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Executive Summary

Sarcomas are malignancies that arise in soft-tissue and bone. They affect all age groups, may arise in any part of the body and are rare. Sarcomas are both misdiagnosed and underreported. In Ontario there are approximately 700 new adult sarcoma cases per year. Treatment is often multimodal and complex and these individuals frequently experience significant morbidity and mortality as a consequence of treatment or disease. The goals of sarcoma management include both cure and functional preservation of involved or adjacent organs and critical structures.

Overall, the appropriate investigation, management and rehabilitation of those with sarcoma require a very high level of coordination among health care disciplines and a high level of sophistication in investigation, treatment delivery and follow up care. These resources are not widely available, and provision of appropriate care represents a significant burden on the Ontario health care system, despite the relatively small numbers treated annually.

Sarcoma care in Ontario is not organized in any formal way. Paediatric patients are usually managed in specialized children’s hospitals. This is not the case for adults. While detailed information on adult care is lacking, only approximately half the estimated numbers of incident cases are treated in specialized centres annually. As a result, inappropriate and delayed care and duplications of investigation and management occur. Similarly, treatment outcomes are not collected for many of Ontario’s sarcoma patients, and there are no formal quality assurance measures in place.

At present, there are three Ontario centres with the largest sarcoma case volumes and concentration of sarcoma-specific expertise located at University Health Network (UHN)/Mt. Sinai (Toronto), Ottawa and Hamilton.

The rarity of sarcomas has been a relative barrier to research in the field. There is limited level I evidence to inform sarcoma management, and only level III-V evidence to inform the organization of sarcoma care. One other major jurisdiction has undertaken a formal evaluation of organization of sarcoma care (National Health Service - National Institute for Health and Clinical Excellence), and their findings are incorporated into this report.

To recognize the needs in the provision of sarcoma care and to optimize care and resource utilization, Cancer Care Ontario (CCO) struck an expert panel of physicians, allied health workers and administrators. Together, they developed recommendations for the organization of the management of adult sarcoma patients in Ontario. The work was supported by CCO’s Program in Evidence-based Care (PEBC), which performed a formal search for evidence to support these guidelines, and for existing guidelines in other jurisdictions.1 Data sources available to CCO were mined to provide information on patterns of care and case costing.

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Recommendations

1. All adults with a confirmed diagnosis of sarcoma should have their case reviewed at a multidisciplinary cancer conference (MCC), and their care supervised by a multidisciplinary sarcoma team (MST).

2. Members of the MST should include experts in sarcoma from the fields of surgical oncology, medical oncology, radiation oncology, imaging and pathology. When appropriate, additional representation from nursing, physiotherapy and others may be included.

3. Community links should be established with the MST to make expert review of imaging and pathology and provision of treatment services easily accessible for those with a provisional diagnosis of sarcoma. A diagnosis of sarcoma should be made by a pathologist with expertise in the diagnosis of these tumours.

4. The MST should have sufficient case volume to maintain expertise. Specialized services and MSTs should be located in three centres in Ontario: Toronto, Hamilton and Ottawa.

5. Definitive surgical care should be provided by those with anatomy-specific expertise in sarcoma management. Where sarcoma specific expertise is unavailable, an anatomy-specific surgical expert will work in consultation with the approved MST.

6. Gynecologic sarcomas have specific management issues, and should be addressed by a gynecologic oncologist specialized in the management of sarcoma. Cases presenting with complex pelvic tumours, especially recurrence involving the pelvic side wall, should involve multidisciplinary assessment by the MST.

7. To ensure optimal outcomes there should be appropriate integration of surgery, chemotherapy and radiation treatment. In some circumstances, this care may be delegated to other centres or to the community, but will remain under the supervision of the MST.

8. Rare benign allied diseases such as aggressive fibromatosis are frequently managed like sarcomas, carrying a similar potential for functional morbidity as sarcomas, and should be grouped with sarcomas for management purposes.

9. Effective rehabilitation is an important part of sarcoma care. Access to appropriate services should be considered a priority, and facilitated.

10. The availability of a tumor bank from which to obtain tissues would assist in the evaluation of new sarcoma biomarkers, either DNA, RNA or protein, as they are identified.

11. Implementation of adequate quality assurance measures is essential for very complex treatments, and should include case discussion at the MCC, expert pathology and imaging review, and radiation quality assurance review.

12. A provincial sarcoma registry and database should be set-up to provide data on outcomes and patterns of practice; and for resource planning and utilization purposes.

13. An appropriate funding model for sarcoma services should be established to ensure sustainable service provision. Funds should support centralization of specialized services and accommodate
advancing clinical practice. Funds should also follow the patient to support collaboration between centres.

Adult Sarcoma Management in Ontario

Current State
Sarcomas are malignancies that arise in soft-tissue and bone. They affect all age groups, may arise in any part of the body and are rare. Treatment is often multimodal and complex and these individuals frequently experience significant morbidity and mortality as a consequence of treatment or disease.

Sarcomas are both misdiagnosed and underreported, and there are currently no Canadian incidence statistics for sarcoma. The adult incidence in the USA is about 1/100,000 for bone and 6/100,000 for soft tissue disease. This translates to approximately 700 new adult sarcoma cases per year in Ontario, and is consistent with 687 and 688 incident cases identified for 2006 and 2007, respectively. Available data does not indicate an increasing incidence.

Much of recent research into sarcoma management has focused on the investigation of the optimal combination and sequencing of different modalities, and use of more limited surgery or improved reconstructive techniques all aimed at preserving function while maintaining a high-level of local tumour control. The goals of sarcoma management include both cure and functional preservation of involved or adjacent organs and critical structures.

Clinical advances and increasing complexities of care have contributed to increasing pressure on the system to satisfy both treatment goals for sarcomas. This presents unique challenges in provision of optimal cancer care. These include:

- Management is usually both complex and multidisciplinary by virtue of the anatomy and natural history of the disease.
- The diversity of disease presentations requires that treatment be highly individualized while still respecting the over-riding principles of sarcoma management.
- The rarity of the disease limits the availability of appropriate sarcoma expertise in imaging, pathology, surgical, medical and radiation oncology. While data related to sarcoma treatment in Ontario are difficult to interpret, the available data estimate that in 2007, there were 149 indexed cancer surgery cases most related to sarcoma, 121 patients received systemic treatment and 294 patients received radiation treatment.
- Understanding of sarcoma and its management is limited in the general medical community. Management may be further complicated when diagnosis is delayed because initial care providers fail to correctly identify a sarcoma, or when the initial care providers undertake an inappropriate intervention at presentation.

Overall, the appropriate investigation, management and rehabilitation of those with sarcoma require a very high-level of coordination among health care disciplines and a high-level of sophistication for investigation, treatment delivery and follow up care. These resources are not widely available, and the provision of appropriate care represents a significant burden on the Ontario health care system, despite the relatively small numbers treated annually.

Sarcoma care in Ontario is not organized in any formal way. Paediatric patients are usually managed in specialized children’s hospitals, but this is not the case for adults. As a result, inappropriate and delayed care and duplications of investigation and management occur. Currently data on adult care is lacking, and a complete

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understanding of the distribution of treatment across the province is difficult to clearly articulate from available data sets. However, while some centralization of services has evolved naturally, a considerable number of patients receive treatment in areas of the province where sarcoma-specific expertise is lacking or the available resources are not utilized. (See Table 1)

Table 1: Patient distribution

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<thead>
<tr>
<th>LHIN</th>
<th>Number of Patients</th>
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<tr>
<td>Central</td>
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<td>Central East</td>
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<tr>
<td>Champlain</td>
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<tr>
<td>Essex St. Clair</td>
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<tr>
<td>Hamilton-Niagara</td>
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<tr>
<td>Haliburton and Halton</td>
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<td>Leeds and Grenville</td>
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<tr>
<td>North East</td>
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<tr>
<td>North East</td>
<td></td>
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<tr>
<td>North Simcoe Muskoka</td>
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<td>North West</td>
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<td>South East</td>
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<td>South West</td>
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<tr>
<td>Toronto Central</td>
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Similarly, treatment outcomes are not collected for many of Ontario’s sarcoma patients, and there are no formal quality assurance measures in place. Presently, the three Ontario centres with the largest sarcoma case volumes and concentration of sarcoma-specific expertise are UHN/Mt. Sinai (Toronto), Ottawa and Hamilton. These centres now treat approximately half of the sarcoma patients in Ontario, up from less than 20% in the 1990s.

The Toronto sarcoma program is one of the largest of its kind anywhere. Surgical expertise is housed at Mt. Sinai Hospital which performs the greatest number of limb salvage surgeries in Ontario, utilizing sophisticated technique and technologically advanced prostheses (other centres engaged in limb salvage surgery are Ottawa and Hamilton). Radiation therapy is provided at Princess Margaret Hospital (part of the UHN group) and the responsibility for administering chemotherapy is shared between Princess Margaret Hospital and Mt. Sinai Hospital.

In 2007/08, 87 chemotherapy patients were treated at UHN/Mt Sinai, with an approximate equal distribution between bone and soft tissue. Some of the regimens used can be among the most complex and potentially toxic employed in medical oncology; in contrast some palliative treatments can be relatively simple single drug regimens. As a leader in advancing chemotherapy treatment for sarcoma, investigational protocols comprised 21% of outpatient treatments in 2008. The referral base for sarcomas UHN/Mt Sinai is stable, however only a portion of patients who require expert care for sarcoma in Ontario actually receive it.
In addition, care is also provided for patients with aggressive sarcoma-like conditions, such as aggressive fibromatosis. These diseases have the potential for causing major morbidity, and even mortality. While required treatment is similar to sarcoma, these cases are classified as benign. They do not appear in cancer data sets, but account for 41% of the outpatient chemotherapy treatments provided at UHN/Mt Sinai in 2008.

The rarity of sarcomas has been a relative barrier to research in the field. It is extremely difficult to obtain high-level evidence to support the use of specific regimens for rare subtypes of rare diseases. Oncologists who treat sarcoma are therefore frequently required to make treatment decisions based on lower levels of evidence than are available for more common malignancies.

There is limited level I evidence to inform sarcoma management, and only level III-V evidence to inform the organization of sarcoma care. One other major jurisdiction has undertaken a formal evaluation of organization of sarcoma care (National Health Service - National Institute for Health and Clinical Excellence), and their findings are incorporated into this report.³

To recognize the needs in the provision of sarcoma care and to optimize care and resource utilization, CCO struck an expert panel of physicians, allied health workers and administrators. Together, they developed recommendations for the organization of the management of adult sarcoma patients in Ontario. The work was supported by CCO’s Program in Evidence-based Care (PEBC), which performed a formal search for evidence to support these guidelines, and for existing guidelines in other jurisdictions. Data sources available to CCO were mined to provide information on patterns of care and case costing.

The Sarcoma Expert Panel held three meetings in 2009: March 19, May 12, and June 25. Panel deliberations were informed by a review of available databases (i.e. Ontario Cancer Registry, Activity Level Records at CCO, Discharge Abstract Data/National Ambulatory Care Reporting System, hospital specific), and the evidence gathered by the PEBC. Focus was also given to each specialty area of practice (i.e. imaging, pathology, radiation oncology, medical oncology, surgical oncology, nursing, administration), a summary of which can be found in Appendix B. Additional communication with the Panel members involved teleconferences and email communication as necessary to formulate the final recommendations.

Recommendations for the Organization of Sarcoma Services in Ontario

1. All adults with a confirmed diagnosis of sarcoma should have their case reviewed at a multidisciplinary cancer conference (MCC), and their care supervised by a multidisciplinary sarcoma team (MST).
   - The MCC provides an essential quality assurance measure for all cancer care, and this recommendation is consistent with CCO guidelines.
   - The MCC should be composed of sarcoma experts from all disciplines, and should comprise the MST.
   - Expertise could be shared between MCCs through establishment of teleconferencing links.
   - The MCC should be the gateway to the MST. Access to the MCC from the community should be facilitated through community educational programs and the presence of an adequate infrastructure.

2. Members of the MST should include experts in sarcoma from the fields of surgical oncology, medical oncology, radiation oncology, imaging and pathology. When appropriate additional

representation from nursing, physiotherapy and others may be included.

- Appropriate imaging and accurate interpretation of imaging and pathology are critical to effective sarcoma treatment. Treatment is frequently delayed, or inappropriately initiated because of an inaccurate or incomplete pathologic diagnosis, and inadequate or misinterpreted imaging.

3. Community links should be established with the MST to make expert review of imaging and pathology and provision of treatment services easily accessible for those with a provisional diagnosis of sarcoma. A diagnosis of sarcoma should be made by a pathologist with expertise in the diagnosis of these tumours.

- The current gateway to the MST is generally from community surgeon to specialist surgeon, and this may be preceded by a series of events that include inadequate or inappropriate imaging, referral for non-expert pathology review, and inappropriate surgical intervention.
- Access to the MST should be facilitated through community educational programs and the presence of an adequate infrastructure and resources. This should facilitate appropriate referral to MCC and reduce the frequency of inappropriate investigations, referrals and interventions.
- Appropriate pathological diagnosis of sarcoma requires expert interpretation of highly sophisticated immunohistochemical and molecular tests. Evidence shows that non-expert pathology interpretation is frequently changed following expert review (Appendix B).

4. The MST should have sufficient case volume to maintain expertise. Specialized services and MSTs should be located in three centres in Ontario: Toronto, Hamilton and Ottawa.

- Available evidence supports the assertion that important outcomes such as local tumour control and good functional outcome are positively influenced by the experience of the treating MST. This is especially true for soft tissue sarcomas of the extremity, and retroperitoneum (Appendix B).
- While the National Institutes for Health and Clinical Excellence recommend a minimum case-load of 100/year to maintain appropriate expertise, in Ontario it is important to optimize service delivery and therefore it is recommended that three Ontario centres be designated as expert centres and location for the MST (Mt. Sinai/UHN, Hamilton, and Ottawa). It is expected that activity at these centres will grow as sarcoma care is encouraged to move from the community to the expert sarcoma centres.
- The expertise and resources needed for expert pathology review are not generally available, and should of necessity, be concentrated in a limited number of sites where there is a sufficient number of cases to maintain competence. As well, these sites should have more than one pathologist with an expertise in the diagnosis of sarcomas to allow for continuous coverage of service and quality assurance.
- Presently, Ottawa and Hamilton do not have the case load to support full-time expertise in all disciplines, and it is recognized that a mechanism should be in place for UHN/Mt. Sinai to support their MCC and MST as required.

5. Definitive surgical care should be provided by those with anatomy-specific expertise in sarcoma management. Where sarcoma specific expertise is unavailable, an anatomy-specific surgical expert will work in consultation with the approved MST.

Appropriate and expert surgical care is the cornerstone of good clinical outcomes for the majority of those with bone and soft-tissue sarcomas, and the treating surgeon should ideally be an expert in both the principles of sarcoma management and the anatomic specifics of the sub-discipline. In practice, sarcoma-specific expertise is frequently limited to orthopaedic oncologists and general surgical oncologists. In instances where a sarcoma-specific expert surgeon is not available, it is appropriate that surgery be
6. Gynecologic sarcomas have specific management issues, and should be addressed by a gynecologic oncologist specialized in the management of sarcoma. Cases presenting with complex pelvic tumours, especially recurrence involving the pelvic side wall, should involve multidisciplinary assessment by the MST.

- Gynecological oncology is an oncologic subspecialty with a history of providing highly specialized multidisciplinary and sarcoma-specific care, and the Committee recognizes that this should continue.
- Participation of gynecological oncologists at the sarcoma MCC for specific cases would encourage standardization of treatment protocols, and to promote early referral from the community.

7. To ensure optimal outcomes there should be appropriate integration of surgery, chemotherapy and radiation treatment. In some circumstances, this care may be delegated to other centres or to the community, but will remain under the supervision of the MST.

- Evidence shows that the addition of radiation and/or chemotherapy to surgery in the management of soft-tissue and bone sarcomas may improve local control, functional outcome and survival for specific individuals. Also, the sequencing and integration of all three modalities can be critical to the outcome, depending on the diagnosis, anatomic location and the extent of disease.
- As with surgery, anatomy-specific and sarcoma-specific expertise is required of the oncologists, radiation planners and therapists. In specific circumstances where this expertise is lacking, patients should be referred to a centre with the necessary expertise.
- Pre-operative assessment is critical to the proper use and integration of the non-surgical modalities, and supports the concept of a centralized, specialized MST.
- The decision to use or withhold chemotherapy should be made by a sarcoma-specific expert medical oncology member of the MST. Adjunctive chemotherapy protocols for sarcoma may be complex and intense, and should be prescribed and supervised by a sarcoma-specific expert familiar with the indications for treatment and the management of treatment related complications (Appendix B).
- In specific circumstances, aspects of treatment may be delegated to qualified community practitioners, under the supervision of the MST.
- Palliative treatment of sarcomas generally includes chemotherapy, but can also include surgery and radiation treatment. The presence of locally advanced and/or metastatic disease does not preclude curative treatment, and the decision to treat with palliative intent should be made by the MST. Palliative care of sarcoma patients may be delegated to qualified practitioners in the community following assessment by the MCC and MST.
- The decision to use or withhold radiation treatment should be made by a sarcoma-specific expert radiation oncologist member of the MST. Sarcoma radiation treatment requires expert supervision since appropriate timing of radiation treatment with respect to the other modalities, radiation dose, treatment volume and treatment technique will all potentially affect local tumour control and functional outcome. A sarcoma-specific radiation treatment centre should be resourced to provide high-precision radiation treatment to diverse anatomic sites (Appendix B).
- In specific circumstances, treatment may be delegated to qualified practitioners at a local centre, under the supervision of the MST.
8. Rare benign allied diseases such as aggressive fibromatosis are frequently managed like sarcomas, carrying a similar potential for functional morbidity as sarcomas, and should be grouped with sarcomas for management purposes.

- MSTs are also required to manage a rare group of allied bone and soft-tissue diseases which are not malignant, but have the potential to recur locally, and may result in significant morbidity and functional loss. The principles of management of these conditions are often similar to those for sarcoma.
- Formal inclusion of these rare conditions into the MCC and MST would provide for improved case identification, improved community access for treatment, and recognition that these cases place an additional burden on the MST in competition for resources.

9. Effective rehabilitation is an important part of sarcoma care. Access to appropriate services should be considered a priority, and facilitated.

- The majority of sarcomas involve the extremities. Short and long-term rehabilitation following treatment is essential to optimal recovery of function, especially with regard to physiotherapy services.
- Recovering patients require ready access to appropriate rehabilitation services, and information and guidance regarding available resources.

10. The availability of a tumour bank from which to obtain tissues would assist in the evaluation of new sarcoma biomarkers, either DNA, RNA or protein, as they are identified.

- In addition to facilitating quality assurance, the banked samples, blood and tumour, will be used to apply these new biomarkers to previously diagnosed tumours to confirm the classification of the sarcoma type.

11. Implementation of adequate quality assurance measures is essential for very complex treatments and should include case discussion at the MCC, expert pathology and imaging review, and radiation quality assurance review.

- The overall principles of sarcoma management are well-established, but the diversity of diagnoses and presentations frequently require treatment to be complex and highly individualized. Quality assurance of all aspects of decision-making and treatment delivery are essential to both the provision of high-quality treatment and the optimal use of available resources.
- Recognized quality assurance tools used in Ontario include MCC case discussion, expert pathology and imaging review, and peer review of radiation treatment plans. These should be implemented in each MST.
- Quality assurance indicators include proportion of provincial cases discussed at the MCC, and treatment outcomes, such as survival, local control and functional outcome.

12. A provincial sarcoma registry and database should be set-up to provide data on outcomes and patterns of practice; and for resource planning and utilization purposes.

- A provincial adult sarcoma registry/database would act as a unique national resource for sarcoma care and provide information on incidence, patterns of care and outcome, and would provide a unique national resource for sarcoma care.
- A research database currently housed at Mt. Sinai and accessible to other centres should be investigated for the purposes of statistical analysis and system planning.
Appendix A: Cancer Care Ontario’s Expert Panel on Sarcoma: Terms of Reference

Background
In response to cost pressures reported by Ontario’s primary sarcoma service provider, Mt. Sinai Hospital (MSH), Cancer Care Ontario (CCO) has initiated the Sarcoma Review. The Program in Evidence Based Care (PEBC), sarcoma experts, and several CCO program areas will also participate in an expert panel to provide support and to develop recommendations for sarcoma treatment in Ontario.

Mandate
The Sarcoma program review will examine Ontario’s ability to meet demand for sarcoma treatment services and to advise on action required to ensure that Ontarians receive equitable access to high-quality services now and in the future.

Specific Responsibilities
The Expert Panel will address issues of quality of care, access to services, and funding, with support from the PEBC and the Surgical, Systemic and Radiation Programs at CCO. The Systemic Treatment program will lead the program review of sarcoma treatment services available in Ontario and will involve the expertise of the disease site groups (DSG) members, the MSH, other Ontario sarcoma programs, the Systemic and Radiation Treatment Programs, and the PEBC to deliver an advisory report to the Executive Team of CCO which includes:

- Develop evidence and consensus-based guidelines for the organization of sarcoma treatment and services;
  - Availability of and/or need for evidence-based guidelines to inform the organization and operation of sarcoma treatment services
  - Actual or potential barriers to providing high-quality care
  - Recommendations regarding centralization of sarcoma services in support of quality care standards
  - Assessment of current ability to monitor quality of sarcoma treatment services
  - Recommendations for quality assurance evaluation and monitoring on sarcoma services

- Define infrastructure needs (e.g. resources, data management, reporting) to provide a comprehensive sarcoma patient management program; and feasibility of alternate service delivery models
  - Review of the current costs associated with the provision of sarcoma services, including costs of prostheses, chemotherapy, radiation treatment, surgery, laboratory, and length of stay specific to the intensive level of care these limb-salvage patients require
  - Pros and cons of existing funding mechanisms for sarcoma services
  - Recommendations for improvement in the funding model, as needed

- Provide advice to CCO, government, and providers that will ensure ongoing, appropriate access to high-quality sarcoma treatment in Ontario.
  - A mechanism for the monitoring and evaluation of access to quality sarcoma treatment services for patients across Ontario
  - Current and estimated demand for sarcoma treatment services over an appropriate planning horizon
  - Any current and future gap between demand and capacity in Ontario
  - Recommendations for quality assurance evaluation and monitoring of sarcoma services
PEBC is charged with developing the practice guideline and will include an environmental scan (international) to look for evidence, about organizing a program for a specialized population. Treatment typically involves surgery, combined with radiation and systemic therapy. However, patients often require complex management of their disease and the best organization of care has yet to be determined. The goal is to see if sarcoma treatment should occur in a centralized model of care, as opposed to a de-centralized model by determining which model provides the most beneficial health outcomes for patients. This panel will provide expert input, guidance and direction throughout the course of the Sarcoma Program Review Project.

Terms of Office
The Sarcoma Expert Panel Chair is Dr. Charles Catton. This term is estimated to be completed by the end of October 2009. The Panel will be supported by the following divisions within CCO:

Health System Planning
- To assess current planning capability for sarcoma in Ontario and advise on planning parameters and processes for the future

Public Affairs
- To advise on project plan to ensure optimal impact of the project
- To assist with formulation and delivery of final advice

Informatics
- To provide data and analysis about sarcoma demand and capacity

Regional Programs and Performance Management
- To advise on performance management mechanisms and issues regarding implementation of panel recommendations within the regional cancer programs

Systemic Treatment Program
- To oversee project management, provide support and ensure alignment with strategic initiatives within the CCO Systemic Treatment Program

Radiation Oncology Program
- To provide program input and ensure alignment with strategic initiatives within the CCO Radiation Program

Surgical Oncology Program
- To provide program input and ensure alignment with strategic initiatives within the CCO Surgical Oncology Program

Reporting
The Chair is accountable to the Executive Team of Cancer Care Ontario via the Vice President of Clinical Programs and Chair of the Clinical Council.
Meeting Schedule
The Expert Panel will meet as required to address specific issues of concern. This group is estimated to complete their work by the end of October 2009. Efforts will be made to optimize efficiency by utilizing teleconferencing, as necessary.

The Expert Panel is expected to hold three meetings as follows:

Meeting 1:
Review of terms of reference, preliminary review of available data, and agreement on next steps

Meeting 2:
Formulation of recommendations

Meeting 3:
Final approval of recommendations

Meeting Minutes
Minutes will be kept of all meetings and be distributed to all committee members and to the members of the Sarcoma Expert Panel.
Appendix B: Sarcoma Management in Specialty Areas

The following reflects the detailed discussions of the Expert Panel with regard to the sub-specialties involved in providing comprehensive sarcoma services. These discussions informed the compilation of the Panel’s recommendations.

Imaging
Imaging is an essential part of diagnosis, treatment planning, response evaluation and surveillance of patients with soft tissue sarcoma (STS). Given the rarity of STS, the wide range of sarcoma types and distribution of disease in all anatomic locations within the body, the imaging evaluation of the STS is particularly challenging.

- The interpretation of STS related imaging is difficult in itself. Without exception, patients’ significant current and past clinical history, physical findings and detailed data on any previous therapy should be provided to the medical imager prior to performing the scan.
- It is desirable that the imaging evaluation of STS, especially those within complex anatomic areas (base of skull, spine, intrathoracic, intraperitoneum and retroperitoneum) be performed or reviewed at specialized centers, and specifically by radiologists trained in principles of surgical oncology and with expertise in the appropriate anatomic site of disease. The participation of medical imagers in STS multidisciplinary rounds is of paramount importance. It ensures attainment of clinical findings vital to the interpretation of imaging findings and direct communication of imaging results to clinicians.
- Additional work-up imaging for STS is sometimes required in completing the disease assessment. This additional imaging, such as MRI, often requires specialized techniques and intensive monitoring. Conversely, a single adequately performed imaging scan might often answer all of the issues in question and additional imaging might be superfluous and result in increased delay and costs. In both cases, therefore, the consent and direct involvement of a radiologist with expertise in both STS of a specific anatomic region and the indicated imaging modality, will result in appropriate use of resources and ensure quality results. Decisions as to the imaging method of follow-up should similarly be made in consultation with the said imaging expert.
- The choices of imaging modalities for STS depend on the specific disease and its anatomic location. In some cases, specialized modalities as MRI and PET scanning and techniques such as tumour perfusion and diffusion evaluation scanning are indispensible and should be available to the patient.
- Quality assurance is an integral part of any diagnostic field. Appropriate quality assurance measures must be in place to ensure and verify optimal outcomes, including accuracy of diagnosis and prediction of disease extent.

Surgical Oncology
Surgery is the mainstay of sarcoma management, both for primary tumors of bone and soft tissue. Surgery is the sole treatment modality for many bone sarcomas (e.g. chondrosarcoma) and soft tissue sarcomas (e.g. small and superficial extremity sarcomas, and some retroperitoneal sarcomas). Treatment of sarcomas by surgery alone should take place by a surgeon with sarcoma-specific expertise in a designated sarcoma center under the auspices of a sarcoma MST. However, the majority of bone and soft tissue sarcomas in all anatomic locations, including extremity, retroperitoneum and other less common locations require multidisciplinary treatment, or at least multidisciplinary consultation, which should be organized pre-operatively to allow the best sequencing of treatment modalities to optimize patient oncologic and functional outcomes. For example, bone sarcomas including osteosarcoma, Ewing sarcoma and non-osteogenic spindle cell sarcomas require treatment with surgery and chemotherapy and less commonly radiation, with chemotherapy being the optimal initial modality. In comparison, local management for most soft tissue sarcomas includes pre-operative radiation followed by surgery, with chemotherapy being used less frequently.

Sarcoma-Specific Surgical Specialists
For sarcomas located in the extremities and retroperitoneum, the two most common anatomic locations, sarcoma-specific surgical specialists are already in place at the three surgical sarcoma centers in the province, which each have multidisciplinary sarcoma teams. Surgical oncologists with retroperitoneal expertise are also in place at these three centers, however, multidisciplinary care for these very complex patients is not as well developed or as consistent at each center as already exists for the extremity population. Sites that will continue to provide care for patients with retroperitoneal sarcoma will need to develop better multidisciplinary pathways to ensure coordinated care is both available and provided to these patients to ensure best outcomes. For patients with sarcomas in less common anatomic locations, their management should be directed by the sarcoma MST in conjunction with surgeons having anatomy-specific expertise (e.g. ENT surgical oncologists for head and neck sarcomas).

**Tumour Prosthesis Implants**

The use of tumour prostheses for limb salvage surgical procedures has been steadily increasing over the past decade and a half. With more advanced radiologic imaging, better understanding of sarcoma biology, better chemotherapy and radiation, limb salvage rates have been progressively increasing while amputations are now infrequent. In the 1990s, approximately 60% of patients were candidates for limb salvage while 40% required an amputation. Currently, almost 95% of patients undergo limb sparing surgery. For paediatric bone sarcomas, “growing” or expandable tumor prostheses have recently become available which allow progressive lengthening of the prosthesis to match physiologic skeletal growth in the opposite limb. In addition, patients with metastatic cancer are also living longer and presenting to orthopaedic sarcoma specialists with more advanced osseous disease. These patients frequently require complex limb reconstructive surgeries necessitating implantation of sarcoma tumor prostheses. All these clinical reasons have led to increased use of expensive limb salvage tumour prostheses.

**Non-Cancer Diagnoses Treated by Sarcoma Specialists**

There are a large number of benign bone (e.g. fibrous dysplasia, aneurysmal bone cyst) and soft tissue tumours (large/deep lipomas and atypical lipomatous tumors, aggressive fibromatosis, extensive pigmented villonodular synovitis) which are all referred for management to sarcoma centers as they require sarcoma-specific surgical expertise and frequently multidisciplinary consultation and management as well. Although not malignant, these diagnoses have in common with sarcomas the potential to recur, the need for specialized multidisciplinary care and treatment protocols that may result in significant morbidity and functional loss. Their costs to hospitals can be high, similar to other bone and soft tissue sarcomas.

**Allograft and Bone Graft Substitutes for Reconstruction**

Allograft bone from accredited Tissue Banks is another major non-recoverable cost for sarcoma programs. Allograft bone is frequently required for reconstruction of major bone defects following sarcoma resection. Allograft bone and bone graft substitutes are also frequently needed for osseous reconstruction following resection of many types of benign bone tumours.

**Complications of Limb Salvage Surgery**

Complications of limb salvage surgery remain a frequent problem leading to morbidity for patients. Revision procedures following index cancer surgery for sarcomas do not count towards incremental surgical oncology volumes, yet their costs to the hospital are often higher than the original index sarcoma surgical procedure. Going forward, costs for complications of sarcoma treatment need to be included in surgical oncology or sarcoma-specific funding. For bone sarcomas, revision surgery for complications such as mechanical failure may require partial replacement of an expensive prosthesis, while treatment for infection usually requires removal of the original implant as part of a two-stage exchange procedure requiring insertion of a brand new implant during the second operation. With the common use of preoperative radiation to facilitate best functional outcomes for patients following combined surgery and radiation for soft tissue sarcoma, up to 35% of patients suffer major wound healing complications. These patients often require prolonged and repeated hospitalizations, repeat surgery often requiring free and rotational tissue transfers, as well as prolonged wound care and rehabilitation in
hospital as well as in the community. There are increasing numbers of spontaneous long bone fractures related to the late effects of previous radiation and surgical treatment of extremity sarcoma. These fractures are difficult to treat and often require numerous operations and expensive limb salvage tumour prostheses for reconstruction. Resection of retroperitoneal sarcomas can be even more complex than in the limb, with complication rates reaching 50%.

**Extended Length of Stay for Sarcoma Patients**

Following extremity sarcoma surgery, patients require complex sarcoma-specific physiotherapy which is not typically available outside of large centers providing sarcoma specialty care. This is particularly true for the majority of patients following bone sarcoma resection and prosthetic reconstruction, and often necessitates keeping patients in the hospital longer, and then trying to transition them with a physiotherapist in the community. In addition, following major resection of pelvic bone sarcomas, pelvic and retroperitoneal soft tissue sarcomas, and after sarcoma procedures requiring free tissue transfers to allow limb salvage or closure of major soft tissue defects, patients often require long periods of bed rest post-operatively leading to longer than expected hospitalization. Since sarcomas are so rare, there are no sarcoma-specific Canadian Institute for Health Information (CIHI) codes against which this can be realistically compared for length of stay analysis.

**Patient Navigator**

Sarcoma care is frequently very complex with patients being treated by surgeons, radiation and medical oncologists, pharmacists and physiotherapists to name but a few. Treatment protocols are complicated and complications of treatment are frequent. For all these reasons, sarcoma patients would be well served by a patient navigator/oncology case worker within the major sarcoma programs to help coordinate their care. Currently there is no health care individual available to take on this responsibility within sarcoma programs, which leaves gaps in patients’ continuity of care.

**Quality Assurance**

Specific to the surgical management of sarcomas is an ongoing assessment related to treatment outcomes including local and systemic disease control, surgical complications, as well as assessments related to function and quality of life. Establishment of a provincial sarcoma database would allow all three adult sarcoma centers to collect and compare the same data elements to assist in prospective documentation of patient outcomes.

**Nursing**

The patients and families that are diagnosed with and undergo specialized cancer treatment for sarcoma deserve the most current, seamless and coordinated cancer services available. To this end, the value provided to the patient, his or her family and the rest of the specialized oncology team is augmented by the addition of an advanced oncology registered nurse with advanced education preparation.

The Canadian Association of Nurses in Oncology (CANO) supports the advanced oncology nurse as one of three competency-based oncology nursing roles⁴. This individual is prepared at a Master’s level (MScN or equivalent), ideally with an oncology specialty. Furthermore, additional certification as an acute care nurse practitioner is desired and specialty certification oncology is also strongly suggested.

The domains of the advanced oncology nurse dovetail nicely with the work being done to enhance the approach to care for paediatric or adult patients diagnosed with sarcoma. Specifically, the domains supporting the role of the advanced oncology nurse in sarcoma management:

- Advanced clinical practice is necessary to liaise with all of the members of the multidisciplinary team. This may also require the nurse to work in more than one institution depending on the patient population

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⁴ Canadian Association of Nurses in Oncology, *Roles in Oncology Nursing*, p. 4
(e.g. paediatric, adult or both). Furthermore, navigation through the cancer care continuum begins when the person first enters the cancer care system and continues as the individual receives treatment and care, returns to their own community, and then re-enters the system as necessary.  

- Education of the team as a whole and the advanced oncology nurse is specific to sarcoma as a disease but also to provide care that is based upon theory, science (physiologic and psychological sciences), and incorporates principles of evidence-based practice, best practice or available evidence.  
- Research as an independent team member and as a part of the team as a whole, is within the role of the advanced oncology nurse and further supports access of the patient and family to the most current information related to sarcoma care.  
- Leadership is a core component of the competencies of the advanced oncology nurse and is essential to individuals undergoing patient-centred, individualized multidisciplinary sarcoma treatment as healthcare environments are increasingly complex. Strong and effective nurse-leaders help to ensure that the patient receives care from appropriate providers and resources are allocated to support quality of life. Leaders also work towards change at an operational level within organizations and at the level of policy-making, in order to facilitate improvement in the system as a whole.  

Pathology  
There are a number of studies that when taken together demonstrate that having a pathologist with expertise in the diagnosis of sarcoma on the MST is critical for the proper treatment of the patient.  

The essential findings of these studies include:  
- In up to 22% of tumours there was a change in the diagnosis from sarcoma to non-sarcoma when a case was reviewed by a sarcoma pathologist.  
- 9% of malignant cases were reclassified as benign and conversely, 6% of benign tumours were reclassified as malignant following review by an expert.  
- Re-evaluation of biopsies by an expert sarcoma pathologist can result in changes to the diagnosis that results in alterations in treatment and prognosis.  
- In 40% of sarcomas sent for a second opinion 19% of these were not reviewed by a pathologist with expertise in sarcomas. This confirms the need for a mechanism to ensure that cases are referred to a pathologist with the appropriate expertise.  
- The literature suggests that more than one pathologist, with similar expertise, should review difficult cases as diagnosis error rates drops from 4% to 0.5% when a case is shown to another expert pathologist.  

In total these studies confirm the necessity for a pathologist with sarcoma expertise to ensure proper treatment of the patient. This will also ensure proper handling of the specimen to ensure that the treating clinician will receive all the information necessary for patient care. While the use of telepathology and digitized slides can facilitate specialist pathologist review and participation in multidisciplinary tumour boards, there are several pressures that limit access to an expert consultation.  

Molecular Analysis  
Molecular evaluation of sarcomas has become the standard of care within the past five years. Ongoing studies have indicated that genetic profiling may be a more accurate way to classify sarcomas and we will need to incorporate this into practice. At present not all cases require this analysis as chromosomal translocations have not been identified for all sarcomas. As practice evolves and services become centralized to areas of expertise

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5 Canadian Association of Nurses in Oncology, Rationale for Standards of Care, p.2  
6 Canadian Association of Nurses in Oncology, Rationale for Standards of Care, p.4  
7 Canadian Association of Nurses in Oncology, Rationale for Standards of Care, p.4  
8 Thway and Fisher, Sarcoma, 2009  
9 Lenhardt et al, JSO, 2008
these costs would increase.

**Specialized Equipment**

Specialized equipment is necessary for the processing of sarcomas as these tumors can occur in bone, a very hard tissue that requires different processing techniques than those used for soft tissue, before the specimen can be cut into sections for histological evaluation. Equipment supplies such as Faxitron, a decalcification machine, and heavy duty microtomes are necessary for appropriate handling of sarcoma specimen. Having the proper equipment will help in the retention of specially trained technologist and pathology assistants, with expertise in this area and who are critical for this type of processing.

**Quality Assurance**

Advances in the treatment of sarcoma will only come from advances in our understanding of disease biology. Expertise and resources must be available to evaluate new tumour markers as they become available and ensure standardization and validation of technique. A tumour bank will be helpful in establishing the prognostic and predictive value of new markers.

Histology review by a pathologist with sarcoma expertise is critical for quality assurance. Having sufficient numbers of pathologists at each site (Mt. Sinai has three, Hamilton and Ottawa each have one) may be problematic given the limited tumour volumes. It may be necessary to partner with another Centre of Excellence to facilitate second opinions/consultations for difficult cases and provide backup during vacation and illnesses. This could be facilitated by whole slide imaging and telepathology, and established in such a way as to also allow for remote participation in tumour board rounds.

**Personalized Medicine**

As discussed, improved understanding of disease biology will drive advances in sarcoma treatment. To this end evaluation of the tumour/patient genomic profile is critical. Although not yet the standard of care, it is clear within the next few years that tumours will be analyzed and classified by SNP arrays and gene expression arrays as the literature is beginning to indicate that this is a more accurate way to classify tumours. This type of analysis will also be able to predict responsiveness to therapy (pharmacogenetics). We will need to have this capability if we wish to deliver state-of-the-art care to sarcoma patients. The role of proteonomics in diagnosis and treatment is as yet unknown.

**Medical Oncology**

Chemotherapy is used as (neo) adjuvant-curative and palliative treatment for patients with soft-tissue and bone sarcomas. While this is a much more “portable” therapy when compared with surgery or radiation therapy, expertise for appropriate management of sarcoma patients is not widely available. As in radiation therapy and sarcoma surgery where major expertise and technical support are required in order to deliver expert care, medical oncology sarcoma-specific expertise is required to optimize patient outcomes. It is impossible to envision a system or program wherein diagnostic expertise (imaging, pathology) and loco-regional therapeutic interventions are concentrated in one venue with systemic therapy being dispersed or in isolation. In order to provide a consensus opinion on this matter, six medical oncologists identified as “leads” from six different institutions and geographic locations within Ontario were engaged in discussions that focussed on the desirability and potential impact on patient care, clinical outcomes, opportunities for improvement in sarcoma specific outcomes and for meaningful contributions to research if sarcoma care were to be delegated to “high volume” institutions only. Three themes emerged from these discussions that support this concept; the need for expertise and familiarity with sarcomas, recognition of the uniqueness of sarcoma systemic therapies, and the need for research and progress.

**The Need for Expertise and Familiarity with Sarcomas**
Sarcomas in adults are among the rarest of human malignancies. Added to this is the vast number of histological and anatomical subtypes, each of which poses unique diagnostic and therapeutic challenges.\(^{10}\) \(^{11}\) \(^{12}\) \(^{13}\) It is widely acknowledged that the majority of medical oncologists have limited experience or training in the management of sarcomas and familiarity with sarcomas is difficult if not impossible to achieve when only the odd patient is seen from time to time. While consultation with peers at higher volume centres might permit the procurement of advice on the management of individual cases, in the majority of centres this does not translate to “expert” or even “best” care. A lack of familiarity with specific, recommended sarcoma treatment protocols and their potential risks or complications, may in fact prove dangerous to patients and potentially lead to an adverse effect on patient outcomes. In a field where the benefits of systemic therapy are controversial, guidelines themselves are prone to interpretation and bias, particularly by those who are inexperienced in the field. This is of critical importance, as systemic treatment has been demonstrated to have a significant impact on patient outcomes, including survival, when it is prescribed correctly in particular circumstances.\(^{14}\) \(^{15}\) For example, neoadjuvant chemotherapy in patients with osteosarcoma has dramatically altered long-term survival\(^{16}\) \(^{17}\) \(^{18}\) \(^{19}\), as has targeted therapy with tyrosine kinase inhibitors for patients with metastatic gastrointestinal stromal tumours (GIST).\(^{20}\) In the absence of new systemic treatment developments, progress in health-related outcomes for sarcoma patients (freedom from distant relapse and improvement in overall survival) is dependent on the appropriate application of existing therapies.

**Recognition of the Uniqueness of Sarcoma Systemic Treatments**

The systemic treatment used for the treatment of soft tissue and bone sarcoma are among the most unique, complex and challenging regimens developed in the field of solid tumour malignancies. These range from simple ones such as single agent doxorubicin, to more complicated ones such as intermediate or high-dose ifosfamide delivered in hospital with appropriate hydration and urothelial protection, to highly complex regimens involving high-dose methotrexate which may require in-hospital monitoring of drug levels and appropriate measures to reduce toxicity.\(^{21}\) \(^{22}\)

Recent development of histology-specific treatments requires oncologists to be familiar and up to date and to possess specific expertise in prescribing and monitoring. Most notably, this has occurred in the management of

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GIST, where the advent of imatinib has led to a greater than fourfold increase in survival in patients with metastatic or unresectable disease. Following imatinib, there has been an exponential increase in knowledge and therapeutic options, including other tyrosine kinase inhibitors, requiring awareness, knowledge and expertise on the part of oncologists involved in the management of this rare disease. Similar progress has been made in the management of patients with uterine leiomyosarcomas, in whom the identification of a unique combination involving gemcitabine and docetaxel provokes a high response rate, including complete responses.23 24 25

The Need for Research and Progress
Patients with high-risk soft tissue sarcomas have at least a 50% chance of developing subsequent metastatic disease with its grave impact on overall survival. Adjuvant systemic treatment has been demonstrated in two meta-analyses to provoke a meaningful improvement in disease-free and overall survival, although the absolute benefit of such therapy is small and less than 10%. This highlights the absolute need for progress in this field. Improvements in survival in these patients will only come with better systemic therapies in the adjuvant or metastatic settings. In general, the future of systemic therapy of sarcoma lies in histology-specific therapy. It is highly likely that future therapies will cost more and that previously untreatable patients with specific histologies will become candidates for new treatments. In a rare disease, with even rarer subtypes, such progress requires international collaboration. This paradigm shift is already occurring as evidenced by the development of tyrosine kinase inhibitors for the treatment of GIST, gemcitabine and docetaxel combinations for uterine leiomyosarcomas, trabectedin for the specific management of lipo and leiomyosarcomas and paclitaxel for the management of angiosarcomas. A concerted effort is required at accrual of patients to clinical trials which would be facilitated by an unbiased approach to research at high volume centres, rather than the submission of one or two patients per year from low volume centres.

Systemic treatments for sarcomas have become increasingly expensive. In part this is attributable to drug costs as the available drugs have clearly expanded from single agent doxorubicin to more challenging and much more expensive regimens that include combinations with ifosfamide or taxanes. Expert delivery of such therapies frequently requires supportive measures such as growth factors, hospitalization or drug level monitoring. When considered for the occasional patient at a ‘low volume’ center, unit costs may be absorbed more readily. However, due to lack of available expertise, it is increasingly common for sarcoma patients to seek opinions and therapy or to be referred to ‘high volume’ or more experienced centers, and the ensuing costs for such centers become unsustainable. Assignment of sarcoma care to ‘high volume’ centers will not only permit excellent, uniform multidisciplinary care of all patients in the province but should also lead to a more judicious allocation of resources.

Radiation Oncology
Radiation treatment is an essential adjunct to surgery for STS, both for optimizing local control26 27 28 29 and functional outcome30 31.
• The effective integration of surgery and radiation treatment for the treatment of STS requires multidisciplinary pre-operative consultation and close collaboration and cooperation between all disciplines. This is essential to appropriately select patients for combined treatment, to select the optimal sequencing of modalities and to minimize the risk of additive treatment-related toxicities.

• STS may arise in any anatomic location, and both disease specific expertise and anatomy specific expertise are required to treat all patients with STS effectively. The depth and breadth of experience and expertise necessary to treat every patient will only be found in the largest and most highly specialized centres. It is appropriate that patients with the rarest and most complex sarcomas be referred to these centres for management. Examples of these would include some sarcomas involving the spine, base of skull, head and neck, intra-thoracic and retroperitoneal anatomic sites.

• Similarly, highly sophisticated technical radiation treatment requirements are necessary to provide optimal radiation treatment care for the largest number of patients with sarcoma. For all patients, these requirements include an adequate infrastructure to provide expert disease specific imaging and pathology support, 3D treatment planning capability, sophisticated immobilization capability, IMRT capability, and volumetric soft-tissue on-line verification capability. For selected cases, MRI image fusion capability, 4D treatment planning capability, CNS stereotactic and body stereotactic radiation treatment are required.

• Appropriate quality assurance measures must be in place to ensure and verify optimal outcomes. These include expert imaging, pathology, surgical and medical oncology consultation, multidisciplinary tumour board discussion, pre-treatment peer review of radiation treatment plans, and periodic evaluation of long term outcomes.


## Appendix C: Expert Panel Members

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<tr>
<th></th>
<th>Name</th>
<th>Qualification</th>
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