.	The current standard of care for high-dose radiation to a site such as the brain is that the case is reviewed in a MCC and the same should be applied to for spine SBRT. The decision making for patient selection is still maturing and all central nervous system (CNS) cases, including spine, should be discussed in an MCC and this is in line with the CNS management guidelines in final development and the established brain SRS organization care guideline.
3. *The MCC performing spine SBRT should include the individuals above for the safe delivery of spine SBRT in Ontario oncology centres.* Consider adding "proper selection of patients"	Thank you. We have added this into the recommendation
4. *Recommendation 4: Diagnostic myelogram should not be discouraged when clinically indicated.* Myelograms are sometimes acquired when patients cannot undergo MRI. The acquisition of myelogram sometimes can only be performed at a diagnostic radiology facility. By discouraging the acquisition of diagnostic myelogram, are we removing opportunities of some patients from being treated by SBRT?	Increasingly, a myelogram is not applied in the treatment planning for spine SBRT with appropriate MRI. A myelogram puts the patient at risk of complications as it is an invasive procedure. It can be performed when clinically needed but should not be considered first line nor a replacement for MRI.
5. *MR axial T1 and T2 sequences should be acquired without gadolinium; if contrast-enhanced sequences are required then they are incremental to be fused* I do not understand the meaning of the term incremental in this context.	Standard of care is T1 and T2; if a post gadolinium axial is requested then it represents a third sequence to be fused. We have clarified this in the Guideline.
6. *SBRT for patients with oligometastases increasingly becomes a standard of care, the demand for spine SBRT will only increase* This might be a bit too strong. An increasing use of SBRT among patients with oligometastases - yes Standard of care - this is unclear.	SBRT for patients with oligometastases is increasingly considered in their management plan and, as a result, the demand for spine SBRT will only increase.
7. *Recommendation 6* Long-term follow-up of cancer patients should be guided by the biology of the disease and not SBRT MCC. It should not require a MCC discussion to develop a long-term follow-up plan for a patient treated with spine SBRT 3+ years ago.	The MCC can inform the decision for follow-up until evidence-based recommendations emerge.
8. The SC24 study suggests that spine SBRT is very safe, with lower VCF rate than conventional radiotherapy. High-	When long-term data are observed, as the SC24 trial was limited to a six-

Comments	Responses
grade toxicities are rare. How does one justify the use of MRI in SBRT spine patients in comparison to patients treated with conventional radiotherapy?	month follow-up, late fractures are observed and tend to be more serious requiring intervention.
9. Perhaps the Working Group wishes to clarify whether the MCC should be done prior to treatment being recommended/booked, or just at some point so the case (and already delivered external radiation therapy plan) can be reviewed. It is mentioned in Section 2 that the radiotherapy QA should ideally be done prior to treatment delivery, but there's no qualifier for timing for the MCC. Wording on pages 15 and 16 imply the MCC should be involved in patient selection	MCC discussions should be done prior to simulation as it is the decision making that is being reviewed. Treatment plan QA is ideally performed before treatment is initiated.
10. Recommendation 4, Simulation paragraph Consider adding "…no more than 14 days (including weekend days and statutory holidays) *from the treatment delivery date…"*	Thank you, we have updated the recommendation to include this.
11. Recommendation 4, MRI Parameters paragraph It may be worthwhile explicitly stating in this paragraph that MRI at 1.5T is preferred over 3T (due to increased geometric distortion at 3T)	The Working Group feels you can use 3T if proper QA of the MRI is completed by the medical physicist; this is outlined in the roles and responsibilities of the medical physicist.
12. Qualifying Statements for Recommendation 4 It may be worthwhile highlighting the role of the MRI charge technologist, particularly in the community setting where the MRI physician lead and MRI charge technologist may be primarily responsible for protocol planning, patient immobilization, image acquisition, etc…	The Working Group feels at this stage this specification is not required.

RAP Review and Approval

Three RAP members reviewed this document in January 2023. The RAP conditionally approved the document February 6th, 2023. The main comments from the RAP and the Working Group's responses are summarized in Table 5-2.

Table 5-2. Summary of the Working Group's responses to comments from RAP.

Comments	Responses
1. The overall objective of the document does not reflect the importance of follow-up.	We have modified the objectives of the guideline to better reflect the recommendations in the guideline. Patient follow-up is considered to be an important part of the safe delivery of SBRT to patients in Ontario.
2. Recommendation 6: Any access issues need to be identified here. In the current context of imaging backlogs, there might be a concern around access to surveillance imaging. How does this compare to other documents that outline radiation approaches in bone metastases?	We have included "Implementation Considerations" in Section 2.

Comments	Responses
1. The overall objective of the document does not reflect the importance of follow-up.	We have modified the objectives of the guideline to better reflect the recommendations in the guideline. Patient follow-up is considered to be an important part of the safe delivery of SBRT to patients in Ontario.
3. Recommendation 6: "*This sentence is not clear to me. Is it the clinical context?*" *The details of the follow-up plan may be clarified at the discretion of the MCC based on the histology of the spine metastases and the clinical oncology*	Thank you, we have corrected the text to read "clinical context". The details of the follow-up plan may be clarified at the discretion of the MCC, taking into account the clinical history of the patient and histology of the tumour.
4. Make clear that this is a consensus-based guideline, add this to the title	Because this guideline is primarily based on the consensus of the Working Group members, we have added this to the title of the guideline for transparency
5. For the evidence review, ensure sufficient detail to be clear and reproducible	Details of the methodology used for the search of published data and subsequent data collection can be found at the beginning on Section 4 and the literature search strategies used can be found in Appendix 4

Patient and Caregiver-Specific Consultation Group

4 patients/survivors/caregivers participated as Consultation Group members for the Working Group. They reviewed the draft recommendations and provided feedback on its comprehensibility, appropriateness, and feasibility to the Working Group's Health Research Methodologist. The main comments from the Consultation Group are summarized in Table 5-3.

Table 5-3. Summary of the Working Group's responses to comments from the Consultation Group.

Comments	Responses
1. Where do nurses fit into the multi-disciplinary team?	Nurses are an integral part of the continuum of care for the spine SBRT treatment program. Because they do not require training specific to SBRT delivery, we have not included them as stand-alone personnel requirement for the multi-disciplinary team; however, they are included in the supporting personnel in the qualifying statements in Recommendation 1.
2. Patients should know the potential side-effects of spinal SBRT prior to undergoing the treatment. Which member of the MCC will be responsible for this?	Thank you, we have added this into the responsibilities for the radiation oncologist/most responsible physician
3. Will there be an accreditation program for these SBRT centres of excellence?	This was outside of the scope of this guideline; however, this may be considered at the time of program implementation

4. Will patients be able to search and find out where these accredited centres are located?	This was outside of the scope of this guideline; however, this may be considered at the time of program implementation
5. Are the recommended volumes for these centres?	There is currently no literature available on optimal volumes for spine SBRT centres; however, the Working Group believes that the above recommendations are all-encompassing and appropriate to provide safe and effective spine SBRT treatment.

EXTERNAL REVIEW
External Review by Ontario Clinicians and Other Experts

Targeted Peer Review

3 targeted peer reviewers from the United States who are clinical experts in their fields were identified by the Working Group. All agreed to be the reviewers (Appendix 1). Results of the feedback survey are summarized in Table 5-4. The main comments from targeted peer reviewers and the Working Group's responses are summarized in Table 5-5.

Table 5-4. Responses to nine items on the targeted peer reviewer questionnaire.

	Reviewer Ratings (N=3)				
Question	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the guideline development methods.					3
2. Rate the guideline presentation.			1		2
3. Rate the guideline recommendations.				1	2
4. Rate the completeness of reporting.				1	2
5. Does this document provide sufficient information to inform your decisions? If not, what areas are missing?				2	1
6. Rate the overall quality of the guideline report.				1	2
	Strongly Disagree (1)	(2)	Neutral (3)	(4)	Strongly Agree (5)
7. I would make use of this guideline in my professional decisions.					3
8. I would recommend this guideline for use in practice.					3
9. What are the barriers or enablers to the implementation of this guideline report?	Readers might note the large number of pages and be discouraged from actually reading the document. Only a subset of readers will care to read the development methods or key evidence so maybe those could be appendices. I think the guidelines are very straightforward. The only possible barrier to implementation				

	may be that every case be discussed in multi-disciplinary conference. Whereas multi-disciplinary review is critically important to the success of SBRT spine programs, constraining review to a presumably weekly conference may impede timely delivery of set-up care. Much of our review is done in clinic, over Zoom, and by email. I think documenting multi-disciplinary review is critical but constraining it to conference specifically is unnecessarily burdensome.

Table 5-5. Summary of the Working Group's responses to comments from targeted peer reviewers.

Comments	Responses
1. I was confused about the organization of the document initially but comments at the top of each section help to clarify the purpose of each section. Large sections of text in the document are almost exact copies of each other. I wonder if the guidelines could be the main document and the sections with the Key Evidence, etc., could be appendices? This organization may encourage more people to read the document rather than be discouraged when they see the document length. My experience is that most people just want to read the recommendations and they care less about the details behind the recommendations.	Once the guideline is posted to the Ontario Health/CCO website, Section 1 is published separately for those readers looking for a short summary of the recommendations; because of this, some repetition in wording will occur.
2. The committee did a superb job in the development of the guidelines. Small changes may improve this from a pragmatic standpoint: 1) Excluding patients who have contraindications to MR from receiving SBRT may be overly broad exclude patients who would significantly benefit. Simulation and f/u can be with PET or myelogram/CT etc. 2) Routine clinical evaluation at 3 month intervals for the first year, i.e. 4 MR's may be excessive although clinical checks in that time period are important and very reasonable. Reducing the the MR requirements to 2 to 3 in the first year or at any point for new or recurrent symptoms different from baseline. Fracture-related symptoms may additionally be evaluated with CT or plain x-rays in lieu of MR.	1) This is an MR based treatment and utilization of CT alone is not recommended and this is concordant with international recommendations. Even if you have a myelogram, this does not obviate the role of MRI to determine the tumour characteristics and extent. 2) At present the recommendation is in line with international practice and recommendations. Until we have more data driven approaches to determining patient and histology specific factors to personalize followup, the primary concern in patient safety. Fractures develop most often within the first year and the risk continues in the long term. Determination of iatrogenic vs fracture associated with tumour progression requires MRI, in addition to other imaging including CT and Xray etc. Similar to follow-up practices of brain SRS, routine imaging is required given the risk associated with high dose radiation within/adjacent to critical tissues at risk of serious adverse events.

Comments	Responses
3. Contouring of the target is such an important part of the process, consider adding a citation to the Consensus guidelines on contouring for spine sbrt.	We have included contouring recommendations to Recommendation 4 and have included citations to guidelines that are recommended to guide practice.
This may be overly ambitious for guideline, but it may be important to include target delineation, target dose recommendations and current constraints for organs at risk	Thank you; however, clinical recommendations were outside the scope of this organizational guideline.
Page 5 "Multiple simulation MRI sequences may be required based on the number and location of the spinal segments to be treated to ensure accurate fusion to the treatment planning computed tomography (CT). For example, when treating a T12 and a L5 metastasis, then the simulation MRI should include as a minimum acquisition from T11 to L1 and from L4 to S1 and not one imaging set from T11 to S1." *- Do all Ontario centres use this scanning strategy?* "If a treatment-planning CT myelogram is performed then the intrathecal contrast should be injected just prior to the treatment-planning CT, such that the CT is acquired in the simulation suite with the patient immobilized in the treatment position and contrast in place. The acquisition of a diagnostic CT myelogram, which is not acquired with the patient immobilized and in the treatment position, is discouraged as fusion to the treatment-planning CT is an additional potential source of error. It is important to note that this procedure does not replace the process of acquiring treatment planning MR images for fusions." *- How long do you require the patient to lie down after the CT myelogram? In most US centres, patients are required to lie down for 2 hours.*	Yes this would be a standard of care as it is not possible to get volumetric imaging of the entire spine and fuse reliably so the areas are broken up into regions associated with the target volume. Beyond the scope to make granular medical recommendations. Practice should be based on the clinician/multidisciplinary teams recommendations and local practice.
Page 6 In postoperative cases where the patient cannot have a CT myelogram, one will need to use a treatment planning MRI to delineate target and spinal cord. Will you consider using a 1.5 T and an artifact reduction technique?	An MRI is always to be done and it is optional if a CT myelogram is to be performed if the MRI cannot allow delineation of the spinal cord or fusion impaired due to distortion etc, Myelograms are not routine and do not inform target volume delineation. Field strength is a decision the local team must make with their radiology department as the evolution of sequences continues. Therefore, firms recommendations on the strength of MRI are outside the scope.
This is the most comprehensive and evidence-based guideline on spine SBRT process I have come across. I am the medical director of a national accreditation program in SRS and SBRT in the US and am also the lead for spine disease	Thank you

Comments	Responses
site, so I am familiar with the process. This guideline is of excellent quality.	

Professional Consultation

Feedback was obtained through a brief online survey of healthcare professionals and other stakeholders who are the intended users of the guideline. All radiation oncologists in the PEBC database were contacted by email to inform them of the survey. In total, 88 radiation oncologists were contacted. 14 (16%) responses were received. 7 stated that they did not have interest in this area or were unavailable to review this guideline at the time. The results of the feedback survey from 7 people are summarized in Table 5-6. The main comments from the consultation and the Working Group's responses are summarized in Table 5-7.

Table 5-6. Responses to four items on the professional consultation survey.

	Number 7 (8%)				
General Questions: Overall Guideline Assessment	Lowest Quality (1)	(2)	(3)	(4)	Highest Quality (5)
1. Rate the overall quality of the guideline report.				3	4
	Strongly Disagree (1)	(2)	(3)	(4)	Strongly Agree (5)
2. I would make use of this guideline in my professional decisions.			1	2	4
3. I would recommend this guideline for use in practice.			1	1	5
4. What are the barriers or enablers to the implementation of this guideline report?	Not sure a "one-size-fits-all" follow-up schedule applies to all spine SBRT patients. This is a very comprehensive guideline that should be a "go to" guideline to setting up a spine SBRT program. I do not see any major barriers to its implementation. Some recommendations might be difficult to execute in health care systems with a less centralized radiation oncology. This is a well written and clear document. The only potential barrier is MRI capacity for follow-up. However, overall this is a small number of patients so I think this is surmountable.				

Table 5-7. Summary of the Working Group's responses to comments from professional consultants.

Comments	Responses
1. On page 3, "Medical dosimetrist" is listed twice.	Thank you, this has been corrected.

CONCLUSION

The final guideline recommendations contained in Section 2 and summarized in Section 1 reflect the integration of feedback obtained through the external review processes with the document as drafted by the GDG Working Group and approved by the GDG Expert Panel and the PEBC RAP.

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Appendix 1: Affiliations and Conflict of Interest Declarations

GUIDELINE DEVELOPMENT GROUP		
WORKING GROUP		
Name	**Speciality**	**Declarations of Interest**
Arjun Sahgal Working Group Chair Radiation Oncologist	Radiation Oncologist Sunnybrook Cancer Centre	Dr. Sahgal declares the following conflicts: Received any grants or other research support, either as principal or co-investigator, in any amount, from a relevant business entity: 2020 – 2022 **Co-Investigator**. Pilot RCT study on feasibility of "supra-marginal" surgical resection of malignant gliomas (G-SUMIT: Glioma Supra Marginal Incision Trial). PI: Pirouzmand F, CI: **Sahgal A**. 370,000 CAD [Grants]. 2019 - 2024 **Co-Investigator**. Ultrasound-mediated drug delivery to the spinal cord. Canadian Institutes of Health Research (CIHR). PI: O'Reilly M. Collaborator(s): Allen C, Aubert I, Fehlings M, Kerbel R, Rutka J, **Sahgal A**. 673,200 CAD. [Grants] 2019 - 2021 **Co-Investigator**. A pilot study to evaluate magnetic resonance imaging (MRI) as a tool to improve pharmacologic management for patients diagnosed with glioblastoma multiforme (GBM). Odette Cancer Centre Practice-Based Research and Innovation (PBRI) Seed Grant. PI: Nathoo D. Collaborator(s): **Sahgal A**, Tseng CL, Soliman H, Myrehaug S, Chow E, Lau A, Campbell M, Moroney C, DeAngelis C, Pasetka M, Saloojee S. 9,000 CAD. [Grants] 2019 – 2020 **Co-Investigator.** Quality of Life Research, Brain Tumour Foundation of Canada. PI: Korman M. Collaborator(s): Moroney C, Isenberg-Grzeda E, Fitch M, **Sahgal A**, Esplen MJ, Bilodeau D. 50,000 CAD. [Grants] 2019 **Co-Investigator**. Reducing the burden of brain metastases among women with metastatic triple negative or HER2+ breast cancer through early detection and intervention. Kavelman Fonn Clinical Trial Grant. PI: Jerzak K. Collaborator(s): Warner E, **Sahgal A**, Stanisz G, Pond G. 50,000 CAD (33,000 CAD + 17,000 CAD matched funds). [Grants] 2019 **Co-Investigator**. Spine stereotactic body radiation therapy (SBRT) planning: Integration and evaluation of clinical diagnostic criteria and stability assessment. Varian Medical Systems. PI: Whyne C. Collaborator(s): **Sahgal A**, Hardisty M, Yee A, Martel A. 137,500 CAD. [Grants]

		Been a principal investigator for a clinical trial involving any of the objects of study, regardless of the source of funding? 2019 – present **Principal Investigator.** The MOMENTUM Study: The Multiple Outcome Evaluation of Radiation Therapy Using the MR-Linac Study. PI: **Sahgal A**. Collaborator(s): Campbell M, McCann C, Vesprini D, Tseng CL. [Clinical Trials]. R*EB#: 110-2019* Published an editorial, commentary, or other clear opinion regarding any of the objects of study: 1. Das S, **Sahgal A**, Perry JR. Commentary: Lomustine-temozolomide combination therapy versus standard temozolomide therapy in patients with newly diagnosed glioblastoma with methylated MGMT promoter (CeTeG/NOA-09): a randomised, open-label, phase 3 trial. Front Oncol. 2020 Jan 31;10:66. **Co-Principal Author.** 2. Das S, **Sahgal A**. Contemporary Management of Intracranial Metastatic Disease. Front. Oncol. Aug 2019;9:818. **Co-Principal Author – Co-Editor.** Other Interests: Advisor/consultant with Varian (Medical Advisory Group), Elekta (Gamma Knife Icon), BrainLAB Board Member with International Stereotactic Radiosurgery Society (ISRS) Co-Chair with AO Spine Knowledge Forum Tumor Past educational Seminars with Astra Zeneca (Honorarium), Elekta AB, Varian (CNS Teaching Faculty), BrainLAB, Medtronic Kyphon Research Grant: Elekta AB, Varian Travel accommodations/expenses: Elekta, Varian, BrainLAB Dr. Sahgal also belongs to the Elekta MR Linac Research Consortium, Elekta Spine, Oligometastases and Linac Based SRS Consortia.
Tim Nguyen	Radiation Oncologist London Health Sciences Centre	No conflicts to declare
Andrew Pearce	CNS Radiation Oncologist North East Cancer Centre	No conflicts to declare
Jeff Greenspoon	Radiation Oncologist Juravinski Cancer Centre	Yes. JG has indicated that his professional income may increase or decrease by substantially more than $10,000 per year, depending on the outcome of the guideline Received any grants or other research support, either as principal or co-investigator, in any

		amount, from a relevant business entity? Yes, Accuray has provided fellowship funding for an SRS/SBRT fellow
Mark Ruschin	Medical Physicist Sunnybrook Cancer Centre	No conflicts to declare
Pejman Maralani	Neuro-Radiologist Sunnybrook Cancer Centre	No conflicts to declare
Fawaz Siddiqi	Neurosurgeon London Health Science Centre	No conflicts to declare
Kelly Linden	Radiation Therapist The Ottawa Hospital	No conflicts to declare
Sarah Kellett	Research Coordinator Program in Evidence-Based Care	No conflicts to declare
EXPERT PANEL		
Name	**Speciality**	**Declarations of Interest**
Shawn Malone	Radiation Oncologist The Ottawa Hospital	S. Malone has the following conflicts to declare: $500 or more in a single year to act in a consulting capacity – Board appointments to Jensen, Astellas, Tersera, ABBVie; Bayer; Knight; Tolmar Travel support from Tolmar and Knight totalling more than $500 in a single year
Kris Dennis	Radiation Oncologist The Ottawa Hospital	No conflicts to declare
Fabio Y. Moraes	Radiation Oncologist Queens Cancer Research Institute	F. Moraes has the following conflicts to declare: Received any grants or other research support, either as principal or co-investigator, in any amount, from a relevant business entity? Astra Zeneca – honorarium for invited lectures. Astra Zeneca – research grant Queens CTAQ research grant Published an editorial, commentary, or other clear opinion regarding any of the objects of study https://pubmed.ncbi.nlm.nih.gov/31895403/ https://thejns.org/focus/view/journals/neurosurg-focus/50/5/article-pE1.xml
Philip Wong	Radiation Oncologist Princess Margaret Cancer Centre	P. Wong has the following conflicts to declare: Received any grants or other research support, either as principal or co-investigator, in any amount, from a relevant business entity? BMS and AstraZeneca for research grants not directly related to spine SBRT

Roger Smith	Neuro-Radiologist Toronto Western Hospital	No conflicts to declare
Raj Grover	Community Radiologist Simcoe Muskoka Regional Cancer Centre	No conflicts to declare
Sunit Das	Neuro-surgeon St. Michaels Hospital	S. Das has the following conflicts to declare: Employment, regardless of salary or benefits – Provincial Lead, CNS Cancers, Ontario Health
Mikki Campbell	Radiation Therapist and Manager of Certification at the Canadian Association of Medical Radiation Technologists.	M. Campbell has the following conflicts to declare: Received any grants or other research support, either as principal or co-investigator, in any amount, from a relevant business entity: Elekta Ltd.: co-PI on unrestricted educational grants Had managerial responsibility for an organization or department that has received $5,000 or more in a single year from a relevant business entity, even if you did not personally benefit? If so, please provide the name of the organization, your capacity in that organization, and the name of the relevant business entity in the comment box: At Sunnybrook Health Sciences Centre as Manager of Strategic Initiatives with Elekta Ltd. Please describe any other interests you may have that you believe to be relevant with respect to this guidance document: AOSpine International - consultancy and services for content expertise in spine oncology and knowledge exchange/ translation

TARGETED PEER REVIEWERS		
Name	**Speciality**	**Declarations of Interest**
Simon Lo	Radiation Oncologist (Seattle, Washington, USA)	S. Lo has the following conflicts to declare: Published an editorial, commentary, or other clear opinion regarding any of the objects of study? Dunne EM, Liu MC, Lo SS, Sahgal A, the changing landscape for the treatment of painful spinal metastasis: is Sterotactic Body Radiation Therapy the new standard of care? Clin Oncol (R Coll Radiol) 2022 May; 34(5): 325-331
Paul Mendin	Medical Physicist (UT Southwestern Medical Center; Dallas, Texas, USA)	P. Mendin has no conflicts to declare
Mark Bilsky	Neurosurgeon (Memorial Sloan Kettering Cancer	M. Bilsky has the following conflicts to declare:

	Center, New York, New York, USA)	financial or material support (for example, gifts, travel, or support) of **$500** or more in a single year? Gave talks for both Varian and Novalis, with totals over $500 (2017) Published an editorial, commentary, or other clear opinion regarding any of the objects of study? Multiple papers on the integration of SRS into modern treatment paradigms for malignant primary and metastatic spine tumors

Appendix 2: Literature Search Strategy

EMBASE and MEDLINE

1. radiosurgery.mp. or exp radiosurgery/ or exp gamma knife radiosurgery/ or exp stereotactic radiosurgery/ or exp radiosurgery/ or radiosurger*.mp. or cyberknife.mp. or exp CyberKnife/ or cyber-knife.mp. or exp stereotactic radiosurgery/ or exp stereotactic body radiation therapy/ or stereotactic.mp. or sbrt.mp. or sabr.mp. or stereotactic spinal radiotherapy.mp. or stereotactic spinal radiosurgery.mp. or srs.mp. or stereotactic ablative.mp.
2. exp stereotactic procedures/
3. (sbrt or sabr).mp.
4. ((stereotactic or stereotaxic) and (body or ablat:) and radiation therap:).mp.
5. ((stereotactic or stereotaxic) and (body or ablat:) and radiotherap:).mp.
6. or/1-5
7. (Neoplasmata or metastasis or metastases or metastatic or neoplasm or neoplasms or cancer or cancers or carcinoma or carcinomas or tumor or tumors or tumour or tumours).mp.
8. (spine or spinal).mp.
9. 7 and 8
10. 6 and 9
11. (comment or letter or editorial or note or erratum or letter erratum or abstract or short survey or news or newspaper article or patient education handout or case report or historical article).pt. or abstract report/ or letter/ or case study/
12. exp animal/ not (exp human/ or humans/)
13. 11 or 12
14. 10 not 13

Appendix 3: Guideline Document History

GUIDELINE VERSION	SYSTEMATIC REVIEW		PUBLICATIONS	NOTES and KEY CHANGES
	Search Dates	Data		
Original 19<XX>	<X to X>	Full Report	Peer review publication. Web publication.	N.A.
Version <X> 20<XX>	<X to X>	New data added to original Full Report	Updated web publication.	<Add, if relevant>