Cancer Care Ontario

Action Cancer Ontario

Managing System Pressures for Sarcoma Service Delivery in Ontario

Expert Panel Report 2009

Ontario

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Table of Contents

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Introduction

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, and, in Ontario, approximately 700 new adult sarcoma cases per year are registered. Treatment is often multimodal and complex and these individuals frequently experience significant morbidity and mortality as a consequence of treatment and/or disease. The goals of sarcoma management include both cure and functional preservation of involved and/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 heath care system despite the relatively small numbers treated annually.

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 management of adult sarcoma patients in Ontario. The work was supported by CCO's Program in Evidence-based Care (PEBC), who 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. This report follows the companion piece *Expert Panel Report: Adult Sarcoma Management in Ontario*.

The incidence of sarcoma in Ontario is not expected to grow. That said sarcoma diagnosis and treatment is becoming increasingly complex and expensive, as for many other types of cancer. Sarcoma treatment has made great advances in recent years. More sophisticated methods of diagnostic assessment, more aggressive chemotherapy, improved radiation and surgical technique supported by the availability of high-quality prosthesis have improved care and patient outcomes.

Sarcoma services in Ontario are not currently delivered in a coordinated fashion. Three centres treat the largest volume of adult sarcoma patients: Ottawa, Hamilton and Toronto (Mt. Sinai/UHN)). Toronto (Mt Sinai/UHN) being the largest and most comprehensive of the treatment centres. No formal relationships exist between these expert centres and other hospitals in the Province. Ontario needs an organized system of sarcoma services to ensure wide access to the appropriate expertise and resources needed to provide high-quality patient care and efficient service delivery.

The informal development of a sarcoma care program in Ontario led to unintended system challenges. For example, the Mt. Sinai hospital has long been involved in sarcoma care, and after affiliation with Princess Margaret Hospital (PMH) in 1995 became the Centre for Excellence for sarcoma surgery and pathology in Ontario, and one of the top sarcoma care centres in North America. However, as a designated non-cancer centre facility, this work has not been adequately resourced. Three areas of care have been identified which require additional resources and support as Ontario sarcoma programs mature and continue to advance care:

- Molecular diagnostics and expert pathology review
- Delivery of newer, more expensive chemotherapy regimens

[1] Catton C, Coakley N, Verma S, Messersmith H, Trudeau M, *Multidisciplinary Specialist Care for Sarcoma: Evidence Summary*. Evidence-based Series #11-9. Cancer Care Ontario. May 2010.

- Prosthetics for limb salvage surgery

Molecular Diagnostics and Expert Pathology Review

Studies confirm that it is essential to have a pathologist with sarcoma expertise to provide optimal sarcoma care, however several pressures exist that limit access to expert consultation.

Consult review and funding

Most community hospitals do not perform a complete pathological analysis for sarcoma patients because they lack the expertise and numbers to warrant the purchase of the necessary reagents and/or specialized equipment (electron microscope). These community hospitals will either perform a more limited examination with the resources they have available, or refer the case to another site, which is not always a Centre of Excellence for a second pathology opinion. We need to ensure that all cases are referred to a Centre of Excellence for review by a pathologist with expertise in sarcoma diagnosis. To ensure there is always pathology coverage it may be necessary for sites other than Mt. Sinai (which has three pathologists onsite) to partner with another Centre of Excellence to facilitate second opinions/consultations for difficult cases/backup during vacations 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 multidisciplinary cancer conferences. Support for pathologists' time and this technology will be necessary. OHIP billing for reimbursement of the technical costs (technical fees) incurred during the evaluation of referred-in consult cases has recently been removed. The inability of the reference centre to recover their technical costs limits their ability to provide essential pathological assessments for all sarcoma patients diagnosed in the community.

Costs include expenses generated by immunohistochemical staining which is required in most cases and molecular analyses. Also, part of these additional costs would be related to the increased numbers of cases that are referred in from designated non-sarcoma sites in the province.

Molecular analysis of sarcomas

Molecular evaluation (examining DNA/RNA) of sarcomas has become the standard of care within the past five years. Ongoing studies show that genetic profiling may be a more accurate way to classify sarcomas and guide management, and this is already being incorporated into practice elsewhere.

Currently, there is no molecular analysis billing and no incremental monies have been provided for this testing. Pathology department funding is obtained from the hospital global budget and incremental billing for molecular analysis has not been provided to date (the money comes from global budgets). These funding envelopes have also been subject to budget cuts as demonstrated by a 10% reduction at Mt. Sinai hospital last year. It is becoming increasingly difficult to support the existing molecular tests and impossible to establish new tests necessary for the proper diagnosis and management of sarcomas.

Not all cases require molecular analysis. However, as services become centralized to areas of expertise these departments will experience cost increases that their department cannot absorb.

Personalized medicine

Advances in the treatment of sarcoma will only come from greater understanding of disease biology. Evaluation of the tumor/patient genomic profile is critical to the delivery of state-of-the-art care. This type of analysis will also permit prediction of responsiveness to therapy (pharmacogenetics and radiogenetics).

Clearly as the results from these methodologies are better understood and they are applied more widely, the number of cases requiring this analysis will increase.

Delivery of Newer, More Expensive Chemotherapy Regimens

Advances in chemotherapy treatments have come in recent years and systemic therapies for sarcomas have become increasingly expensive. In part this is attributable to drug costs as the available drugs have clearly expanded. Therapies for sarcomas 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 (one of the cornerstones of osteosarcoma treatment) which may require in-hospital monitoring of drug levels and appropriate measures to reduce toxicity.

The most notable progress has occurred since the release of imatinib for metastatic GIST in 2002. This has led to a greater than four-fold increase in survival in patients with metastatic or unresectable disease. More recent advances include expanded use in the adjuvant setting.[2]

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. Of note, in 2003 Grier et al. demonstrated significantly improved outcomes in Ewing's sarcoma with the addition of ifosfamide and etoposide to the standard chemotherapy regimen,[3] and this practice has since been adopted for a variety of other sarcomas.

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. Though expensive and toxic, this regimen is regarded by sarcoma oncologists as the premier therapy to be offered to patients with this histological subtype.

Funding for the cost of systemic treatment drugs in Ontario is currently provided through a mix of mechanisms including the New Drug Funding Program (NDFP), hospital global budgets and C1S per case funding to cancer centres for outpatient treatments. Etoposide, ifosfamide and docetaxel containing regimens are the most expensive, not reimbursed through the NDFP, and are not likely to be addressed through this mechanism in the future due to the relatively small number of patients affected. As a non-cancer centre ineligible for C1S per case funding, Mt. Sinai has faced considerable pressure in the last several years in providing these treatments.

On the leading edge in the utilization of advancing chemotherapy protocols, Ontario facilities have been challenged to fund the costs of these treatments. For example, Mt. Sinai hospital has been supported with a specific allocation of funds from CCO to cover the cost of drugs for the last several years.

Implementing a transparent and sustainable funding structure for sarcoma chemotherapy is required to support ongoing high-quality care in Ontario.

Prosthetics for Limb Salvage Surgery

The use of tumor 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. In addition, more patients with metastatic cancer are being managed.

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[2] DeMatteo et al, Adjuvant imatinib mesylate after resection of localized, primary gastrointestinal stomach tumour: a randomized, double-blind, placebo-controlled trial. *Lancet 2009;373:1097.104.*

[3] Grier et al, Addition of Ifosfamide and Etoposide to Standard Chemotherapy for Ewing's Sarcoma and Primitive Neuroectodermal Tumor of Bone. *N Engl J Med 2003*; 348:694-701.

Many of them are living longer, presenting with more advanced osseous disease and require tumour prostheses for reconstruction.

The cost of limb salvage prostheses has also continually increased as manufacturing modifications have been implemented to help minimize complications and improve functional outcomes. Based on advances, newer prostheses provide significant advantages for patients yet often come with higher costs. Much of these improvements have been based on the progressive work being done in Ontario. For example, the Toronto Sarcoma Group was instrumental in identifying a major manufacturing flaw in the commonly used Kotz Tumor Prosthesis System which led to a major change in stem design. As a result of this research, the fixed-hinge joint design of the older style tumor prostheses has changed to a rotating-hinge type of joint which should help minimize mechanical complications requiring revision surgery and improve patient function. Until recently, a very inexpensive type of one-size-fits-all shoulder prosthesis known as a long stem Neer was used for proximal humerus reconstruction but this is no longer being manufactured. In its place, the Stryker Proximal Humerus Prosthesis system, which is modular and easier to use, has become the standard worldwide. Another shoulder innovation came with the Stanmore Reverse Proximal Humerus Prosthesis which provides superior shoulder function in specific instances and has become the standard of care in these situations. Each prosthesis design modification and innovation has led to new state of the art implants which are significantly more expensive. Typically once these changes are implemented, older less expensive options are no longer manufactured or available for use.

There have also been a few recent new additions to options for tumour prosthetic reconstruction which provide better functional results for anatomic areas where none were previously available. In addition, some recent design options are used infrequently because of cost alone. For example, research has shown that silver coating of tumor prostheses can decrease infection rates thereby minimizing revision surgery. However the cost of silver coating is currently so high, that it isn't feasible to use this innovation in our current health care system where prosthesis costs are already such a burden on operating room budgets.

Recently (in 2009), allografts provided by the Bone Bank, commonly used for reconstruction of specific types of defects, began to be invoiced directly to the hospital. This is yet another new cost which is not considered in the surgical oncology incremental funding formula, and therefore provides yet another financial burden on hospitals with sarcoma surgical programs.

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.

All these reasons have increased usage and related costs. Ottawa, Hamilton and Mt. Sinai all perform limb salvage surgery. Pressures at Mt. Sinai have been the most significant with program growth over the past several years (due to both increased number of cases, improved technology). With increased centralization of services and management by the multidisciplinary sarcoma team (MST) specialists, volumes are expected to increase.

Recommendations for Managing System Pressures for Sarcoma Services in Ontario

1. **CCO and the Ministry should investigate the appropriate funding mechanism required to support specimen sample review by an expert sarcoma pathologist who is part of a multidisciplinary sarcoma team (MST) and,**
    a. **that pathologist should be supported with appropriate infrastructure, including resources for molecular testing,**
    b. **molecular analysis is critical to current sarcoma care and reimbursement should align with any Ontario genetic strategy.**

2. **Care for sarcoma patients should be reimbursed at the same rate for Cancer Centres or non-Cancer Centre hospitals when care is provided by members of the MST.**

3. **The cost of prosthesis implanted in limb salvage surgery should be reimbursed on a per case basis, when implanted by a surgical oncologist who is part of a MST.**

4. **A performance management process should be implemented at CCO to monitor and evaluate quality indicators and access to care for sarcoma services funded under these recommendations.**

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