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# **Ensuring Access to High Quality Bone Marrow and Stem Cell Transplantation Services in Ontario**



*Report of the Advisory Panel*

*2007/2008*

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## Summary of Recommendations

### ACCESS and FUNDING

**1. The MOHLTC should provide funding beginning in 08/09 to address an existing shortfall in transplant centres. A volume-based funding model, in which the funding follows the patient, administered by the provincial oversight body is recommended.**

The funding should cover;

- a) Updated case costs as identified by the Panel
- b) All transplants
- c) The full episode of care, including activities not included in the existing funding formula (e.g. HLA typing and donor search, including work-up of patients who are subsequently unable to proceed to transplant)
- d) Costs for establishing and maintaining collection of the provincial minimum data set
- e) Cost of acquiring and maintaining accreditation from the Foundation for Accreditation of Cellular Therapy (FACT)

**2. The MOHLTC should approve and fund one additional autologous program immediately. Future growth in existing centres and development of any new centres, should be funded based on population need, as identified by a population planning model.**

There is an immediate need for an additional autologous transplant program in the Greater Toronto Area to address long waiting times at the University Health Network. Sunnybrook Health Sciences Centre, which has an existing research-funded program, is recommended to take on this role.

Kingston General Hospital should be considered for a future allogeneic program.

**3. The MOHLTC should review “donor matching” and “HLA typing” services to assess whether centralizing them would improve efficiency of the system.**

**4. The MOHLTC should endorse the establishment of a high quality, efficient, publicly accessible national cord blood registry, as has been recommended by Canadian Blood Services.**

### QUALITY

**5. The MOHLTC should require all Ontario transplant centres, including autologous-only programs, to achieve and maintain FACT accreditation.**

**6. The MOHLTC, through the provincial oversight body, should ensure that standardized indicators of quality and access are regularly monitored at the hospital, LHIN and provincial levels.**

#### SYSTEM COORDINATION AND OVERSIGHT

**7. The MOHLTC should immediately appoint and fund an existing organization to provide provincial oversight to ensure ongoing equitable access to high quality bone marrow and SCT services.**

This oversight body will:

- Advise the MOHLTC on provincial-level issues
- Support the LHINs and hospitals by providing provincial-level planning, and monitoring of access and quality
- Administer program funding

**8. The oversight body, in conjunction with a network of provincial experts, should be accountable for establishing, within 1 year, and maintaining critical functions related to planning, funding and quality, including:**

An evidence- and consensus-based list of *recommended indications* for which transplants should be performed in Ontario, building on the work initiated by the Panel and CCO's Program in Evidence-Based Care, and revised regularly as new evidence emerges;

An *annual review process of the actual indications* for which transplants were completed, to ensure consistency of practice and equity of patient access across the province;

A process to *review and track out of country transplant requests*, in conjunction with the Ministry, to ensure consistency of decision-making, value for money, and to identify need for changes in service provision in Ontario;

A *planning framework* which includes a volume forecasting model for program growth and establishment of new programs based on patient need. The model should take into account minimum volume recommendations from the FACT;

A *communication mechanism* to:

Share the recommended indications and other relevant program information, in a usable format, with all program and referring physicians, and

Acquire feedback from centres on the impact of changing indications, on access, quality and cost, and

Promote sharing of information among all Ontario transplant centres, both adult and pediatric;

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A provincial ***minimum data set*** to be used for planning and quality monitoring, building on an existing, well-established data set where possible;

Recommendations for a ***funding model*** that addresses complexity and changes in demand, likely via volume-based funding, that ensures funding follows patients;

A ***process for monitoring quality*** at the provincial level against national and international comparators where available;

A ***process for monitoring the funding and accountability model*** to ensure it sufficiently supports quality and access goals, and takes into account changes in volume, cost and complexity.

The opportunity to centralize the above for both adult and pediatric services should be explored.

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## Introduction

### What is SCT?

Stem cell transplantation (SCT) is an essential component of treatment for selected patients with lymphoma, leukemia, myeloma, stem cell and immunologic disorders. It involves administration of high-dose chemotherapy, sometimes accompanied by total body radiation, to destroy a patient's diseased cells. In doing so, the patient's bone marrow is also destroyed. Bone marrow plays an important role in manufacturing blood cells and building the immune system. Once the marrow is destroyed, immature stem cells are infused into the patient, with the intention that these cells will regenerate the patient's bone marrow, and that this new marrow will go on to produce normal, non-diseased, blood cells.

Stem cells can be acquired from several sources. Traditionally, they were extracted from the marrow of large bones, such as the hip bone. This procedure is usually called *bone marrow transplant*. Stem cells are now commonly extracted from a donor's peripheral blood through a process called apheresis. This procedure is usually referred to as *stem cell transplant*. Though stem cells are easier to acquire from peripheral blood, it can be challenging to acquire sufficient cells for transplant. A novel approach is the technique of acquiring stem cells from the umbilical cord at the time of birth. *Cord blood transplants* are used primarily for pediatric treatment, since the number of cells available is often insufficient for an adult transplant. The use of stem cells has in large part supplanted the use of bone marrow as a source of stem cells, particularly for autologous transplantation. For the purposes of this report, the term SCT will be used to describe the procedure, regardless of the source of cells.

In some cases, the stem cells used may be the patient's own. In this type of transplant, called *autologous*, the bone marrow is removed from the patient and stored for re-infusion. In circumstances for which autologous transplant is not feasible, a genetically similar donor may be used as a source of stem cells. This type of transplant is called *allogeneic*. Genetic similarity is determined by a blood test called human leukocyte antigen (HLA) testing or *typing*. This involves review of proteins that appear on the surface of white blood cells and other tissues in the body. These HLA points determine tissue compatibility between a patient and a donor. Testing is intended to find the closest match available, as this reduces the risk of potentially life-threatening complications of rejection or graft-versus-host-disease.

Siblings offer the greatest chance of being compatible (25%). Other relatives, including parents and children have a much lower chance of being compatible. Fewer than 40% of transplant candidates in Canada will have an HLA-compatible related donor. If a related donor cannot be found, donors are sought from a volunteer donor registry. The larger donor pool that such registries provide means an increased likelihood of finding a match. Transplants done from unrelated donors are riskier as unrelated donors are not as closely compatible and complication rates are higher. Improvements in how typing is done are leading to a drop in that risk. If a full match cannot be obtained, a less close match may be used. In these cases the marrow may be manipulated via a process called *t-cell depletion* prior to transplant to reduce the risk of complications.

The high-dose chemotherapy or chemoradiotherapy required for this process poses the risk of severe damage to the liver, lungs, heart or other major organs, especially if the patient is older or has a pre-existing health problem. A technique called *mini-transplant*, also called non-myeloablative or reduced-intensity conditioning transplant has been emerging over the past decade. This technique

avoids the traditional high-dose therapy, making the procedure safer in patients of older age or with pre-existing health problems.

SCT is intensive, highly specialized treatment that offers potential for cure or prolonged disease control in patients with selected blood-related cancers and other conditions. The administration of this therapy requires a team with expertise in multidisciplinary cancer care as well as availability of tertiary care infectious disease, imaging, surgery (if bone marrow harvest is required), and critical care services. Despite improved outcome for such patients with new chemotherapeutic and antibody therapy, SCT remains an essential component of treatment for these patients. Figures 1 to 3 illustrate the most common patient journey.

Figure 1: Patient Journey, Pre-Transplant Phase of Care

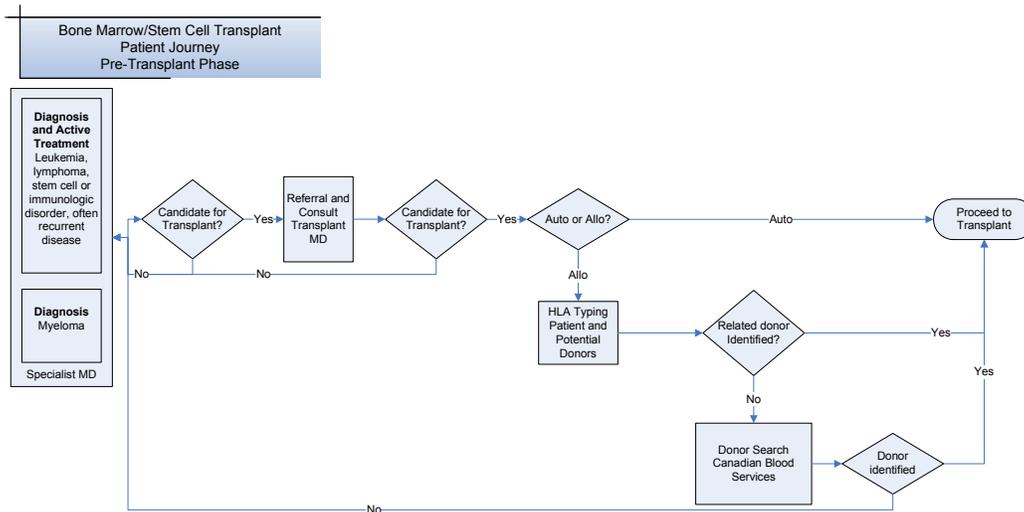


Figure 2 Patient Journey, Autologous Transplant

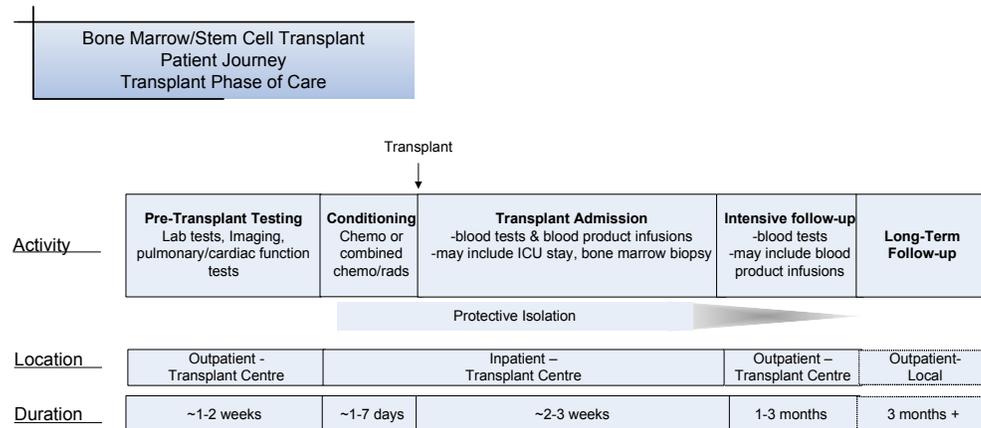
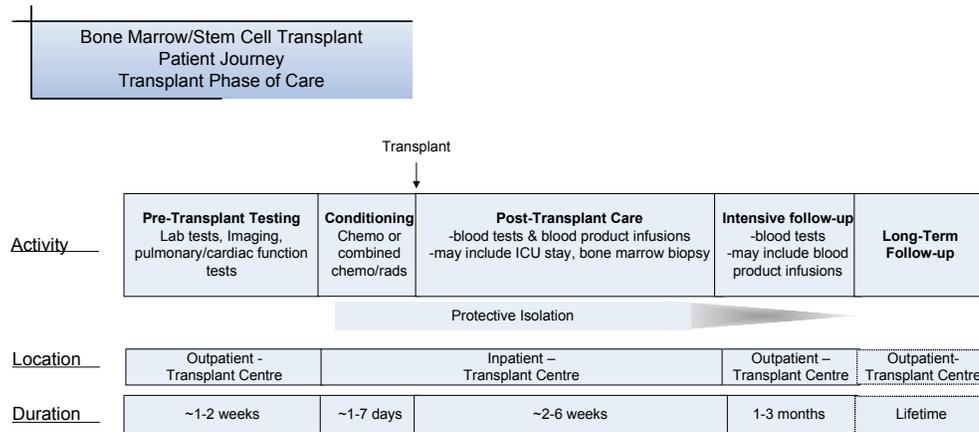


Figure 3 Patient Journey, Allogeneic Transplant



### The Need for a Review of Services

In 2007, several of the Regional Cancer Programs raised concerns about their ability to meet demand for transplant services. In a letter to Cancer Care Ontario (CCO) in September 2007, University Health Network (UHN), Ontario’s largest provider of transplant services, indicated their cost pressures were so significant that they had begun restricting access to patients outside of their immediate catchment. At the same time, the Deputy Minister of the Ministry of Health and Long-Term Care (MOHLTC) requested a review of these issues, as well as advice on the need for a national cord blood bank.

## Methods

### Convening a Panel

CCO convened a panel of stakeholders to assist in understanding the issues related to transplant services and to formulate advice. Dr. Kevin Imrie was appointed to Chair the panel. Dr. Imrie is co-chair of the provincial Hematology Disease Site Group. He was selected in part as he is well-versed in transplant issues but is not directly associated with one of the government funded transplant programs. Dr. Imrie and CCO leadership appointed the remaining panel membership, with input from all regional cancer programs. The panel included representatives from all Ontario transplant centres, both clinical and administrative. It also included a selection of physicians that refer patients for transplant and a representative from the MOHLTC Priority Services Branch. A LHIN representative was desired, but could not be arranged during the short timeframe of the review. During the mandate of the panel, representatives from Canadian Blood Services and Sick Childrens’ Hospital were invited to contribute to the deliberations. See Appendix 1 for the terms of reference of the advisory panel, and

Appendix 2 for the membership.

### **Survey of Transplant Centres**

The panel formulated a survey to be completed by all transplant centres in order to create an accurate and current picture of the service landscape in Ontario. A copy of the survey is included in Appendix 3. It contained three sections:

- Section A collected descriptive information about the programs. All centres completed this section.
- Section B asked centres to share policies and related program documentation. No centres submitted documents.
- Section C asked centres to provide detailed volume data for transplants and related activity. All centres completed this section.

Survey results are described throughout this report.

### **Literature Review**

The Panel determined that a review of current literature was required to understand indications for which there is sufficient evidence to support use of transplant. The last formal review in Ontario had been completed in the early 90's. The review would serve several purposes:

- a) Allow the panel to comment on whether or not current service provision in Ontario is consistent with current evidence,
- b) Provide a publishable list of indications for which transplant should be available in the province, as a guide to both transplant programs and referring physicians,
- c) Serve as a foundation for a population-based planning framework.

The reviewers were also asked to search for information about quality standards and quality monitoring.

This work of the literature review was assigned to CCO's Program in Evidence-Based Care (PEBC) at McMaster University and the panel's Quality Working Group. The research questions explored were:

1. What are the accepted indications for SCT?
2. What measures are commonly reported to assess transplant outcomes?
3. Are there published standards guiding performance of transplantation?

The target population reviewed was adult cancer patients being considered for treatment that includes either bone marrow or SCT.

The review was conducted in accordance with the PEBC evidence-based guidance development cycle. Recommendations have been formulated and are included in Appendix 4. Once the practitioner feedback phase of the guideline development cycle is complete, the document will be made publicly available, as per CCO standard practice, at [www.cancercare.on.ca](http://www.cancercare.on.ca).

### **Environmental Scan**

The panel conducted a limited scope telephone and Internet-based environmental scan to acquire information from relevant organizations including Canadian Blood Services (CBS), the Foundation for Accreditation of Cellular Therapies (FACT), the Centre for International Blood and Marrow Transplant Research (CIBMTR), the Canadian Blood and Marrow Transplant Group (CBMTG), Health Canada and the European Group for Blood and Marrow Transplantation (EBMT). Results from this review are described throughout this report. The panel also reviewed the reports and recommendations from an Ontario steering committee struck to review similar issues in the early 90's.

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## Acquiring Available Data

In order to acquire inputs for volume tracking and planning, CCO's Informatics Unit mined administrative data sets including the Discharge Abstract Database (DAD) and National Ambulatory Care Reporting System (NACRS) of the Canadian Institute for Health Information (CIHI), Ontario Health Insurance Plan billing data, CCO's Activity Level Reporting (ALR) data, and the CBMTG for any transplant services related data. Findings from this review are described in the Data Availability section of this report. Data on out-of-country requests for transplant were provided by the MOHLTC, as were inter-provincial billing rates. Detailed volume data were also solicited in the transplant centre survey. Analysts conducted a patient-level reconciliation of the centres' manually submitted data with the CIHI dataset. Detailed case costs were provided by the four transplant centres at which it was readily available.

## Formulation of Recommendations

The panel held three well-attended, in-person meetings and a follow-up teleconference. Panel members reviewed the information provided from the literature review, the environmental scan and the administrative data sets. They deliberated on the questions described in the panel terms of reference and came to consensus on the recommendations outlined in this report.

## Review of Recommendations

Comments on draft recommendations were invited from *Canadian Blood Services*, *CCO's Provincial Leadership Council* and *Clinical Standards, Guidelines and Quality Committee of the Board*. Review and discussion with LHIN representatives is desirable and should be solicited in the near future. The recommendations pertaining to evidence-based indications will follow usual PEBC processes for practitioner feedback before being published.

## What lessons can be learned from the past?

This is not the first time that access to transplantation services has been a problem in Ontario. In 1990, transplant centers approached the Ministry of Health (MOH) regarding service capacity pressures, long waiting times and the increasing out-of-country transplants for Ontarians. In April 1992, the MOH established a task force of transplant directors at the provincial centers, chaired by Dr. Hans Messner. Medical and financial working groups were formed. The goal of the initiative was to establish a provincial transplant management system to ensure equal access for all eligible patients to appropriate care through efficient use of resources.

Specifically, the task force's objectives were to:

- Define eligibility criteria for transplant
- Establish a registry to collect data on transplant
- Establish a coordinated waiting list
- Establish and validate an urgency scoring system
- Track the number of patients awaiting transplant
- Report on activities of the registry
- Evaluate and report patient outcomes
- Evaluate results of transplants for "developmental" indications

The committee recommended:

- Both definitive and developmental indications should be considered for provincial funding (developmental indications would be targeted for detailed outcome tracking)
- A base level of activity be established and funded for each centre
- A one-time injection of funds should be provided to eliminate back-log
- A process should be put in place to eliminate funding shortfall

In response to the report, the MOH provided one-time funding which assisted in eliminating the backlog of pending cases. The MOH also identified base volumes and created a *priority program* which provided volume-based funding, reviewed annually.

However, the remaining recommendations were not funded. The provider network, data collection and urgency scoring were established on a voluntary basis by the transplant centres. These continued for a number of years, but were not sustained. The planned outcomes tracking did not occur.

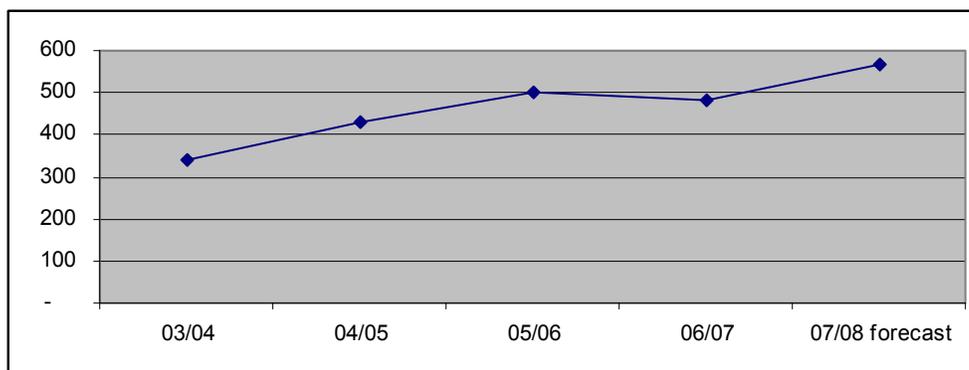
According to those involved, the 93/94 process resulted in a reduction of wait times which was sustained during the period that volume-based funding was provided. In addition, the list of approved indications gained international note, and helped to ensure access for Ontarians to appropriate transplantation. However, the planned benefits from the implementation of the other recommendations never came to fruition and Ontario is faced today with many of the same problems reported 15 years ago.

## Access to Services

### Ontario's SCT Services

**Volume Trends** Overall transplant volumes are increasing rapidly in Ontario, growing 66% in the last five years (Figure 4).

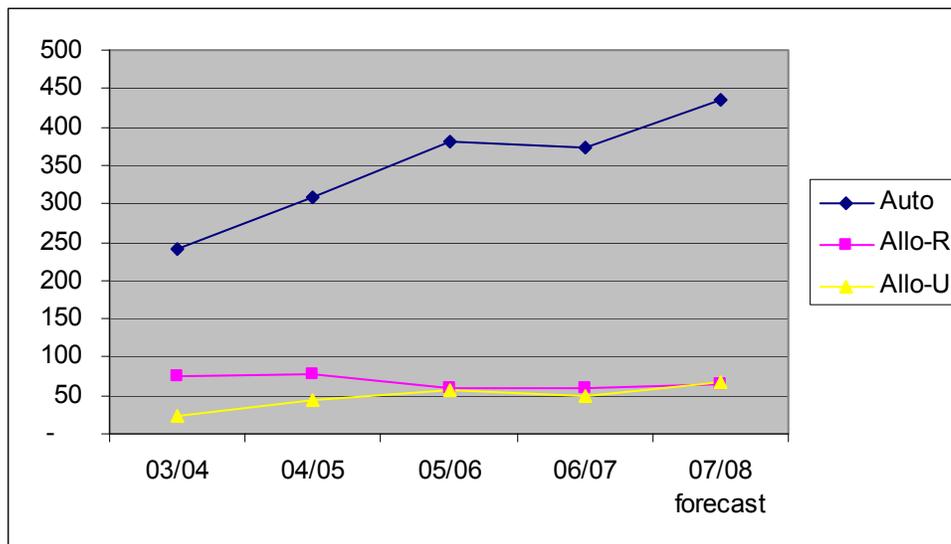
Figure 4 Transplant Volume Trend 2003/04 to Present



Source: 2008 Transplant Centre Survey

In response to new evidence over the course of the past few decades, indications for transplant have been added and others have been removed from service in Ontario. The science regarding indications continues to evolve rapidly, as does the science on technique. The latter focuses primarily on modifying the transplantation process to accommodate patients who are sicker and were not previously thought to be able to withstand the treatment. An increasing donor pool, provided by growing international volunteer registries, also means that finding a match is more likely. The volume increase to date has been driven by increases in autologous transplantation, the least complex and costly (Figure 5).

Figure 5 Transplant Volume Trend 2003/04 to Present – By Transplant Type



Source: 2008 Transplant Centre Survey  
(Auto=autologous, Allo-R=allogeneic related, Allo-U=allogeneic unrelated)

**Ontario’s Current Services** There are currently seven centres providing adult SCT services in Ontario. They are located in Toronto (2), London, Hamilton, Ottawa, Sudbury and Kingston, with all centres doing autologous transplants, and fewer doing the higher complexity allogeneic procedures. One of the centres, Sunnybrook Health Sciences Centre which currently receives no public funding for transplantation, only performs transplants as part of funded research studies. Pediatric transplants are centralized at Toronto’s Sick Children’s Hospital. See Figure 6 for a list of the types of transplant completed at each of Ontario’s adult transplant centres, and Figure 7 for the volumes from the most recent complete year of data collected from the centres. In addition to these volumes, there were four research-funded transplants at Sunnybrook and 86 pediatric transplants performed at Sick Children’s Hospital.

Figure 6 Type of Transplants Performed in Ontario’s Transplant Centres<sup>1</sup>

	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
<b>Transplants</b>							
<b>Autologous</b>							
Auto-BMT	X	X	-	X	-	-	-
Auto-SCT	X	X	X	X	X	X	X
<b>Allogeneic</b>							
BMT-related	X	X	X	X	-	-	-
BMT-unrelated	X	X	X	-	-	-	-
SCT-related	X	X	X	X	-	-	-
SCT-unrelated	X	X	X	-	-	-	-
Mini-transplants	X	X	X	X	-	-	-

Source: 2008 Survey of Transplant Centres

<sup>1</sup> Throughout this report the following short-forms are used for transplant centers: Ottawa = Ottawa General Hospital; PMH=University Health Network, Princess Margaret Hospital; Hamilton = Hamilton Health Sciences; London = London Health Sciences; Sudbury = Sudbury Regional Hospital; Kingston = Kingston General Hospital; Sunnybrook = Sunnybrook Health Sciences Centre.

Figure 7: Actual Transplant Volumes, Funded Centres, Ontario 2006/07, by Centre

	Actual per survey 06/07			
	AT	AL-R	AL-U	All
London	27	20	0	47
Kingston	16	0	0	16
Sudbury	14	0	0	14
UHN	199	46	19	264
Hamilton	47	17	12	76
Ottawa	65	19	18	102
<b>Province</b>	<b>368</b>	<b>102</b>	<b>49</b>	<b>519</b>

Source: 2008 Transplant Centre Survey

AT=autologous, AL-R= allogeneic related, AL-U=allogeneic unrelated

**Capacity Issues** Transplant program directors were asked to comment on whether there is sufficient capacity in the system to meet current demand. See Figure 8 for a summary of their responses. It reveals that capacity pressures vary across the province. All centres, however, expressed the view that funding is the primary threat to access at the present time.

Figure 8 Program Directors' View of Current System Capacity

	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
HLA typing	▲	▲	▲	▲	•	▲	▲
Laboratory testing (other than for typing)	▲	▲	▲	▲	•	▲	▲
Leukapheresis	▲	▲	▲	▲	▲	•	▲
BM harvesting	▲	▲	▲	▲	•	•	N/A
Radiation treatment	▲	▲	▲	▲	▲	•	▲
Chemotherapy	▲	▲	▲	•	▲	▲	▲
ICU beds	▲	▲	▲	•	▲	▲	▲
Inpatient beds	•	•	▲	▲	▲	▲	•
Outpatient clinic capacity	▲	•	•	▲	▲	▲	▲
Human Resources	▲	▲	•	•	▲	•	•

▲ Meeting Demand
• Insufficient to Meet Demand

Source: 2008 Survey of Transplant Centres

**System Planning** Planning for transplant services is done primarily at the hospital program level. As of 07/08, transplant volumes are included as a provincial service in the LHIN-hospital accountability agreements. On a LHIN-wide basis the number of procedures is very small. Several LHINS do not offer any transplant services. There is a high degree of inter-LHIN patient traffic, not only for transplant but also for stem cell collection and storage. The Panel felt that low volume, high-cost, high-complexity interventions such as transplant would benefit from a provincial level planning framework, based on a population-based demand model. Services should be placed as close to home as is economically reasonable provided safety and quality standards can be met.

*The Panel recommends that future growth in existing centres and development of any new centres, should be funded based on population need, as identified by a population planning model, taking into account minimum volumes from accreditation standards.*

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**Out-of-Country Services** Data from the MOHLTC regarding out of country procedures from 1992/93 to 2006/07 reveal that the Ontario government funds an average of only one out-of-country transplant per year. Acute myeloid leukemia appears to be the most common indication for such procedures. There were no data available on the number of requests for out of country services that were declined.

**Wait Times** Only one Ontario transplant centre reported the tracking of wait times (PMH). There are no standardized wait time data for transplant and transplant-related activities available provincially. While the Panel agreed that tracking wait times is desirable and should be pursued, more pressing priorities have been emphasized in the Panel’s recommendations at this time.

No funded centres report having a formal procedure in place to refer patients elsewhere if wait times become excessive. Some panel members noted that informal mechanisms for re-referral do exist. Panel members reported anecdotally, that there are longer than acceptable waits for some patient populations in selected areas and the lack of information with regard to service availability at the provincial level presents a challenge to ensuring equitable access to high quality care.

**Acute Access Problem in the GTA** Toronto area Panel members reported an acute problem with unacceptably long wait times for myeloma patients in the Greater Toronto Area (GTA), which is currently served only by the PMH. In the survey, PMH was the only centre that noted not having capacity to perform more transplants if more funding was made available. Adding to this pressure is the fact that PMH has traditionally transferred up to 10% of transplant patients to a community hospital close to the patient’s home for post-transplant inpatient care. New accreditation standards will preclude this practice of “*day-one transfers*”.

With the large rise in transplant volume and rapid population growth, it is not surprising that the ability of one funded transplant centre to serve the entire GTA is limited. Furthermore, PMH is a full-service centre that has expertise to complete the most complex procedures. The panel agreed that there is an immediate need to establish an additional autologous centre in the GTA to ensure that PMH’s capacity to complete the more specialized procedures is not compromised. Sunnybrook Health Sciences Centre was considered an obvious choice since it has infrastructure in place for its research-funded program.

*The MOHLTC should immediately fund the establishment of one additional autologous program in the GTA.*

Kingston General Hospital indicated a desire and readiness to add allogeneic services to their transplant program. The proposed planning model should be used to evaluate the need for transplant in Southeastern Ontario. Should the model reveal that such a program would meet minimum volume standards for quality, expansion of transplant services at Kingston General Hospital should be considered.

*Kingston General Hospital should be considered for a future allogeneic program.*

### **Access to Pre-transplant Procedures**

**Ontario’s Current Services** Two Ontario centres, Ottawa and PMH offer all pre-transplant services. For the remaining centres, some services are completed by another transplant centre or by a Canadian Blood Services laboratory (See Figure 9). CBS maintains one accredited stem cell lab in Ottawa, operated by its patient services division. CBS does not anticipate expansion of these services, as they are not part of its future business model.

Figure 9 Location of Ontario’s Pre-Transplant Services

Pre-Transplant Procedures	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
HLA Typing	X	X	X	X	X	X	
Bone Marrow Harvest	X	X	X	X			
Procurement of Stem Cells from Peripheral Blood	X	X	X	X	X	X	X
T-cell depletion		X	X				
Cyropreservation	X	X	X	X	X		X

Source: 2008 Transplant Centre Survey

**The Need for Review of HLA Typing and Donor Search Services** HLA typing and donor search are costly and time-consuming activities. HLA-typing activity far exceeds the number of transplants done. This is because there are many patients for whom a donor cannot be identified, and others who fail to make it to transplant for medical reasons. In the survey, Hamilton reported that they type twice as many patients than the number that actually proceeded to transplant. The cost of typing is increasing significantly. This is driven by several factors, including the requirement for costly “high resolution typing class 1” testing that is now required to secure an American donor. Improvements in typing have the potential to make transplantation safer due to reductions in complications relating to graft-vs.-host disease. The Panel felt a review is needed to assess whether centralizing these services would result in system efficiencies.

*The MOHLTC should review “donor matching” and “HLA typing” services to assess whether centralizing them would improve efficiency of the system.*

### Cord Blood Banking

Some ethnic and racial groups are relatively under-represented in unrelated marrow registries, thus decreasing the likelihood of finding a successful match. Cord blood banks can enrich representation of certain HLA types by targeting racial and ethnic groups currently under-represented in traditional registries. In addition, because stem cells harvested from cord blood are so immature, studies have shown that cord blood transplants are successful even when fewer HLA points match.

The majority of pediatric transplants in Canada are now done using banked cord blood. Though becoming common in pediatric care, only two such transplants have been done for adult patients in Ontario, both at PMH. The primary draw back to using cord blood for adult transplants continues to be the low numbers of available cells. New techniques and technologies are in development to address this limitation. Cord blood transplants have been increasing rapidly in the U.S. and in Europe. The pace of uptake in Canada has been slower, possibly to do difficulties in accessing cord blood in the absence of a Canadian bank.

There is currently only one small, publicly funded bank in Canada which is run by Héma-Québec. It can cost \$50,000 or more to access cords from volunteer donor banks. Several private banks exist in Canada. These allow individuals to store cords for use at their own direction only.

In recent years, the provincial deputy ministers of health asked CBS to develop a proposal for a national cord blood bank. CBS completed a feasibility assessment and consultation process, and are currently in the process of completing a business plan and model for review by the provinces in June 2008. The proposed bank will focus on ethnic diversity to match Canadian demographics, and will also ensure that cords not required for Canadian patients will be available to international registries. The Canadian Blood and Marrow Transplant Group (CBMTG) and the Canadian Hematology Society have endorsed the CBS plan for a national cord blood bank.

Following deliberations, the Panel recommended the establishment of a national cord blood registry in order to increase the opportunities for finding matched donors for Canadians, as opposed to relying solely on costly access to the registries of other jurisdictions. A national registry is expected to offer efficiencies over development of separate provincial registries.

*The MOHLTC should endorse the establishment of a high quality, efficient, publicly accessible national cord blood registry, as has been recommended by Canadian Blood Services.*

### Measuring and Monitoring Transplant Volumes

In an effort to understand the volume of transplant activity in the province, the panel reviewed provincially available administrative data sets. It was quickly determined that administrative data sets did not provide the information the Panel desired. A survey of transplant centres solicited information on the type of information tracked by individual centres and requested actual data for various key services.

**CIHI Data** The first cut of CIHI data presented to the Panel did not have face validity. A period of refinement of the data definitions, including a case-by-case reconciliation for several centres explained most of the variation, leaving a discrepancy of 4%. The variation was more significant for allogeneic (13%), than for autologous (2%) (Figure 10). It is notable that transplant patients at PMH who require intensive care services, are discharged from PMH and admitted to Mount Sinai Hospital for this portion of their hospital stay only. This scenario, while ideal for quality of patient care, leads to anomalies in the administrative data.

Figure 10: Comparison of Volume Data from Survey to CIHI Data 06/07

	Actual per survey 06/07				Actual per CIHI 0607			Variance		
	AT	AL-R	AL-U	All	AT	AL	All	AT	AL	All
London	27	20	0	47	26	18	44	-1	-2	-3
Kingston	16	0	0	16	14	0	14	-2	0	-2
Sudbury	14	0	0	14	9	0	9	-5	0	-5
UHN	199	46	19	264	196	67	263	-3	2	-1
Hamilton	47	17	12	76	43	21	64	-4	-8	-12
Ottawa	65	19	18	102	70	32	102	5	-5	0
Sunnybrook	4	0	0	4	6	0	6	2	0	2
<b>Province</b>	<b>372</b>	<b>102</b>	<b>49</b>	<b>523</b>	<b>364</b>	<b>138</b>	<b>502</b>	<b>-8</b>	<b>-13</b>	<b>-21</b>
<b>% Variance</b>								<b>-2%</b>	<b>-9%</b>	<b>-4%</b>

Source: CIHI DAD and 2008 Transplant Centre Survey

AT=autologous, AL-R=allogeneic related, AL-U=allogeneic unrelated

AL=allogeneic (unspecified)

The most significant concern with the use of administrative datasets was the inability to track whether or not the donor was related or unrelated. Though fields for this information exist in the CIHI data, they are not mandatory and were not well completed. Panel members felt that the ability to track transplants in this way is essential for proper system planning, management and quality monitoring, given the important differences in resource requirements and expected outcomes. Requesting changes to the CIHI datasets should be considered in the future. The Panel noted several benefits of the CIHI dataset, including:

- a) the ability to examine data by patient residence,
- b) the ability to utilize Ontario Case Costing data for the transplant centres that participate,
- c) ability to analyze other resource utilization data such as inpatient length of stay.

**Other Data Tracked by Transplant Centres** All centres report tracking stem cell procurement activity, and most track volumes in addition to what gets submitted to CIHI. All centres reported that they are currently or will soon report data to CBMTG. With the exception of Sunnybrook, all centres currently report or plan to report to CIBMTR. Upon review of the currently available data in each of these registries, it was apparent that the Ontario data currently within them is inconsistent and incomplete. See Figure 11 for additional details about data collected by Ontario’s transplant centres.

Figure 11 Supplementary Data Tracked by Ontario Transplant Centres

	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
3.3 Do you track the number of patients referred to your centre for consideration of a transplant, but who do not proceed to transplant?	N	Y	N/A	N	N	N	Y
3.4 Do you track the number of patients for which you conduct HLA typing, who do not proceed to transplant?	N	N	Y	N	N	N/A	N
3.5 Do you track the number of patients for whom stem cells are procured, but do not proceed to transplant?	Y	Y	Y	Y	Y	Y	Y
3.6 Do you track transplant volumes other than via health records abstraction for CIHI?	N/A	Y	Y	Y	N	Y	Y

Source: 2008 Transplant Centre Survey

**Canadian Blood and Marrow Transplant Group (CBMTG)** is a national, voluntary organization whose mission is to provide leadership and promote excellence in patient care, research and education in the fields of blood and marrow transplantation. Paying members may submit their own statistics and have access to summary statistics. The data set includes procedures by indication, age-group, stage of disease (first complete remission or subsequent), type of transplant, and type of donor. The Panel felt that this data set contained the minimum elements required for system planning and quality measurement.

**The Center for International Blood and Marrow Transplant Research (CIBMTR)** is a collaboration of the U.S. National Marrow Donor Program® and the Medical College of Wisconsin's International Bone Marrow Transplant Registry and Autologous Blood and Marrow Transplant Registry. It is a research focused organization. One of its key activities is transplant-focused biostatistics and maintaining and making available a large clinical database of related blood and marrow transplants. CIBMTR collects patient data on allogeneic blood and marrow transplants worldwide, and patient data on autologous blood and marrow transplants performed in North and South America, from more than 450 transplant centers from 48 countries. Submission of data to CIBMTR is a requirement of FACT accreditation (see subsequent section about accreditation). The Panel, in opting to mandate FACT accreditation for all Ontario transplant centres, is requiring that the CIBMTR minimum data set

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become Ontario's minimum data set. Exploration of a method to allow provincial access to the Ontario data should be explored, as this data will provide a key tool for the functions of a provincial oversight body being recommended by the Panel in subsequent sections of this report.

***European Group for Blood and Marrow Transplantation (EBMT)*** The Panel felt that data from the EBMT is of good quality and completeness and noted that this registry provides outcome indicators that should serve as comparators for Ontario. EBMT member centres are required to submit a minimum data set. They are subject to audits and on-site visits to assess compliance with guidelines, and adhere to minimum volume standards.

***Health Canada*** Recent changes in federal regulations require centres performing allogeneic transplants to submit data on bone marrow and stem cell collection processes and adverse events to Health Canada. At the time of the survey, only two Ontario centres had initiated this reporting.

***The Need for an Ontario Database*** There was a strong consensus among Panel members that a provincial minimum dataset, with standardized data definitions and contents, should be established. Prior work to establish such a registry in the early 90's did not succeed due to lack of sustainable funding. The Panel noted that the presence of good, complete data requirements outlined by both CBMTG and CIBMTR mean that no additional work should be done in Ontario on data definitions. Rather, Ontario centres should comply with existing standards from one of these two databases in order to provide the information needed for system planning and quality monitoring.

Typing, matching and procurement activity are not tracked in these data sets. The Panel felt it was important for system planning and funding that a mechanism be identified to track these activities in a standardized way in Ontario.

*A provincial minimum data set should be established to be used for planning and quality monitoring, building on an existing, well-established data set where possible.*

## Quality of Services

### Indications

The Panel noted that the last formal review of evidence and identification of indications for which transplant should be performed in Ontario was completed in the early '90's. The Panel conducted a literature review and environmental scan to update this list, and recommended that the list be reviewed at a minimum of every two years to ensure Ontario practices are consistent with best available evidence. The list, a summary of the relevant evidence, and the methodology for developing the list are available in the ***Appendix 4: Draft Evidence-Based Series #6-5: Section 1. SCT in adults: recommendations***. The final version will be made publicly available on CCO's web-site. The Panel noted that the list of recommended indications should be made broadly available to referring physicians, and a process to raise awareness of the list should be undertaken. Panel members also suggested that a listing of locations of various transplant-related services be made available in a usable format to all potential referring physicians. Figure 12 provides an overview of the indications, by centre, for which transplant is performed in Ontario. The Panel felt that current practice is consistent with current evidence.

*A communication mechanism should be developed to share the recommended indications and other relevant program information in a usable format, with all program and referring physicians, and promote sharing of information among all Ontario transplant centers, both adult and pediatric*

**Rare Indications** There are some indications for which experts would agree that transplant is appropriate, but the circumstances are so rare that it is not feasible to build up a sufficient evidence-base to include them on the list of recommended indications. The Panel suggested that a provincial network of experts review the Ontario transplant data annually, to ensure consistency of practice across the province (to promote equity of access) and to ensure that apart from transplants in this category, all others performed are consistent with the recommended indications list.

*The Panel recommends an annual review process of the actual indications for which transplants were completed, to ensure consistency of practice and equity of patient access across the province.*

Figure 12 Location of Transplant Services in Ontario, by Indication

Indication	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
CML	•	•	•	•			
CLL	•	•	•	•			
AML	•	■ •	•	■ •			
APL	•	■ •	•	■ •			
ALL	•	•	•	•			
NHL	■ •	■ •	■	■ •	■	■	■
Indolent NHL	■ •	•	•	•		■	■
HL	■ •	■	■	■ •	■	■	
MM	■ •	■	■	■ •	■	■	
MDS	•	•	•	•			
AA	•	•	•	•			
Myelofibrosis	•	•		•			
Amyloidosis	•	■	■		■	■	
Solid Tumours	■	■		■		■	
Autoimmune Disorders	■	■					

■ Autologous  
• Allogeneic

Source: 2008 Transplant Centre Survey

<sup>1</sup>Full names of the diseases are available in Appendix 4

**Age Thresholds** Most centres report using age thresholds as a criterion for determining eligibility for transplant. Age thresholds are used as a proxy for “fitness for transplant”, for which no other readily available measure has been identified. The Panel did not address the issue of age thresholds, but wished to flag the practice for further review in the future.

*An evidence- and consensus-based list of recommended indications for which transplants should be performed in Ontario should be made readily available, and should be updated regularly to reflect new evidence.*

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### Quality indicators

Figure 13 illustrates that the number and type of quality indicators tracked by Ontario’s transplant programs varies. No standard definitions exist to ensure the indicators can be compared across centres.

*Figure 13 Quality Indicators Currently Tracked by Ontario Transplant Programs*

Outcome Indicators Tracked	Ottawa	PMH	Hamilton	London	Sudbury	Kingston	Sunnybrook
Serious adverse events	X	X	X	-	-	X	-
30-day mortality	X	X	-	-	-	X	-
100-day mortality	X	X	X	-	-	X	-
Disease control	X	X	-	-	-	X	-
Reasons for failure of transplant	X	X	X	-	-	X	-
Performance status	X	-	-	-	-	-	-
		second cancers and second transplants					
Other	-		-	-	-	-	-

Source: 2008 Transplant Centre Survey

The Panel agreed that a suite of standardized quality indicators should be developed and maintained to ensure the safety and quality of care for Ontario patients.

**Mortality Rates** Mortality rates, often 10- and 100- day post-transplant are commonly accepted indicators for transplant. Longer term rates are emerging, given the improvements in outcomes seen in recent years. CCO Informatics performed Kaplan-Meier survival analysis using the Ontario Cancer Registry to calculate Ontario’s mortality rates. There was insufficient time within the mandate of this Panel to fully review the findings and come to consensus on methodology and comparators. However, the feasibility of calculating mortality rates using the Ontario Cancer Registry was established, and preliminary results indicated that Ontario mortality rates are in line with other jurisdictions. The Panel also recommended tracking of a longer-term survival measure of two or three years.

**SCT Outcome Database** This U.S. data collection system was launched in July 2007 with the goal to collect outcomes data on all patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood or other) from a donor. CIMBTR is responsible for administration of data collection and analysis of the data. Details are available at <http://www.cibmtr.org/DATA/SCTOD/index.html> . The Panel recommended exploration of implementation of this database as a standard for Ontario in order to facilitate quality tracking and benchmarking.

*The MOHLTC, through the provincial oversight body, should ensure that standardized indicators of quality and access are regularly monitored at the hospital, LHIN and provincial levels.*

### Accreditation

**Foundation for Accreditation of Cellular Therapies (FACT) Accreditation** FACT accreditation is the worldwide standard for transplant programs. Four centres in Ontario report that they are pursuing FACT accreditation. Panel members felt strongly that this process would provide a high level of quality assurance that is critical for high-complexity services. They noted that the process for

achieving accreditation can be lengthy and recommended that centres be given several years for this process. The Panel felt that most well-established, larger programs could be accredited by 2010. All centres noted the costs of applying for, preparing for, and maintaining accreditation. External fees for FACT accreditation are \$25,000 per centre, plus \$6,000 per year for maintenance thereafter.

FACT accreditation covers broad criteria including facility infrastructure requirements, safety, training for clinical and support staff, quality management plan, document management, independent audit, outcomes analysis, error, accident, adverse event, complaint monitoring, evaluation and reporting, policies and procedures, and more. It also specifies minimum volume requirements.

*The MOHLTC should require all Ontario transplant centres, including autologous-only programs, to achieve and maintain FACT accreditation.*

## Funding of Services

### Background

In 1993, a provincial “Bone Marrow Transplant Network” was convened by the Ministry. This group made recommendations about evidence-based indications for BMT and a funding formula. From that period forward, the MOHLTC provided volume funding under the “Priority Programs” banner to hospitals providing SCT services. Service volumes were re-adjusted in 98/99. In response to a perceived shortage in capacity, a transplant program in Kingston was initiated in 03/04.

In fiscal 04/05, once the volumes were felt to have stabilized, the Ministry identified a baseline number of cases for each centre and rolled a ‘per case’ funding amount into the global budgets of the transplanting hospitals. The 1993 case cost data was used to determine the rate (Table 1). Oversight of these services was transferred to the Ministry regional offices to facilitate local planning at that time.

*Table 1: Bone Marrow Transplant Case Costs 1993.*

Transplant Type	Average Case Costs
Autologous	\$45,000
Allogeneic-Related Donor	\$60,000
Allogeneic-Unrelated Donor	\$85,000

*Source: 1994 Bone Marrow Transplant Financial Working Group Report*

As of 07/08, the funding and accountability for provision of services now lies with the LHINs. SCT is specifically identified in the Ministry-LHIN accountability agreements. Since these services are considered a provincial service by the Ministry, LHINs must notify the Ministry if volumes drop below the baseline volumes identified in the accountability agreements.

In today’s model, it is expected that LHINs will identify and address any funding pressures or access issues related to these services in their LHIN. LHINs may escalate issues to the Ministry if required. LHIN-Hospital accountability agreements specify a baseline volume. If a baseline volume is not met, LHINs are required to reduce funding accordingly.

The Panel noted that it is unclear what mechanism will be put in place within the LHIN structure to reallocate volumes between LHINs.

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## Updated Case Costs

The Panel struck a working group of knowledgeable representatives from the transplant centres for which case costs were available. This group came to consensus on a costing methodology for transplants, based on the methodology used in 1993. A line-by-line cost review was undertaken. Extreme outliers were removed. An average of the remaining costs was used for each line. Membership of the working group and details of the methodology are available in Appendix 5. The updated costs, shown compared to the rates used when funding was allocated to hospital global budgets in 04/05 are illustrated in Figure 14.

Figure 14 Updated Case Costs Compared with Most Recent Funded Rate for Transplant

	Funded Rate	Current Actual	Variance	
Auto	\$ 45,000	\$ 36,000	\$ 9,000	20%
Allo-R	\$ 60,000	\$ 86,000	-\$ 26,000	-43%
Allo-U	\$ 80,000	\$ 124,000	-\$ 44,000	-55%

The findings were not unexpected. Transplant centres were aware of significant increases in the cost of allogeneic transplants, largely related to high costs of procurement. In addition, the 1993 model had excluded costs of HLA typing, which were included in the updated version.

Some Panel members expressed continuing concern that the updated case cost for allogeneic transplants, unrelated donor, may be too low. Further review should be undertaken in future. It is notable that the updated case costs are less than the current inter-provincial billing rate of \$129,219 plus \$1,838 per day after 25 days (MOHLTC, Priority Services, 2008).

Other areas for future review include the cost of single versus double transplants (more than one donor used to ensure adequate cellular volume) and the issue of whether myelo-ablative procedures are more costly than non-myeloablative.

**Funding Should Follow the Patient** The Panel discussed several scenarios for which the funding model does not necessarily match the pattern of expenditure. Out-sourced procurement, cryopreservation, typing services and inpatient services (e.g. day one transfers) are all examples where the expense to the public system occurs outside of the transplant centre. The Panel agreed that future funding models should take this into account. The inter-provincial billing model of separating procurement, transplant and post-transplant care should be considered as a model for Ontario. This would also provide a mechanism to fund the high costs of typing and matching patients who subsequently are not able to proceed to transplant.

**Volume-based Funding** The Panel felt strongly that a volume-based funding model should be reinstated for transplant services. Volume-based funding provides flexibility required to ensure ongoing access for high-intensity, low volume services such as SCT, for which the science is rapidly changing. It also provides the opportunity for volume-based service agreements to which quality requirements can be appended. The Panel felt that given the relatively small numbers of procedures, case-based funding could be applied to all cases. It is recognized that some cancer services have volume funding for only incremental cases over and above a base number. This model could also work for transplant, but consideration must be given to the fact that the base “rate”, the amount that was rolled into global budgets, was based on sorely outdated case costs.

**Support for Quality Standards and Planning** In order to maintain consistent, high quality, accessible services, data tracking is required. Lack of funding for this aspect of the 93/94 report

recommendations meant the tracking mechanism was not sustained, and resulted in another “crisis” in access. The Panel strongly recommends that funding be made available for provincial oversight (described later in the report) and for local resources for data management and quality (including accreditation).

*The MOHLTC should provide funding beginning in 08/09 to address an existing shortfall in transplant centres. A volume-based funding model, administered by a provincial oversight body is recommended. The funding should cover; a) Updated case costs as identified by the Panel, b) All transplants, c) The full episode of care, d) Costs for establishing and maintaining collection of the provincial minimum data set e) Cost of acquiring and maintaining accreditation from the Foundation for Accreditation of Cellular Therapy (FACT)*

*The model should take into consideration that some centres outsource various aspects of transplant care, and funding should follow accordingly.*

## System Governance and Oversight

Upon inception of the Panel, it was noted that the transplant program directors had not connected on issues of mutual importance, such as those in the panel mandate, since the early 1990s. There was consensus that a mechanism should be put in place to immediately reinstate formal lines of communication between all SCT programs in order to ensure proactive review of issues and to prevent future crises related to access, quality or safety.

The Panel agreed that provincial oversight is essential to ensure ongoing equitable access to high quality bone marrow and SCT services.

This oversight body should:

- Advise the MOHLTC on provincial-level issues
- Support the LHINs and hospitals by providing provincial-level planning, and monitoring of access and quality
- Administer program funding

The oversight body should ensure regular updates of the evidence- and consensus-based list of **recommended indications** for which transplants should be performed in Ontario, building on the work initiated by the Panel and CCO’s Program in Evidence-Based Care. CCO’s Provincial Hematology Disease Site Group should be considered for this role.

The oversight body should facilitate the coming together of the network of transplant programs. An expert group of this network could undertake an **annual review process of the actual indications** for which transplants were completed, to ensure consistency of practice and equity of patient access across the province. The oversight body should develop and implement a **process for monitoring quality** at the provincial level against national and international comparators where available. This group could also contribute to the **review and tracking of out of country transplant requests**, in



against benchmarks. In fact, even basic transplant volumes cannot be tracked provincially through existing administrative data sets. This provides a fundamental barrier to quality monitoring and system planning. The regulatory environment internationally has increased expectations for data reporting and quality monitoring. In these areas, Ontario is falling behind international standards.

Within its recommendations, the Panel has laid out a plan to provide cost-effective oversight of this provincial service, and mechanisms to ensure appropriate access, and consistently high quality and safety of services.

## Appendices

### *Appendix 1: Advisory Panel Terms of Reference*

Cancer Care Ontario (CCO) is convening a panel of stakeholders to review Ontario's ability to meet demand for SCT and to provide advice on action required to ensure that Ontarians receive equitable access to high-quality SCT services now and in the future. The Panel will address issues of quality of care, access to services, and funding.

#### Deliverables:

The panel shall deliver an advisory report to the Executive Team of CCO, with the following information:

#### Quality

- Availability of and/or need for evidence-based guidelines to inform the organization and operation of SCT services
- Recommendations for staffing, infrastructure and clinical education at transplant centres, in sufficient detail to guide funding recommendations
- Indications for transplant which there is a strong evidence-base.
- Current ability to monitor quality of SCT services in Ontario
- Actual or potential barriers to providing high quality care
- Short- and long-term recommendations for action by providers and/or government and/or others to address the identified barriers and ensure appropriate access to high quality SCT services in Ontario. This may include recommendations about quality measurements and quality oversight.
- Advice on the need for an ongoing communication forum for BMT/SCT services providers and funders

#### Access

- Availability of and/or need for evidence-based guidelines to determine eligibility (indications) for SCT
- Advice as to whether or not certain services might be better offered in a more centralized fashion
- High-level commentary about current HLA typing services offered in Ontario
- High-level commentary about cord blood and the potential for a cord blood registry, including acknowledgment of the Ontario's government's support of a national cord blood initiative
- Current and estimated demand for SCT over a 10-year horizon, including commentary on whether we anticipate significant changes to eligibility for transplantation based on emerging evidence
- Current service levels and resource use in Ontario



- Public affairs – to assist with formulation and delivery of final advice
- Informatics – to provide data and analysis about BMT 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

#### Accountability

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.

#### Scope:

<u>In Scope</u>	<u>Out of Scope</u>
Adult services, 18 years and over (16, 17 year-olds if treated in adult care units)	Detailed review of pediatric services
Allogeneic and autologous transplants	
All patients treated in Ontario, including out of province/country	
Resource requirements including human, financial, capital; inpatient and follow-up care; laboratory services; critical care services	
Recommendations about revisions to the funding model	
Inventory of available evidence-based guidance	Net-new evidence-based guidance documents
Advice regarding indications for which there is clear evidence supporting transplant	Advice regarding “grey areas”: Indications for which the need for transplant is unclear.
High level commentary about HLA typing and cord blood issues	Detailed recommendations re HLA and cord blood.

## Advisory Panel Membership

<p><i>Panel Chair:</i> Kevin Imrie MD, FRCPC Chair, Hematology Disease Site Group, CCO-PEBC University of Toronto</p> <p>Nan Brooks LLB, MHSA Senior Director, Strategic Relationships University Health Network (UHN)</p> <p>Rena Buckstein MD, FRCPC Head Hematology Site Group Odette Cancer Centre</p> <p>Jose Chang MD FRCPC R.S. McLaughlin Durham Regional Cancer Centre</p> <p>Michael Crump MD Lymphoma Site Leader, Clinical Director, Autologous Stem Cell Transplant Service Princess Margaret Hospital, UHN</p> <p>Sarah Downey Executive Director Princess Margaret Hospital, UHN</p> <p>Bill Evans MD, FRCPC President Juravinski Cancer Centre</p> <p>Jordan Herst MD, FRCPC Clinical Hematologist Sudbury Regional Hospital</p> <p>Kang Howson-Jan MD, FRCPC London Health Sciences Centre</p> <p>Lothar Huebsch MD, FRCPC Transplant Director Ottawa Hospital</p>	<p>Gino Picciano Senior VP and COO Ottawa General Hospital</p> <p>Bryn Pressnail BSc, MD, FRCPC Clinical Director Cancer Program Royal Victoria Hospital</p> <p>Anne Smith MD, FRCPC RVP Cancer Centre of South Eastern Ontario Kingston General Hospital</p> <p>Irwin Walker MBBS, FRACP, FRCPC Director, Hamilton Bone and Marrow Transplant Program McMaster University Medical Centre</p> <p>Patricia Knapp, Saul Melamed, Anthony Cheung Priority Services Ontario Ministry of Health and Long Term Care</p> <p><u>Cancer Care Ontario:</u></p> <p><i>Executive Sponsor:</i> Carol Sawka MD, FRCPC Provincial VP, Chair Clinical Council Cancer Care Ontario</p> <p><i>Project Manager:</i> Jillian Ross RN, MBA Director, Clinical Programs Cancer Care Ontario</p> <p>Judy Burns Director, Regional Programs &amp; Performance Management Cancer Care Ontario</p>
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## Advisory Panel Membership

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### Additional Contributors

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## Working Group Assignments

Access Working Group	Funding Working Group	Quality Working Group
Sarah Downey	Nan Brooks	Jose Chang
Jeremy Hamm	Rena Buckstein	Michael Crump
Jordan Herst (Chair)	Judy Burns	(Chair)
Len Kaizer	Bill Evans	Sherrie Hertz
Patricia Knapp	Lothar Huebsch (Chair)	Kang Howson-Jan
John Matthews	Jeff Lipton	Janet MacEachern
Malcolm Moore	Gino Picciano	Sheila McNair
Bryn Pressnail	Maureen Trudeau	Bryan Rumble
Jillian Ross	Graham	Carol Sawka
Haim Sechter	Woodward	Irwin Walker
Anne Smith		

*Appendix 3: Transplant Centre Survey*

See next page

## Survey of Transplant Centres – January 2008

Cancer Care Ontario has convened a panel to review adult bone marrow and stem cell procurement and transplantation services in Ontario. Each transplant centre has at least one representative on the panel. The panel is addressing issues of quality, access and funding. The government has asked to receive advice in a timely enough way, in order that it may be considered in 08/09 funding allocations. **Please submit via e-mail or fax by Friday, February 8** to the attention of Jillian Ross, [Jillian.Ross@cancercare.on.ca](mailto:Jillian.Ross@cancercare.on.ca) or Fax 416-217-1207

If you have questions about this survey, please contact:

Dr. Kevin Imrie, Panel Chair - [Kevin.Imrie@utoronto.ca](mailto:Kevin.Imrie@utoronto.ca) (416)480-5145

Jillian Ross, Project Manager – [Jillian.Ross@cancercare.on.ca](mailto:Jillian.Ross@cancercare.on.ca) (416)971-9800 ext 1479

Distribution:

Heads of all Ontario Adult Bone Marrow Transplant Programs

- Dr. Rena Buckstein - Sunnybrook Health Sciences
- Dr. Kang Howson-Jan - London Health Sciences
- Dr. Lothar B. Huebsch - Ottawa General Hospital
- Dr. Jeffrey Lipton and Dr. Michael Crump - Princess Margaret Hospital
- Dr. Pedro G. Lopez - Sudbury Regional Hospital
- Dr. Irwin R. Walker - Hamilton Health Sciences
- Dr. John Matthews - Kingston General Hospital

Your responses to the survey are essential to assist the panel in formulating its advice. Given the time constraints, we have divided the survey into three components and request that you send each section as soon as it is available.

Part A: Descriptive Information

Part B: Reference materials

Part C: Data

We have made every attempt to make the survey is concise and request only information that will directly influence the panel deliberations and/or be included in the report. For your reference, we have included rationale for the questions at the start of each section.

With each question, we have allowed room to use for comments if you wish. In addition to general comments, it would be helpful if you would use this area to advise us if you have concerns regarding the clarity of the question and/or if you employed certain assumptions in order to formulate your reply.

Please note that it is our intention to share this information with Panel members and include it in a report that may be made publicly available. If you have any concerns about sharing certain aspects of your responses, please make note of this in the relevant “comments” section.

## PART A: DESCRIPTIVE INFORMATION

**1. Centre Name:** \_\_\_\_\_

### 2. Services Provided

*This information will be used to describe current service provision in Ontario.*

2.1 Please identify the following services are provided by your program directly (check box) and those that you refer out to others.

Service	Our program directly provides.... <i>(check all that apply)</i>	These services are completed for our patients by... <i>(Name org)</i>	Comments
<b>Pre-Transplant Procedures</b>			
HLA Typing	<input type="checkbox"/>		
Bone Marrow Harvest	<input type="checkbox"/>		
Procurement of Stem Cells from Peripheral Blood	<input type="checkbox"/>		
T-cell depletion	<input type="checkbox"/>		
Cryopreservation	<input type="checkbox"/>		
<b>Transplants</b>			
<b>Autologous</b>			
Auto-BMT	<input type="checkbox"/>		
Auto-SCT	<input type="checkbox"/>		
<b>Allogeneic</b>			
BMT-related	<input type="checkbox"/>		
BMT-unrelated	<input type="checkbox"/>		
SCT-related	<input type="checkbox"/>		
SCT-unrelated	<input type="checkbox"/>		
Mini-transplants (non- or partially-myeloablative)	<input type="checkbox"/>		
<b>Post-Transplant Procedures</b>			
Donor leukocyte infusions	<input type="checkbox"/>		

Comment:

2.2 Do you purge stem cells in vitro and if so under what circumstances?

Yes  No  Comment:

2.3 Do you transfer patients to other facilities for collection purposes only?

Yes  No  Comment:

2.4 Do you accept patient transfers from other facilities for collection purposes only? Yes  No  Comment:

2.5 Do you perform day-1 transfers? Yes  No  Comment:

### 3. Data Collection

*This information will be used to describe the ability of the system to monitor activity in a consistent way for planning and management purposes.*

3.1 Do you report your data to the Canadian Blood and Marrow Transplant Group (CBMTG)? *(Check one)*

- We do not/have not in the past report(ed) data to CBMTG.
- We have reported data to CBMTG in the past, but do not currently do so.
- We report data irregularly to CBMTG.
- We currently report all data regularly to CBMTG.

Comment (For those not reporting to CBMTG, please comment on reasons):

3.2 Do you report your data to the Center for International Blood and Marrow Transplant Research (CIBMTR)? *(Check one)*

- We do not/have not in the past report(ed) data to CIBMTR.
- We have reported data to CIBMTR in the past, but do not currently do so.
- We report data irregularly to CIBMTR.
- We currently report all data regularly to CIBMTR.

Comment (For those not reporting to CIBMTR, please comment on reasons):

3.3 Do you track the number of patients referred to your centre for consideration of a transplant, but who do not proceed to transplant?

Yes  No  Comment:

3.4 Do you track the number of patients for which you conduct HLA typing, who do not proceed to transplant? Yes  No  Comment:

3.5 Do you track the number of patients for whom stem cells are procured, but do not proceed to transplant? Yes  No  Comment:

3.6 Do you track transplant volumes other than via health records abstraction for CIHI? (i.e. Do you maintain a program specific database?) Yes  No  Comment:

3.7 Do you track any waiting time data with respect to transplants and transplant related services? Yes  No  Comment:

#### 4. Eligibility Criteria

*This information will be used to describe current service provision in Ontario. It may also be used to provide high-level commentary on the correlation between current evidence and practice, and the degree to which transplants for “developmental” indications are available.*

4.1 For which if the following indications do you perform transplants

Indication	Autologous	Allogeneic	Comment <small>(please note if only related donors accepted)</small>
Chronic myeloid leukemia (CML)	<input type="checkbox"/>	<input type="checkbox"/>	
Chronic lymphocytic leukemia (CLL)	<input type="checkbox"/>	<input type="checkbox"/>	
Acute myeloid leukemia (AML)	<input type="checkbox"/>	<input type="checkbox"/>	
Acute promyelocytic leukemia (APL)	<input type="checkbox"/>	<input type="checkbox"/>	
Acute lymphoblastic leukemia (ALL)	<input type="checkbox"/>	<input type="checkbox"/>	



c) Allo-unrelated      Yes  No  Describe/Comment:

## 5. Program Capacity

*This information will be used to describe self-reported constraints to service provision in the various centres.*

5.1 In your opinion, what is the status of various supporting resources\* in terms of availability to meet current demand? \*Excluding funding, as this is covered elsewhere.

	Currently Meeting Demand	Currently Insufficient to Meet Demand	Comments
HLA typing	<input type="checkbox"/>	<input type="checkbox"/>	
Laboratory testing (other than for typing)	<input type="checkbox"/>	<input type="checkbox"/>	
Leukapheresis	<input type="checkbox"/>	<input type="checkbox"/>	
BM harvesting	<input type="checkbox"/>	<input type="checkbox"/>	
Radiation treatment	<input type="checkbox"/>	<input type="checkbox"/>	
Chemotherapy	<input type="checkbox"/>	<input type="checkbox"/>	
ICU beds	<input type="checkbox"/>	<input type="checkbox"/>	
Inpatient beds	<input type="checkbox"/>	<input type="checkbox"/>	
Outpatient clinic capacity	<input type="checkbox"/>	<input type="checkbox"/>	
Human resources	<input type="checkbox"/>	<input type="checkbox"/>	(please specify roles)
Other (please specify)*	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	
	<input type="checkbox"/>	<input type="checkbox"/>	

5.2 Do you have existing capacity to do more transplants should funding be available: Yes  No  Comment

5.3 Does your program have dedicated inpatient beds?  
Yes  No  Comment:

5.4 Does your program have dedicated ICU beds?

Yes  No  Comment:

5.5 What process do you use for planning/projection of transplant volumes and resource requirements? Describe:

5.6 Do you assign a formal priority or urgency rating to patients? Yes  No   
Comment:

5.7 Do you have a formal process to refer patients to an alternate transplanting centre should your wait times become excessive? Yes  No   
Comment:

5.8 Do you have wait time guidelines and/or targets? Yes  No   
Describe/Comment:

## 6. Quality Assurance

6.1 Status of Foundation for Accreditation of Cellular Therapy (FACT) accreditation

- We are not pursuing FACT accreditation
- We plan to pursue FACT accreditation in future
- We are currently in the process of pursuing FACT accreditation
- We are FACT accredited.

Comment:

6.2 Do you currently report to Health Canada regarding:

	Yes	No	Comment
a) Bone marrow and stem cell collection processes?	<input type="checkbox"/>	<input type="checkbox"/>	

	Yes	No	Comment
b) Adverse events	<input type="checkbox"/>	<input type="checkbox"/>	

6.3 Do you track\* the following outcome indicators? (\*Are the indicators calculated on a regular basis, at least annually, and reviewed by transplant program leadership?)

- Serious adverse events
- 30-day mortality
- 100-day mortality
- Disease control
- Reasons for failure of transplant
- Performance status
- Employment status
- Other (please list)

Comment:

## 7. FUNDING

7.1 Please provide comments about financial barriers and opportunities, and/or the current funding mechanism

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To whom may we address any requests for clarification of the information you have provided in this survey:

Name:

Title:

Contact Information:

### END OF PART A – DESCRIPTIVE INFORMATION

PLEASE SUBMIT VIA FAX (416)217-1207 or EMAIL [Jillian.Ross@cancercare.on.ca](mailto:Jillian.Ross@cancercare.on.ca)

## **PART B: REFERENCE MATERIAL**

**Centre Name:** \_\_\_\_\_

**Do you have any documents you are willing to share which may be of assistance to the panel and/or to other transplanting centres?**

For example:

1. Specifications for your program database
2. Data element definitions
3. Policies and procedures
4. Priority rating score descriptions
5. Other

Please list relevant documents on this sheet and fax this sheet and the documents to Cancer Care Ontario 416-217-1207 Attention Jillian Ross or send via e-mail to [jillian.ross@cancercare.on.ca](mailto:jillian.ross@cancercare.on.ca)

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To whom may we address any requests for clarification of the information you have provided on this survey:

Name:

Title:

Contact Information:

**END OF PART B – REFERENCE MATERIALS** PLEASE SUBMIT VIA FAX  
(416)217-1207 or EMAIL [Jillian.Ross@cancercare.on.ca](mailto:Jillian.Ross@cancercare.on.ca)

## PART C DATA SUBMISSION WORKSHEET

**Centre Name:** \_\_\_\_\_

1. Please share the following data as noted in the tables, where readily available. *This information will be used to validate a data definition from the CIHI data sets, to demonstrate trends, and to forecast activity.*

Include adults 18 and over only, or check the box below

- We are unable to separate out patients by age  (check if this applies)

Report by:

- Fiscal years (April to March)

**Table 1: Transplant volumes by type**

*Please note that this table is based on categories from the Canadian Blood and Marrow Transplant Group (CMBTG). Having compiled information for this survey, you may want to consider submitting to CMBTG if you have not already done so. CMBTG members may do so at <http://www.cbmtg.org/statistics/>. If you are unable to provide the breakdown according to these categories, please use the blank lines at the end of the table to provide summary statistics.*

Transplant Procedures	03/04	04/05	05/06	06/07	07/08 YTD Dec.
1. # of Autologous BMT					
2. # of Autologous PB					
3. # of Allogenic (Myeloablative) / <b>Related</b> / BM					
4. # of Allogenic (Myeloablative) / <b>Related</b> / PB					
5. # of Allogenic (Myeloablative) / <b>Related</b> / Cord					
6. # of Allogenic (Myeloablative) / <b>Unrelated</b> / BM					
7. # of Allogenic (Myeloablative) / <b>Unrelated</b> / PB					
8. # of Allogenic (Myeloablative) / <b>Unrelated</b> / Cord					
9. # of Allogenic ( <b>Non-Myeloablative</b> ) / Related / BM					
10. # of Allogenic ( <b>Non-Myeloablative</b> ) / Related / PB					
11. # of Allogenic ( <b>Non-Myeloablative</b> ) / Unrelated / BM					

Transplant Procedures	03/04	04/05	05/06	06/07	07/08 YTD Dec.
12. # of Allogenic ( <b>Non-Myeloablative</b> ) / Unrelated / PB					
13.					
14.					
15.					
16.					

**Table 2 Additional Data Elements**

Please complete any sections for which the data are readily available.

	03 / 04	04 / 05	05 / 06	06 / 07	07 / 08 YTD Dec.	Not tracked or not readily available	Comments
<b>Referrals</b>							
1. # of Referrals* to your program - Ontario patients						<input type="checkbox"/>	
2. # of Referrals* to your program – Out-of-Province patients (OOP)						<input type="checkbox"/>	
3. # of Referrals* to your program - Not typed (i.e. Pt deemed ineligible for transplant.) Include ON and OOP						<input type="checkbox"/>	
4. # of Referrals* to your program– Typed, but not transplanted Include ON and OOP						<input type="checkbox"/>	
<b>Procurement</b>							

\* requests for consult for possible transplant

	03 / 04	04 / 05	05 / 06	06 / 07	07 / 08 YTD Dec.	Not tracked or not readily available	Comments
5. # of marrow harvest procedures done at your centre						<input type="checkbox"/>	
6. # of stem cell collection procedures done at your centre						<input type="checkbox"/>	
<b>Post-Transplant Care</b>							
7. # of "Day – 1 Transfers"						<input type="checkbox"/>	
<b>Matching and Procurement Related Costs (Referred Out Services)</b>							
<i>Procurement – external source – unrelated donor</i>							
8. # of procurements Stem cells						<input type="checkbox"/>	
9. Fees paid to external source* for procurements						<input type="checkbox"/>	
<i>Procurement – external source – related donor</i>							
10. # of procurements- Bone Marrow						<input type="checkbox"/>	
11. Fees paid to external source* for procurements						<input type="checkbox"/>	
HLA Typing – done outside your centre							
12. # patients typed						<input type="checkbox"/>	
13. Cost* of these typing services						<input type="checkbox"/>	
<b>Additional Volume Statistics</b>							
14. # of donor leukocyte infusions						<input type="checkbox"/>	

	03 / 04	04 / 05	05 / 06	06 / 07	07 / 08 YTD Dec.	Not tracked or not readily available	Comments
15. # of instances of bone marrow purging (auto)						<input type="checkbox"/>	
16. # of T-Cell depletions (allo)						<input type="checkbox"/>	
17. # of patients referred elsewhere <sup>+</sup> in ON for transplant for indications or procedures not done at your centre– total						<input type="checkbox"/>	
18. # of patients referred out due to local access issues						<input type="checkbox"/>	
19. # of pts referred out of provinces for indications not transplanted in ON						<input type="checkbox"/>	

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To whom may we address any requests for clarification of the information you have provided on this survey:

Name:

Title:

Contact Information:

**END OF PART C – DATA SUBMISSION WORKSHEET - PLEASE SUBMIT VIA FAX (416)217-1207 or EMAIL [Jillian.Ross@cancercare.on.ca](mailto:Jillian.Ross@cancercare.on.ca)**

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<sup>+</sup> Within or outside of your LHIN



*Appendix 4: Draft Evidence-Based Series #6-5: Section 1. SCT in adults: recommendations*

<http://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=35448>

*Appendix 5: Membership of Case Cost Development Working Group and Case Costing Methods*

**Ensuring Access to Bone Marrow and Stem Cell Transplantation in Ontario  
Costing Methodology and Costing Working Group Membership**

Costing Methodology  
(Based on UHN Methodology)

**1. Bone Marrow Transplant Program**

a. Dedicated BMT program resources costs

- Allocation of Bone Marrow Transplant program resources based on the type of BMT supported.
- Clinical Coordinators, Clinical Associates and other BMT program FTEs and costs are equally and allocated over autologous and allogeneic transplant procedures.
- Other resources are specific to allogeneic transplants (e.g. 2 dedicated Acute Care Nurse Practitioners that support allogeneic transplants).

**2. Pre-BMT Phase**

a. Ambulatory Clinic costs

- 1-3 months pre-BMT.
- Ambulatory visits to the PMH Autologous and PMH Allogeneic clinics for pre-transplant assessment and treatment planning (this also includes BMT program costs related to donors, prospective donors and prospective transplant recipients who may not go on to receive a transplant).
- **Excludes pre-BMT preparative conditioning regimen of chemotherapy and radiation therapy (UHN receives funding for Systemic Therapy and Radiation Therapy).**
- Costs are higher for allogeneic transplants as the cost reflects resources utilized in testing donor(s), prospective donor(s), and recipients whereas for auto the costs are for the transplant recipient.

b. Outpatient Laboratory costs

- Laboratory work-up pre-BMT includes a wide variety of different test that are carried out both to establish the suitability of patients for a transplant and to maximize the chance of success following transplantation. Lab tests also include pre-screening and testing of donors for compatibility as well as viral testing, testing for diseases and markers on donated stem cells.
- Costs are higher for allogeneic transplants as the cost reflects resources utilized in testing donor(s), prospective donor(s), and recipients whereas for auto the costs are for the transplant recipient.
- **Excludes ambulatory diagnostic imaging (costs recovered through OHIP technical and professional fees).**

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### 3. Bone Marrow/Stem Cell Procurement Phase

#### a. Procurement Costs

- Some bone marrow procurement procedures for allogeneic-related donors are performed in the operating room. The cost of these inpatient procedures is allocated to allogeneic-related transplants (aggregate cost averaged over all allogeneic-related transplant recipients).

#### b. World Wide Search Costs

- For allogeneic-unrelated transplants, the procurement costs is for BMT registry, courier, transportation and other expenses related to a worldwide search for a matching donor. Donors are worked up and harvested at institutions near where they live.

#### c. Aphaeresis Unit Costs

- Aphaeresis Unit: cost of procuring stem cells for transplantation using the process of apheresis. Cost is higher for autologous BMT patients as multiple apheresis procedures may be required prior to transplantation. This is because donors have stem cells that are chemotherapy and radiotherapy naïve, while autologous stem cells have usually been exposed to therapy and hence are less abundant and potentially damaged, thus requiring more phereses to collect adequate numbers.

#### d. BMT Stem Cell Processing Lab (including cryopreservation) Costs

- Autologous patients have a higher frequency and total number of aphaeresis procedures performed (4-6 products) that require stem cell processing. Also, cryopreservation is more common for autologous transplants. This explains the higher costs for autologous transplants.
- In the case of allogeneic transplants, fresh cells are preferred to avoid the loss of cells due to the freezing and thawing process but related collections are usually cryopreserved to increase flexibility of infusions, given the limited number of collection days possible.
- In some cases of allogeneic bone marrow grafts, red cell depletion may be necessary in the case of blood-type incompatibilities and to reduce volume in the case of cryopreservation.

#### e. Tissue Typing HLA costs

- Tissue Typing HLA costs is exclusive to allogeneic transplants. More HLA matching is performed on prospective family donors who end up not matching, explaining the higher cost for allogeneic-related transplants. For unrelated potential donors after family typing reveals the absence of a match in the recipient, there is a need for higher resolution, and hence more expensive typing.
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### 4. Inpatient Transplant Phase

#### a. Transplant

- Acute inpatient admission for the bone marrow transplant procedure.
- Allogeneic transplants have a higher length-of-stay in part explaining the higher acute inpatient cost compared to autologous transplants.
- The allogeneic-unrelated transplant drug costs are higher, reflecting the high cost immunosuppressive agents, anti-fungal, antibiotics and other drugs administered to mitigate against GVHD and other complications of this type of bone marrow transplant.
- Costs include IP nursing, food services, ICU, IP lab, IP diagnostic imaging pharmacy, allied health, food services, and miscellaneous
- **Inpatient costs exclude dialysis, CT Scan, MRI (other UHN funding envelopes).**

## 5. Post-BMT Phase

### a. Ambulatory Visit costs

- Ambulatory visits to the PMH Autologous and PMH Allogeneic clinics for post-transplant follow-up care and maintenance.
- Autologous patients make fewer follow-up visits (~ 8 per patient).
- Due to the risk of post-BMT complications, allogeneic patients are followed for a longer period of time (up to 3 visits per week, for 1 year or longer), explaining the higher post-BMT ambulatory cost.

### b. Outpatient Laboratory Costs

- Following transplantation, the predominant roles of the laboratory are in the monitoring of immunosuppressive drug levels, in the detection of allograft rejection, and in the detection of bacterial infection or viral reactivation. The allogeneic transplants have a higher risk of post-BMT complications, explaining the higher cost of post-BMT laboratory testing.

### c. Transfusion Centre Costs

- Transfusion Centre costs are for blood transfusions to treat post-BMT complications (such as anemia, low platelet counts, etc.) and for intravenous boluses required by some allogeneic transplant patients who become dehydrated because of medications, or who are unable to take some of the routine oral medications.
- **Excludes ambulatory diagnostic imaging (costs recovered through OHIP technical and professional fees).**

## Post-BMT Complications Phase

### a. Emergency room visit costs

- Emergency room visits related to complications/side effects.

### b. Inpatient Admission Costs

- Acute inpatient admissions to treat complications, such as:
  - o Graft-versus-host reaction or disease
  - o Cytomegaloviral disease
  - o Neutropenia
  - o Pneumonia
  - o Bleeding
  - o Sepsis
  - o Infections
- Allogeneic BMT patients are at risk of GVHD and much higher risk of these other diseases and infections, which explains the higher incidence of readmissions to treat post-BMT complications.

### Costing Working Group Membership

CCO	Haim Sechter
CCO	Jeremy Hamm
UHN	Nan Brooks
UHN	Tom Marincic

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UHN	Brian Pollard
Ottawa	Richard Ciavaglia
Ottawa	Sheryl MacDiarmid
Ottawa	Cameron Keyes
Sick Kids	Irene Blais
Sick Kids	Judy Van-Cleaf
Sick Kids	May Seto
London	Brenda Rowswell
Hamilton	Karen Orescanin

*Appendix 6: List of Related Documents*

1. Evidence-Based Series #6-5: SCT in adults. K. Imrie, R.B. Rumble, M. Crump, the advisory panel on bone marrow and SCT, and the Hematology Disease Site Group of Cancer Care Ontario's Program in Evidence-based Care. 2008, publication pending.
2. Report of Financial Working Group. Ontario Provincial Bone Marrow Transplantation Steering Committee. January 21, 1994, unpublished.
3. Report from Ontario's Bone Marrow Transplant Network. June 29, 1993, unpublished.