The Use of Proton Beam Therapy in Canada, the United Kingdom, and Australia: An Environmental Scan of Funding, Referrals, and Future Planning
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Funding: CADTH receives funding from Canada’s federal, provincial, and territorial governments, with the exception of Quebec.
Context

Proton beam therapy (PBT) has been described as a technological innovation that may have the potential to disrupt and transform approaches to cancer treatment. However, its high cost and an absence of evidence to support its clinical effectiveness — for many types of cancer — has resulted in limited patient access and raised questions about its value in real-world settings. Nonetheless, its global adoption has been rapid. There are 63 facilities providing PBT worldwide, an additional 32 facilities are under construction, and 16 more are in the planning stages of development.

PBT is an advanced radiation treatment technology that is intended to reduce the radiation dose to surrounding healthy tissue compared with photon radiotherapy. This may improve short- and long-term patient outcomes, and increase capacity to treat pediatric patients and those with cancer who would be untreatable with photon therapy due to proximity to radiosensitive structures.

At this time, there are no PBT treatment centres in Canada. Patients requiring treatment are referred to out-of-country facilities. One research facility in Vancouver provides PBT for the treatment of intraocular melanomas, but all other cancers require PBT equipment that is only available in other countries. However, Health Canada approved the Mevion S250 in 2015. The Mevion S250 is expected to treat approximately 350 patients per year, and can be used to treat cancers other than intraocular melanomas.

Older, multi-room PBT systems require the physical space of a football field and cost around $200 million. The Mevion S250, by comparison, is a single-room system that costs approximately $25 million. Its size allows for integration into existing hospitals, and improves access to radiation oncology and medical oncology services and expertise. It is unclear if retrofitting a Mevion S250 would require extensive structural changes to an existing facility.

The extent of the clinical demand in Canada for this therapy is unclear. This is likely due to the fact that many of the provinces that fund it only refer the highest-priority patients. In some instances patient cases may be too complex to be treated out of country. As well, the treatment program requires patients (and their caregivers) to be away from home for up to eight weeks, which for some families is not an option. As such, if PBT were available in Canada more patients may be referred by physicians, and more patients and caregivers may accept the treatment.

The purpose of this Environmental Scan is to provide information on the use and funding of PBT that may be useful for strategic planning purposes at the provincial and national level.

Objectives

This CADTH environmental scan reports on the criteria used to select patients for out-of-country referrals across Canadian provinces. It also compares Canadian practice with those of two other countries with similar, publicly funded, health care systems.

This report summarizes information obtained through a literature search and a survey of key informants. The objectives of the Environmental Scan are to:

1. Identify which jurisdictions are considering installing PBT, making decisions on which patients should receive PBT, and sending patients out of country for PBT.
2. Determine how out-of-country PBT is funded.
Methods

The findings presented within this Environmental Scan are informed by responses to the Proton Beam Therapy Survey (Appendix 1), gathered between November 4, 2016, and January 14, 2017, and by a limited literature search.

The literature search was conducted to identify relevant literature from other countries on their practices regarding PBT. Citation searches were made for key references, and reference lists from relevant papers were scanned to identify additional papers. Grey (unpublished) literature was identified by searching relevant sections of the Grey Matters checklist (http://www.cadth.ca/resources/grey-matters).

Survey responses were collected from key jurisdictional informants involved in the management of patients with cancer or the funding of the therapy. Informants were identified by CADTH staff, through professional and clinical networks, or referred through other respondents. A 14-question survey was developed and revised following internal review. The final survey was distributed via email to individuals in all provinces across Canada. Survey recipients were also asked to distribute the survey further to their colleagues, as appropriate. The survey questionnaire is provided in Appendix 1 and the list of participating provincial organizations in Appendix 2.

The survey included dichotomous, nominal, and free-text questions. Quantitative dichotomous (for example, Yes/No) and nominal variables (for example, a list of options) were summarized descriptively by jurisdiction. Open-ended qualitative responses were categorized by theme and summarized narratively. While all provinces were represented by the survey, territories were not represented. When more than one response was received per province and conflicting data were provided, we referred back to the provincial health ministry or cancer agency for clarification.

This report also includes relevant information from countries with publicly funded health care systems that do not currently have access to PBT and must send patients out of country for treatment.

<table>
<thead>
<tr>
<th>Table 1: Selection Criteria for Literature Search</th>
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</thead>
<tbody>
<tr>
<td>Population</td>
</tr>
<tr>
<td>Setting</td>
</tr>
<tr>
<td>Intervention</td>
</tr>
<tr>
<td>Results</td>
</tr>
</tbody>
</table>
Findings

The findings of this report are presented by research question.

**Which provinces and countries are considering purchasing PBT within the next five years and what are the preferred sites?**

**Canada**

The survey responses indicated that three provinces — Alberta, Ontario, and Quebec — are considering purchasing PBT within the next five years. The preferred locations for PBT systems have not been finalized but would likely be cities with proximity to the largest pediatric oncology populations, access to radiation oncologists and medical oncology services and expertise, and the space to accommodate PBT equipment. The Alberta survey response reported that Edmonton and Calgary are being considered for PBT. In Quebec, Montréal would be the most likely city for PBT, and Ontario has not yet determined the preferred location.

A Proton Treatment Facility opened in 1995 in Vancouver. This facility is used exclusively for the treatment of melanoma of the eye. Its fixed beam is not suitable for other cancer types.

**United Kingdom**

In the UK, two publicly funded PBT sites are currently under construction in London and Manchester. The Manchester site will be operational in 2018, and the London site in 2019. These cities were considered by the National Health Service (NHS) to be the most suitable for PBT construction because they provide the best geographical access to patients, and are able to provide optimal clinical services. These services include: access to integrated cancer care by a multidisciplinary team, proximity to radiotherapy centres, access to medical imaging equipment (CT, MRI, and positron emission tomography) for treatment planning, and the availability of pediatric and neurosurgical expertise. A privately funded centre in Newport, Wales, will be operational in 2017.

For more than 25 years, PBT has been available at the Clatterbridge Cancer Centre near Liverpool for the treatment of some cancers of the eye.

**Australia**

There are no existing PBT sites in Australia. However, in 2016, the Victoria Ministry of Health provided $50 million toward the establishment of Australia’s first PBT centre in Melbourne.
Which provinces and countries send patients out of country for PBT?

Canada
The survey responses reported that five provinces currently refer patients out of country for PBT to the US. These include Alberta, Saskatchewan, Ontario, Quebec, and Nova Scotia. Of the provinces that are not currently referring patients out of country, British Columbia plans to do so within the next year. Manitoba, Prince Edward Island, New Brunswick, and Newfoundland and Labrador are not certain they will fund out-of-country PBT in the future.

The survey responses reported that Quebec set up a formal committee to review the selection of referral sites. The criteria include consideration of wait times and language barriers. While no official criteria have been used to select referral sites by other provinces, respondents reported that decisions regarding referral sites are often determined by:

- A history of collaboration
- Sites that already have high volumes of patients
- Experience and access to pediatric oncology expertise.

United Kingdom
The NHS funds the treatment of UK patients at two PBT centres in the US; one in Oklahoma and the other in Florida. A small number of UK patients are treated in Switzerland. According to the NHS, the selected providers were determined using a series of criteria, including clinical experience, spoken English, cost, and wait times.16,17

Prior to referring patients, representatives of the UK’s expert Proton Clinical Referral Panel (PCRP), which advises on patients most likely to benefit from PBT, inspected the PBT centres to ensure they provide high-quality treatment. For children, in particular, it was considered essential that the PBT facilities have access to entire pediatric cancer specialist teams.14

Australia
Australia mostly sends patients to the US for PBT. Less-expensive treatment is available in Europe and Japan, but for reasons relating to language and culture, these centres are often not selected.18
What clinical indications are considered for PBT and for which populations?

Canada

Of the five provinces that fund PBT, Alberta, Saskatchewan, and Quebec fund both adult and pediatric patients. To date, Ontario and Nova Scotia have only referred pediatric patients for treatment. In 2013, Alberta Health Services (AHS) published recommendations to guide provincial clinicians when referring patients for out-of-country treatment. AHS suggested the following clinical indications:

Pediatric and adolescent tumour sites:

- Craniospinal irradiation patients
- Central nervous system (CNS) tumours or lesions: arteriovenous malformations, ependymomas, craniopharyngiomas, CNS germ cell tumours, primitive neuroectodermal tumours, and low-grade gliomas
- Non-CNS tumours: sarcomas including chordoma and chondrosarcoma, rhabdomyosarcoma, Ewing's sarcoma, pineal tumours, and lymphoma.

Adult tumour sites:

- Some CNS tumours or lesions: arteriovenous malformations, benign meningioma, neuromas, craniopharyngioma, CNS germ cell tumours, and low-grade gliomas
- Some non-CNS tumours: sarcomas including chordoma and chondrosarcoma, lymphoma in patients under the age of 30 years, and paranasal sinus and nasal cavity tumours.

As for the other provinces that fund PBT, Saskatchewan reported considering pediatric and adult patients with CNS malignancies located near critical structures. Patients are considered for PBT when other treatment options are not available in Canada and following assessment by a radiation oncologist and discussion at a multidisciplinary tumour board. In Ontario, Cancer Care Ontario does not have specific indications for funding treatment. Instead, recommendations are made by experts on a case-by-case basis. Quebec has referred patients with sarcomas, including chordoma and chondrosarcoma, ocular melanomas, and head and neck cancers. A formal committee, comprised of a medical physicist and physicians, was established to evaluate requests for PBT. As well, the Quebec survey responder indicated that the Institut national d'excellence en santé et en services sociaux is currently developing recommendations for key indications for PBT treatment for Quebec. Nova Scotia reported that it considers pediatric patients with skull malignancies.

United Kingdom

The NHS provides access to PBT to adult and pediatric patients. Table 2 outlines the high-priority clinical indications funded by the NHS.
Australia

According to the Faculty of Radiation Oncology of the Royal Australian and New Zealand College of Radiologists, PBT is considered a suitable treatment for adult and pediatric patients with the following indications:

- Pediatric only: medulloblastomas; ependymomas; craniopharyngiomas; low-grade gliomas, including optic pathways; intracranial germ cell tumours; rhabdomyosarcomas (orbit, parameningeal/head and neck, pelvis); retinoblastomas
- Pediatric and adult patients: chordomas/chondrosarcomas of the base of skull or spine; intraocular melanomas, Ewing sarcomas; spinal/paraspinal bone and soft tissue sarcoma (non-Ewing)
- Adult only: Hepatocellular cancers.

### Table 2: List of indications funded by the NHS for UK patients

<table>
<thead>
<tr>
<th>Population</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric</td>
<td>Chordoma/Chondrosacoma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Craniopharyngioma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Difficult cases (esthe/neuro/liver)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Ependymoma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Ewing sarcoma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Hodgkin's</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Intracranial germinoma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Low-grade glioma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Meningioma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Nasopharynx (head and neck)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Optic pathway glioma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Primary neuroectodermal tumours</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Retinoblastoma</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Rhabdomyosarcoma (orbit, parameningeal, head and neck, pelvis)</td>
</tr>
<tr>
<td>Pediatric</td>
<td>Very young age</td>
</tr>
<tr>
<td>Adult</td>
<td>Acoustic neuroma</td>
</tr>
<tr>
<td>Adult</td>
<td>Chondrosarcoma</td>
</tr>
<tr>
<td>Adult</td>
<td>Chordoma</td>
</tr>
<tr>
<td>Adult</td>
<td>Choroidal melanoma</td>
</tr>
<tr>
<td>Adult</td>
<td>Craniospinal NOS (pineal)</td>
</tr>
<tr>
<td>Adult</td>
<td>Difficult cases</td>
</tr>
<tr>
<td>Adult</td>
<td>Meningioma</td>
</tr>
<tr>
<td>Adult</td>
<td>Ocular/Orbital</td>
</tr>
<tr>
<td>Adult</td>
<td>Paraspinal and spinal sarcoma</td>
</tr>
<tr>
<td>Adult</td>
<td>Primary neuroectodermal tumours (medulloblastoma intracranial)</td>
</tr>
<tr>
<td>Adult</td>
<td>Sacral chordoma</td>
</tr>
</tbody>
</table>
Are other criteria used to determine patient selection?

Canada
AHS recommendations on PBT suggest that numerous factors should be considered during the approval process for PBT, and a diagnosis of an approved indication alone is not sufficient to make a decision. All patient referrals must come from the consultant oncologist who assessed the patient. Before the referral is made, a full multidisciplinary team, including a clinical oncologist, meets to discuss the pros and cons of each case. Approval of the referral must be submitted to the Out-of-Country Health Services Committee, which operates at arm’s length from AHS. Additional and overriding principles for approval and funding include:

- Treatment should be given with curative intent
- Good patient performance status
- Expected survival of the patient should be greater than five years
- Patient must be able and willing to travel
- Patients must be able to live out of country for up to seven weeks.

The survey reported that in Saskatchewan, experts also consider whether appropriate alternative treatment options are available in Canada. Quebec considers if the treatment is given with a curative intent. Nova Scotia considers if tumours lie close to critical organs. Ontario does not use other criteria for patient selection.

United Kingdom
Patients in the UK with high-priority indications are considered by the PCRP and treated overseas within the National Specialised Commissioning Team’s PBT Overseas Treatment Programme. The decision on whether to treat a patient is not limited exclusively to clinical indications. In many instances, a multidisciplinary team, consisting of a radiation oncologist, an oncologist or pediatric oncologist, a medical physicist, a radiation therapist, and a surgeon, advises on suitable patient selection.

The PCRP accepts proposals from clinicians. Even if it approves a case, the final decision resides with the treatment centre. Overriding principles for approval and funding include:

- Treatment should be given with curative intent
- Patient performance status
- No other coincident diagnoses likely to either limit five-year survival or make a prolonged period abroad difficult to manage
- No patient with metastatic disease will be eligible
- Re-treatment cases will not be accepted
- Weight limits on the treatment couches in treatment centres; adult patients at the time of referral should not exceed 150 kg.
The PCRP also ensures that PBT provides a significant advantage as compared with conventional radiotherapy or intensity-modulated radiation therapy by considering the following factors:

- Timing of radiotherapy in relation to other treatments
- Site of tumour
- Radiotherapy target volume
- Target volume dose and dose gradients required
- Tumour and target volume proximity to critical dose-limiting structures
- Patient age and performance status
- Stage and pathology
- Presence, size, and position of metallic implants
- Views of patients and parents
- Patients’ ability to travel.

Australia

In October 2015, the Royal Australian and New Zealand College of Radiologists published a position statement to help patient selection for overseas referrals. In addition to a recognized indication, the advantages and disadvantages of PBT compared with conventional radiation therapy must be discussed on a case-by-case basis, and the decision may require the generation of comparison plans.

Other factors that must be considered include:

- Performance status and patient’s physical ability to travel
- Views of the patient, parent and family
- Timeliness of the treatment start date
- Ability to integrate other treatments such as chemotherapy
- Site of the tumour and its proximity to critical dose-limiting structures
- Patient age
- Tumour stage and pathology
- Probability that overall survival will reach or exceed five years.

A Particle Therapy Referral Committee (PTRC), chaired by a radiation oncologist, discusses each referral case. Before consideration, a multidisciplinary clinical team prepares an evaluation and submits it to the PTRC. The committee reviews referral forms, imaging tests, and operation and pathology reports. Within 10 working days of receiving the referral, the chair provides a written reply on behalf of the committee.
**What year did you first start referring patients for out-of-country PBT?**

**Canada**

**United Kingdom**
The NHS first sent patients out of country for PBT in 2008.²³

**Australia**
No information was identified to indicate when Australia first sent patients out of country for PBT treatment.

**What is your annual volume of referrals since offering this therapy?**

**Canada**
Overall, the responses indicate that at least 30 patients may have received public funding for out-of-country treatment in Canada in 2016. Alberta reported funding for 14 patients, Saskatchewan reported funding two patients, and Ontario reported funding for 12. Quebec reported funding 15 patients for treatment in 2015, and Nova Scotia reported funding approximately one or two patients every year.

**United Kingdom**
Between 2008 and 2014, approximately 400 patients, most of them children, have received public funding for out-of-country treatment.²⁴ According to the UK Department of Health, it was anticipated that the NHS would fund approximately 400 patients per annum by 2014 to 2015.⁹

**Australia**
The Australian federal government funds approximately 10 patients per year to travel overseas to receive PBT.²⁵
Are patient and caregiver travel and accommodation costs covered?

Canada

The survey results reported that in addition to treatment costs, Quebec and Nova Scotia fund patient and caregiver travel and accommodation costs. Saskatchewan and Ontario cover patient treatment costs alone. Alberta funds patient treatment, travel, and hospital accommodation costs. A parent or travel escort is funded for travel if the patient is under 18 years of age, or if a travel escort is medically necessary. Costs not covered in Alberta include the following:

• Costs of take-home drugs, medical equipment, or other supplies
• Private travel medical insurance to cover unexpected medical expenses resulting from an emergency illness or injury unrelated to the services for which funding is authorized
• The cost of meals or accommodations, whether associated with travel in Alberta or to and from out-of-country health service location
• Fees or costs for seat selection, baggage, meals, accommodations, car rental, parking, or other personal expenses associated with the approved travel
• Meals or accommodations for any person(s) accompanying the patient.

United Kingdom

In addition to medical and hospital costs, the NHS funds travel and accommodation costs for the PBT patient being treated overseas, plus costs for a caregiver(s)/parent(s) accompanying the patient. For pediatric patients, two adult caregivers are funded, and for teenagers and adult patients, one caregiver is funded.

Australia

Australia funds patient treatment related costs, as well as travel and accommodation costs. When medically necessary, the travel costs of a caregiver are also covered.

What are your annual costs for patient referrals?

Canada

The average cost for treatment per patient for PBT is estimated at $200,000. According to the survey responses, inclusion of travel and accommodation for patients and caregivers can increase overall costs by an additional $50,000.

United Kingdom

The UK Department of Health anticipated spending approximately £30 million per annum, treating up to 400 patients out of country for the period 2014 to 2015. Between 2010 and 2011, some 50 patients travelled out of country for publicly funded PBT, at a cost of £5 million. The average cost per patient is £100,000.

Australia

The cost of the treatment of a single patient with PBT in the US is between A$200,000 and A$280,000. The federal government funds this treatment under its Medical Treatment Overseas Program.
Limitations

The findings of this Environmental Scan are intended to provide an overview of the current status of out-of-country PBT referral practices in Canada, the UK, and Australia. A full review of the topic was not conducted. The findings of this report are based on a limited literature search and survey responses from Canadian provincial contacts. Canadian territories did not participate in the survey.

Conclusion

Interest in PBT as a treatment option for some cancers continues to increase internationally. The survey results indicated that Alberta, Ontario, and Quebec are considering purchasing the technology within the next five years. The UK has two large facilities under construction in London and Manchester, and Australia has committed funds for the construction of its first facility in Melbourne. In the meantime, five Canadian provinces (Alberta, Saskatchewan, Ontario, Quebec, and Nova Scotia) send patients to the US for treatment, as do the UK and Australia.

In Canada, there are disparities in access to PBT. Of the five provinces that refer patients out of country, all consider pediatric patients and three consider adult patients. As well, the types of cancer funded and the level of funding received are province-specific, with some provinces considering patients on a case-by-case basis and others using recommendations of approved indications.

Approximately 30 Canadian patients were referred for out-of-country treatment with PBT in 2016. These may be the highest-priority cases and may not be representative of the overall number of patients who could have benefited from treatment. The number of appropriate patients for this therapy could potentially increase if PBT were available in Canada. As well, this number may change as new evidence becomes available on the effectiveness of PBT for multiple types of cancer.

Complementing this Environmental Scan, CADTH prepared two Rapid Response reports in 2016. One report compared the clinical and cost-effectiveness of PBT with photon radiotherapy. The report concluded that current comparative evidence does not suggest that PBT is superior to photon therapy from a clinical or cost perspective for the majority of indications. There are concerns regarding the quantity, quality, and generalizability of the available evidence. Current ongoing studies and future investigation into differences in hard clinical end points and long-term outcomes may resolve some of this uncertainty. The other Rapid Response report addressed PBT for the treatment of locally advanced adenoid cystic carcinoma. It identified six non-randomized studies on the clinical effectiveness of PBT for adenoid cystic carcinoma and provided a summary of their abstracts. This report found that three Canadian provinces are considering installing PBT and five provinces send patients out of country for PBT treatment, with each having different funding and selection criteria to determine patient eligibility.
References


Appendix 1: Proton Beam Therapy Survey Questions

Are you considering purchasing PBT in your province/territory within the next five years?
☐ Yes
☐ No

If yes, what is the preferred location(s) for a PBT site?

Were specific criteria used to determine the selection of the PBT site?
☐ Yes
☐ No

If yes, what were the criteria?

Do you currently send patients out of country for PBT?
☐ Yes
☐ No

If yes, which facilities do you refer patients to?

Were specific criteria used to select referral sites?
What year did you first start referring patients for out-of-country PBT?

What is your annual volume of referrals since offering this therapy?

What clinical indications do you consider for PBT and for which populations?

Do you use other criteria for patient selection – and, if so, what are they?
Funding of Proton Beam Therapy

What are your annual costs for patient referrals for PBT?

Do you fund patient travel and accommodation costs?
- No
- Yes, we fund both
- We fund travel only
- We fund accommodation only

Do you fund carer/parental travel and accommodation costs?
- No
- Yes, we fund both
- We fund travel only
- We fund accommodation only

For those that do not currently send patients out of country for PBT, do you plan to do so?
- No
- Yes, this year
- Yes, but not in the immediate future
- Not sure

Have you been refused access to out-of-country PBT, by the host facility, due to limited capacity or other issues?
- Yes
- No
- No, but they set limitations for us
Appendix 2: Information on Survey Respondents

<table>
<thead>
<tr>
<th>Province</th>
<th>Organization Represented by Survey Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>BC Cancer Agency</td>
</tr>
<tr>
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<td>Alberta Health Services</td>
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<tr>
<td>Saskatchewan</td>
<td>Saskatchewan Cancer Agency</td>
</tr>
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<td>Manitoba</td>
<td>Cancer Care Manitoba</td>
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<tr>
<td>Ontario</td>
<td>Cancer Care Ontario</td>
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<tr>
<td>Quebec</td>
<td>Centre hospitalier de l’Université de Montréal</td>
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<tr>
<td>Prince Edward Island</td>
<td>Prince Edward Island Cancer Treatment Centre</td>
</tr>
<tr>
<td>New Brunswick</td>
<td>New Brunswick Medicare</td>
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<tr>
<td>Nova Scotia</td>
<td>Nova Scotia Health Authority</td>
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<td>Newfoundland and Labrador</td>
<td>Eastern Health</td>
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