Bone Marrow Transplants (BMT)
Information for the Certificate of Need (CON) Commission Meeting
March 26, 2009

Issue #1
What quality standards are required for accreditation of a BMT program?

Foundation for Accreditation of Cellular Therapy (FACT)

Taken from the FACT website: http://factwebsite.org/main.aspx?id=850

Cellular Therapy Accreditation Eligibility Requirements (please see second page for BMT requirements specifically)

Clinical Program:

- Must perform autologous and/or allogeneic transplants on adults and/or pediatric patients as appropriate for type of accreditation sought.
- Must use products collected and processed in facilities which meet FACT-JACIE[1] Standards.
- If applying for allogeneic accreditation, a minimum of ten new allogeneic patients must have been transplanted during the twelve month period immediately preceding the application for accreditation and annually thereafter. A clinical program that is accredited for allogeneic transplantation will be considered to have met the numeric requirement for autologous transplantation.
- A program that utilizes more than one clinical site for allogeneic transplantation must have transplanted a minimum of five new allogeneic patients at each site in the 12 months immediately preceding application for accreditation and annually thereafter.

[1] JACIE is the "Joint Accreditation Committee ISCT & EMBT", where ISCT is the "International Society for Cellular Therapy" and EMBT is the "European Group for Marrow and Blood Transfusions". JACIE and FACT work together in establishing criteria for and accrediting BMT services, internationally. ISCT was established in 1992 and is based in the US, while EMBT is EU-based.

- If applying for combined adult and pediatric allogeneic accreditation, the clinical program must have performed a minimum of five allogeneic transplants for each population.
- For a clinical program requesting accreditation for only autologous transplantation, a minimum of five new recipients of autologous transplant must have been transplanted at each site during the twelve month period immediately preceding the application for accreditation and annually thereafter.
- A dedicated transplant team including a Program Director and at least one other physician trained or experienced in hematopoietic progenitor cell therapy must be in place for at least twelve months prior to being eligible for initial accreditation.
- A clinical program performing pediatric transplantation must have a transplant team trained in the management of pediatric patients, and at least one attending physician who is board certified/eligible (or non-U.S. equivalent) in Pediatric Hematology/Oncology or Pediatric Immunology.
- A clinical program director must be appropriately licensed to practice medicine in the jurisdiction in which the program is located, be board certified (or non-U.S. equivalent) in one or more of the following specialties: Hematology, Medical Oncology, Adult or Pediatric Immunology, or Pediatric Hematology/Oncology, and participate regularly in educational activities related to the field of HPC transplantation.
- Must meet or exceed all current FACT-JACIE International Clinical Program Standards.

Collection Facility: Bone Marrow or Apheresis

- Collect bone marrow cells or peripheral blood hematopoietic progenitor cell as appropriate for the accreditation being sought.
- Must use a processing facility that meets FACT standards
- A collection facility, including the medical director and at least one staff member, must have been in place and performing cellular therapy product collections for at least twelve months prior to being eligible for initial accreditation.
- For apheresis collection facilities, a minimum of ten apheresis collection

procedures must have been performed in the twelve months preceding initial application for accreditation.

- For bone marrow collection facilities, a minimum of one bone marrow collection procedure must have been performed in the twelve months preceding initial application for accreditation.
- For renewal accreditation of apheresis collection facilities, a minimum of thirty apheresis collection procedures must have been performed within an accreditation cycle.
- For renewal accreditation of bone marrow collection facilities, a minimum of three (3) bone marrow collection procedures must have been performed within an accreditation cycle.
- Where required, the apheresis collection facility must be registered with the FDA or non-U.S. equivalent for the activities performed.
- The collection facility director must have a medical degree or degree in a relevant science, qualified by postgraduate training or experience for the scope of activities carried out in the collection facility, and participates regularly in educational activities related to cellular therapy product collection and/or transplantation.
- The collection facility medical director must be a licensed physician with postgraduate training in cell collection and/or transplantation, have at least one year of experience in cellular therapy product collection procedures, have performed or supervised at least ten such collection procedures within the last 3 years for apheresis and/or within his/her career for marrow, and participate regularly in educational activities related to cellular therapy product collection and/or transplantation.
- For collection facilities collecting cellular therapy products from pediatric donors, physicians and collection staff must have documented training and experience in performing these procedures on pediatric donors.
- Meet or exceed all current FACT-JACIE International Standards for Cellular Therapy Product Collection.

Processing Facility:

- Process cellular therapy products.
- The processing facility and staff, including a processing facility director and processing facility medical director, must have been in place and

performing cellular therapy product processing for at least twelve months prior to being eligible for accreditation.

- The processing facility director must have a medical or doctoral degree in a relevant science, and be qualified by training or experience for the scope of activities carried out in the processing facility.
- The processing facility medical director must be a licensed physician with postgraduate training and/or one year of experience in the preparation and clinical use of cellular therapy products.
- Meet or exceed all current FACT-JACIE International Standards for Cellular Therapy Product Processing.

Federal Standards

- Facilities that manufacture HCT/Ps (human cell, tissue, and cellular and tissue-based products, including hematopoietic stem cells obtained from peripheral and cord blood) are subject to Title 21 CFR part 1271
- Some are exempted and are regulated under the Public Health Service Act, Section 361
    - If the HCT/Ps:
        - Are minimally manipulated
        - Are intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent
        - Do not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; **and either:**
            - The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
            - The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

        - Is for autologous use;
        - Is for allogeneic use in a first-degree or second-degree blood relative; or
        - Is for reproductive use[2]
    - Minimally manipulated bone marrow does not fall under this regulation
        - Minimal manipulation – "Processing that does not alter the relevant biological characteristics or cells or tissues"[3]
- Bone marrow transplants are regulated by the Health Resources and Services Administration (HRSA)
    - National Marrow Donor Program – A nonprofit agency that contracts with HRSA to operate the National Bone Marrow Donor Registry[4]

<u>Staff Summary</u>

Similar to Michigan's CON requirements, there are transplantation volume requirements before voluntary accreditation may be sought. However, mandatory Federal regulations under HRSA do not address cost, geographic proximity, or a volume requirement.

2 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=1271.10

3 http://www.fda.gov/cber/faq/tisconsfaq.htm

4 http://www.marrow.org/ABOUT/About_Us/Publications/2004_Biennial_Report/PDF/biennial_report_2004_1.pdf

Issue #2
What are the costs associated with BMT (e.g., procedure costs, Medicare or other insurance reimbursement, facility costs)?

Procedure Costs

The cost for any given BMT procedure is contingent upon a variety of factors. These include the patient's insurance coverage, pre-existing health conditions, insurance co-pay, location of the facility, as well as the patient's age and sex.[1] Other fees incurred by the patient are donor search fees, compatibility testing fees, and donor typing fees. Often, the donor testing fees can range from $10,000 to $25,000, without insurance.[2]

The cost of the actual harvesting of donor cells varies depending on whether or not the donor is related to the patient. A transfusion from an unrelated donor can cost anywhere between $15,000 and $50,000; for a related donor, the price drops to around $3,500 to $5,000. Some insurance groups will cover the operation cost plus any travel expenses for the donor.[3]

The fee for the transplant itself varies greatly based upon the aforementioned factors. In general, however, the price of the average BMT

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[1] Bone Marrow Transplant- Questions and Answers. *Health Grades website* http://www.healthgrades.com/procedures/profile/Bone_Marrow_Transplant#costs_of_Bone_Marrow_Transplant

[2] Cost of Bone Marrow Transplant- National Bone Marrow Transplant Link http://www.nbmtlink.org/resources_support/rg/rg_costs.htm

[3] Ibid.

procedure is steep. The price can vary depending on whether the transfusion is autologous (of the patient's own cells), related allogeneic (of the patient's biological parents or siblings) or unrelated allogeneic (of an unrelated donor). Various sources cite slightly differing costs for each type of transfusion. One source prices autologous transplants at around $50,000 to $100,000 and allogeneic transplants at around $150,000 to $200,000.[4] A 1999 study done by the Duke Clinical Research Institute found that the average cost for a BMT was $193,000 (in 1999 dollars) though in this study there was no distinction made between allogeneic and autologous transplants.[5] In total, a patient can expect to spend from $300,000 to $530,000 on an unrelated allogeneic transplant, excluding post-operative outpatient care.[6,7] An autologous transplant will cost around $225,000, excluding post-operative outpatient care.[8] Autologous transplants are usually lower in cost as they do not involve donor cell testing and harvesting fees.

BMT Facility Costs

Information for establishing a new facility could not be located.

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4 Ibid.

5 "Costs and characteristics of patients who undergo bone marrow transplant (BMT)" Friedman JY, Reed SD, Glendenning A, Schulman KA. Duke University Medical Center.

6 "Remarks to the National Bone Marrow Donor Roundtable" Elizabeth M. Burke, Ph. D. 26 September 2002 http://newsroom.hrsa.gov/speeches/2002speeches/NMDP.htm

7 http://bmtbasics.org/index.php?option=com_content&task=view&id=67&Itemid=44

8 Ibid.

To maintain an up-to-date BMT facility, the University of Michigan has spent $1.5 million to update its stem cell processing lab; $0.5 million to expand tissue typing lab and diagnostic equipment; and $0.5 million for other laboratory equipment. When operating costs are taken into account, the total cost for updating and expanding BMT services in the last year were $8 million.[9]

BMT Insurance Costs

Insurance companies will usually cover most of the cost of the BMT operation. However, there are some aspects of the transplant that insurance may not cover:

- Donor testing
- Transplants for rare diagnoses
- Home health care
- Relocation costs if the transplant requires the patient to move to a different location[10]

BMT Medicare Costs

Medicare does cover the cost of the BMT operation, as well as any costs incurred by any potential donor matching and harvesting.[11]

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[9] Source: Henry Ford Hospital, testimony at February 5, 2009 CON Special Commission Meeting

[10] http://www.marrow.org/PATIENT/Plan_for_Tx/Planning_for_Tx_Costs/Insurance_and_Transplant_Cover

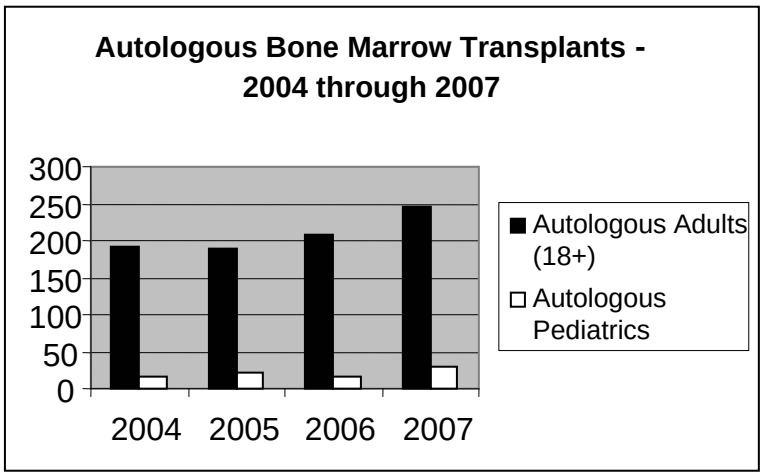
[11] http://leukemia.about.com/od/financialconcerns/a/BMTInsuranceGui.htm

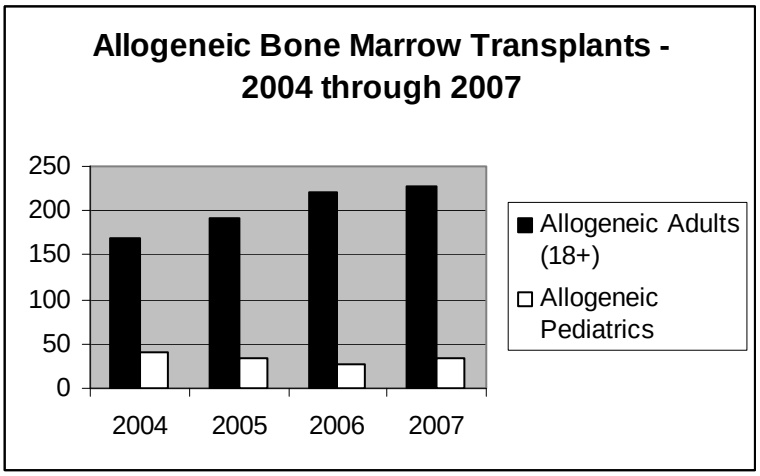
Staff Summary

Costs for BMT depend on a variety of variables, including patient age, sex, health status, geographic location, and insurance coverage, as well as type of transplant, with autologous transplants costing significantly less than allogeneic transplants. The costs of establishing a new transplant center were unable to be located. However, the University of Michigan estimates approximately $8 million in operating and upgrade costs in the last year.

Issue #3
Is the need for additional BMT services in Michigan supported by recent state data trends?

Michigan Bone Marrow Transplantation Services 2004 through 2007				
	Autologous		**Allogeneic**	
	Adults (18+)	Pediatrics	Adults (18+)	Pediatrics
2004	191	15	170	41
2005	190	22	192	34
2006	207	16	221	26
2007	245	30	228	33





Patients leaving Michigan for BMT services

- In West Michigan, 213 patients per year are eligible for BMT
  - 67 are treated in Michigan
  - Remaining 146 either leave Michigan or opt out of treatment[1]
- 96% of patients eligible for a BMT transplant within Michigan have the procedure done in Michigan[2]
- From 2000 to date, 167 Priority Health members in Michigan have undergone BMT
  - 23 pediatric patients underwent treatment at DeVos Pediatric Center
  - Of the rest:
    - 60% went to University of Michigan
    - 20% went to Karmanos Cancer Center
    - 20% went outside Michigan[3]

[1] Source: Spectrum Health, testimony at February 5, 2009 CON Special Commission Meeting

[2] Source: Henry Ford Hospital, testimony at February 5, 2009 CON Special Commission Meeting

[3] Source: Priority Health, testimony at February 5, 2009 CON Special Commission Meeting

Bone Marrow Transplant (BMT) Referrals Information Provided by Facilities for the March 26, 2009 CON Commission Meeting

1) The number of referrals for BMT made by the facility to out-of-state facilities.

	2007		2008		2009 (to-date)		Total	
	Pediatric	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**
Beaumont	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
Henry Ford	See notes	0	See notes	0	See notes	0	See notes	0
Karmanos	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
University of Michigan	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
St. John	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
Spectrum	0	See notes	0	See notes	0	See notes	0	See notes

2) The number of referrals for BMT made to Michigan facilities.

	2007		2008		2009 (to-date)		Total	
	Pediatric	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**
Beaumont	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
Henry Ford	See notes	See total	See notes	See total	See notes	See total	See notes	3
Karmanos	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
University of Michigan	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
St. John	See notes	See notes	See notes	See notes	See notes	See notes	See notes	See notes
Spectrum	0	Pending	0	Pending	0	Pending	0	Pending

3) The number of referrals for BMT received from out-of-state facilities.

	2007		2008		2009 (to-date)		Total	
	Pediatric	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**
Beaumont	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Henry Ford	n/a	0	n/a	0	n/a	0	n/a	0
Karmanos	Not Provided	Not Provided	See notes	See notes	Not Provided	Not Provided	-	-
University of Michigan	5	15	8	19	4	4	17	38
St. John	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Spectrum	0	n/a	0	n/a	0	n/a	0	n/a

4) The number of referrals for BMT received from Michigan facilities.

	2007		2008		2009 (to-date)		Total	
	Pediatric	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**	**Pediatric**	**Adult**
Beaumont	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Henry Ford	n/a	14	n/a	25	n/a	3	n/a	42
Karmanos	Not Provided	Not Provided	See notes	See notes	Not Provided	Not Provided	-	-
University of Michigan	79	257	58	299	14	53	151	609
St. John	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Spectrum	15	n/a	13	n/a	4	n/a	32	n/a

Notes:
n/a = not applicable to the facility

Beaumont Notes:
Beaumont does not collect or maintain referral data - BMT referrals to other facilities and programs are made by medical Oncologists who are in private practice so this is not tracked on any hospital data base.

Henry Ford Notes:

Henry Ford does not have information regarding pediatric referrals. These would be done at the discretion of the pediatrician and the patient's insurance.

Karmanos Notes:

1) For question number three: "Canada: 2, Florida: 1, and Ohio: 14." Therefore, for 2008 they had 17 referrals from out-of-state facilities. This total includes both adult and pediatric patients.

2) For question number four: "246" referrals from Michigan facilities for 2008. This total includes both adult and pediatric patients. Karmanos provided a break-down of the referrals by county in Michigan in both a map and data table format.

University of Michigan Notes:

1) For question number one "UMHS estimate one (1) referral per year for adult and pediatric BMT combined."

2) For question number two "Referrals to other Michigan facilities are usually made for insurance related reasons. UMHS does not formally track referrals for BMT to other Michigan facilities."

St. John Hospital supplied the following information to MDCH:

Dr. Tapazaglou - about 10 patients per year - mostly to KCI, 1 to Henry Ford, 1 to U of M
Dr. Coello - about 2 patients per year - to KCI
Pediatrics - 4 patients to U of M
Dr. Agnone - maybe 2 per year, about 4 last year - to KCI
Great Lakes - 33 patients - 27 to KCI, 5 to Henry Ford, 1 U of Washington
Dr. Al-Katib - about 24 patients - 20 to KCI, 3 to U of M, 1 to out of state (no site listed)

Spectrum Notes:

1) Information regarding out-of-state referrals is not available.
2) Pending receipt of adult information for referrals to Michigan facilities.

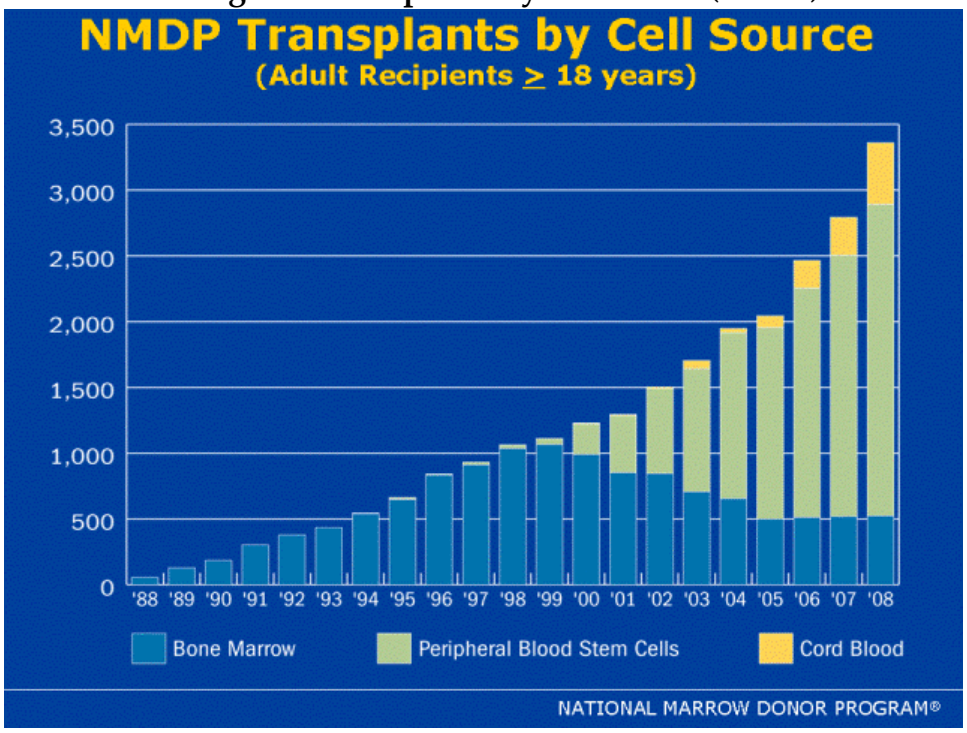
Staff Summary

While the number of BMTs performed in Michigan has increased from 2004 to 2007, both for autologous and allogeneic transplants, the data do not reflect a substantial rise in demand for these services.

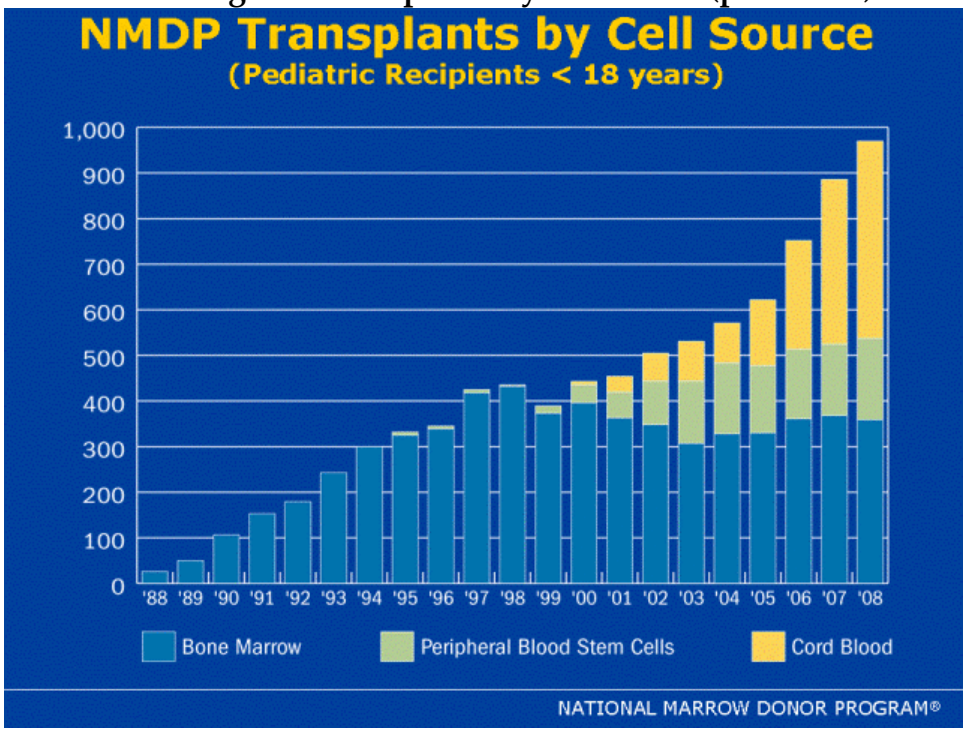
Issue #4

Is the need for additional bone marrow transplant services in Michigan supported by national data reflecting BMT and other stem cell transplant treatments over the past 20 years?

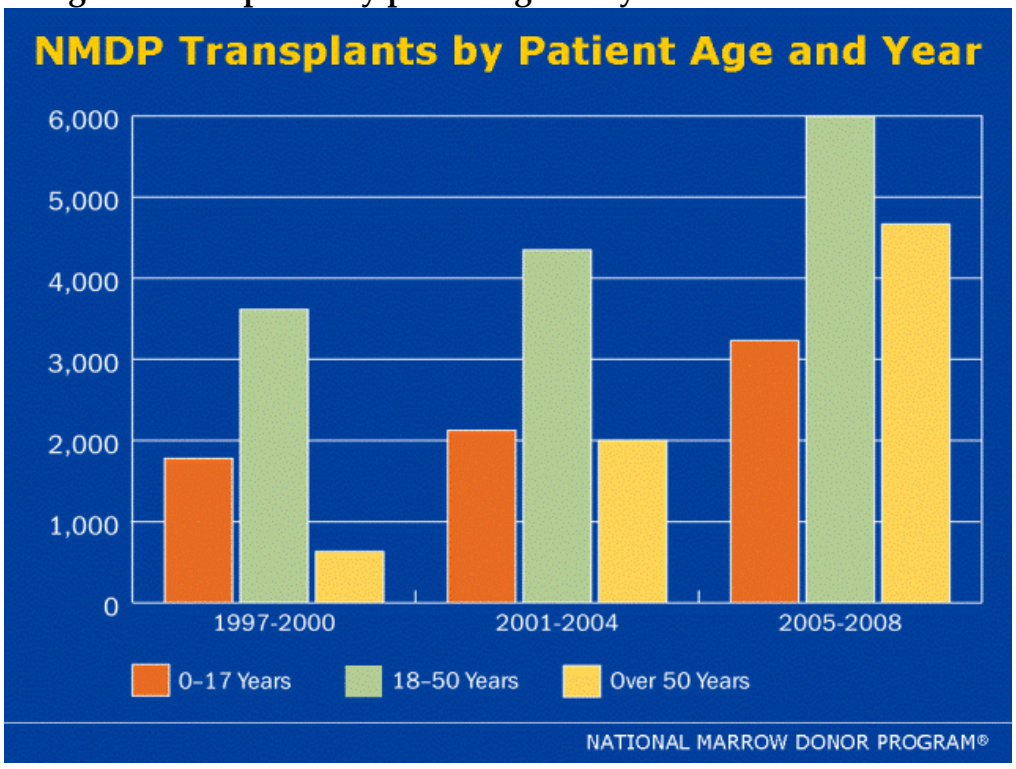
Number of allogeneic transplants by cell source (adults)



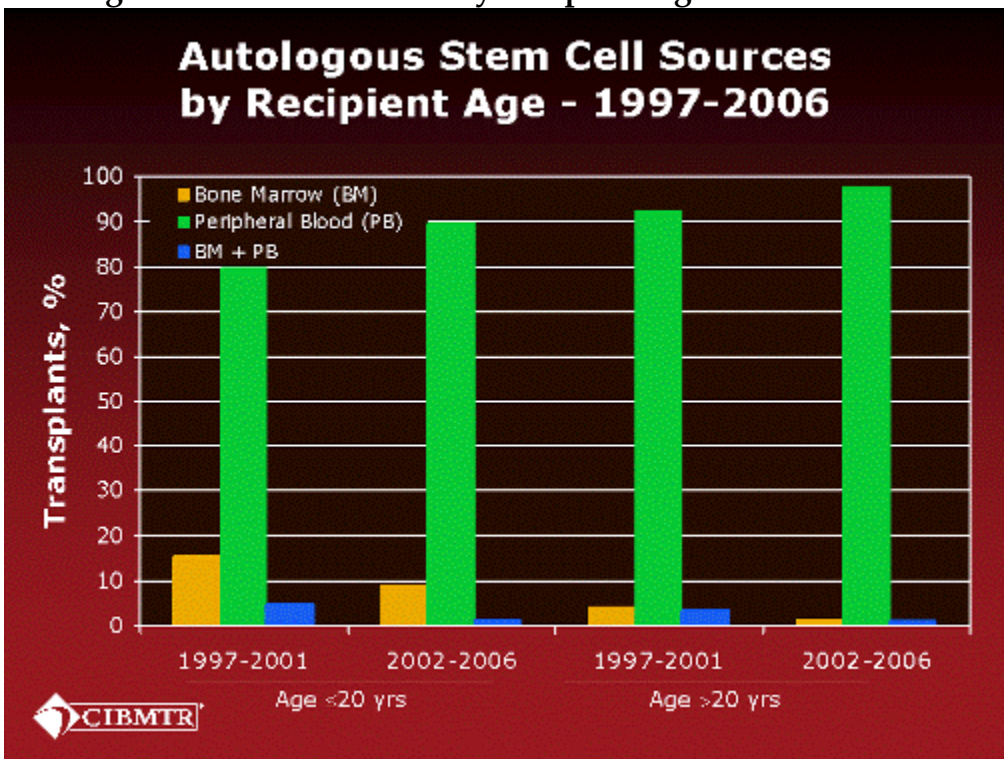
Number of allogeneic transplants by cell source (pediatrics)



Allogeneic transplants by patient age and year



Autologous Stem Cell Sources by Recipient Age



Autologous transplants rely almost exclusively on Peripheral Blood Stem Cells rather than marrow due to:

- Easier collection of cells
- More rapid hematopoietic recovery
- Easier graft manipulation (e.g., CD34+ cell selection, tumor cell purging)

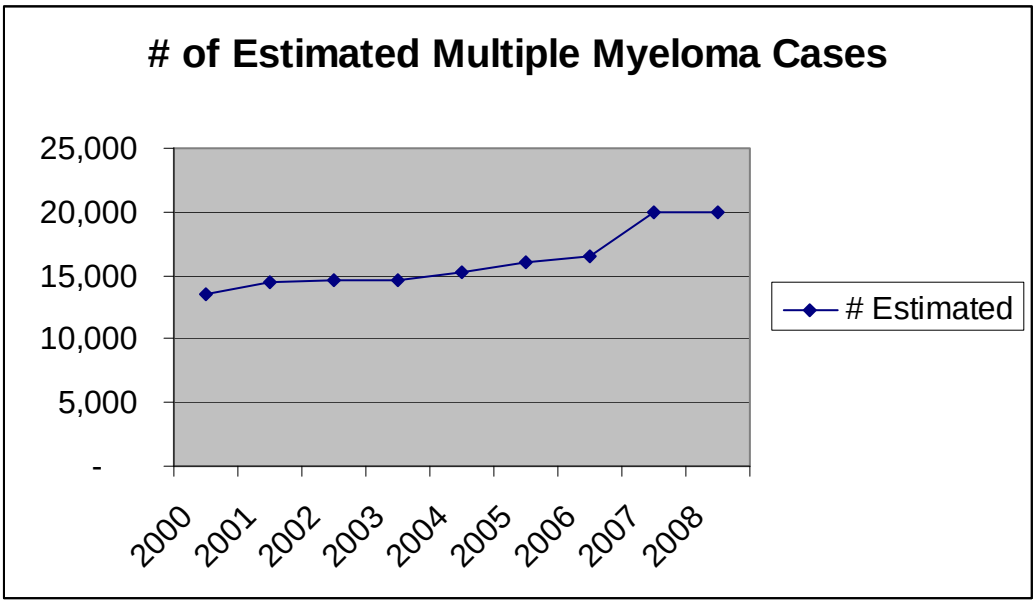
Staff Summary

For adult allogeneic transplant recipients, use of bone marrow for stem cell transplantation purposes is declining. Increasingly, adult transplants are performed using peripheral blood stem cells, or the stem cells found in the bloodstream. However, for pediatric allogeneic transplants, bone marrow and peripheral blood stem cell transplants numbers remain steady, concurrent with a rise in cord blood transplantation. Among autologous transplant recipients, nearly 100% of procedures utilize peripheral blood stem cells, reducing the percentage of bone marrow as a source to nearly zero.

Although transplants from all stem cell sources for all age groups have risen, the most dramatic increase can be observed in patients over the age of 50. From the time period between 1997 – 2000 to the time period spanning 2005 – 2008, transplants in this population have increased nearly eightfold.

Issue #5
Is the need for additional BMT services in Michigan exacerbated by a growing number of cases of multiple myeloma?

"The estimated frequency of multiple myeloma is 5 to 7 new cases per 100,000 persons per year." (http://multiplemyeloma.org/about_myeloma/index.php)



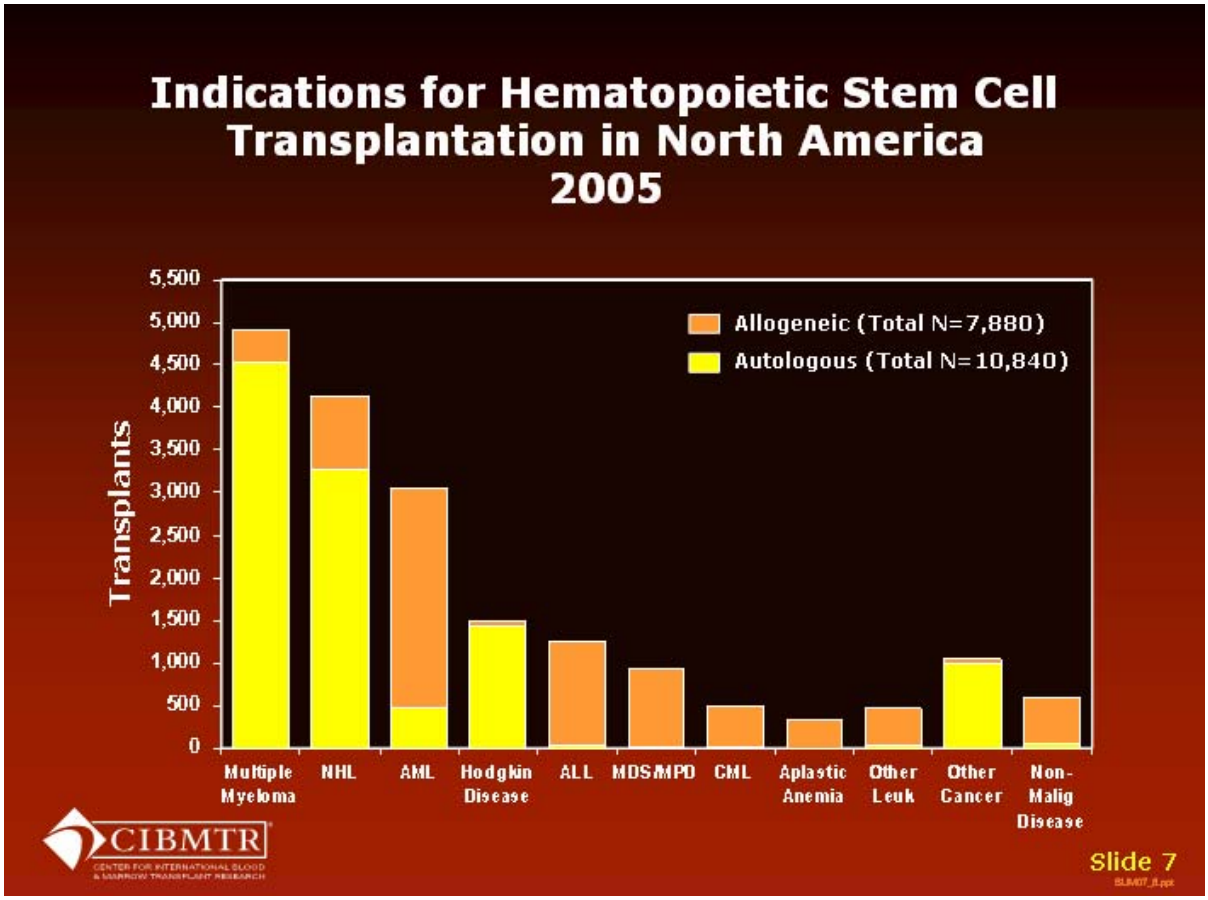
New cases of multiple myeloma in the United States American Cancer Society www.cancer.org	
2008	19,920
2007	19,900
2006	16,570
2005	15,980
2004	15,270
2003	14,600
2002	14,600
2001	14,400
2000	13,600

Please note: These are estimates and calculated by different means. Some projections are based on the Surveillance Epidemiology End Results (SEER) program at the National Cancer Institute, which collects information from specific geographic areas representing only 26 percent of the US population.

Numbers of multiple myeloma cases by year of diagnosis Michigan residents, 1998 - 2006 Source: Michigan Resident Cancer Incidence File. Includes cases diagnosed in 1998 – 2005 and processed by the Michigan Department of Community Health, Vital Records and Health Data Development Section by November 26, 2007 *Data for 2006 are provisional	
1998	635
1999	562
2000	609
2001	582
2002	613
2003	605
2004	619
2005	628
2006*	647*

Age statistics

- Median age at diagnosis is 70[1]
- Half of people diagnosed with multiple myeloma are over 71 years old[2]
- Only 1% of cases are found in people younger than 40[3]



NHL = Non-Hodgkins Lymphoma
AML = Acute Myelogenous Leukemia
ALL = Acute Lymphoblastic Leukemia
MPS/MPD = Myelodysplastic/myeloproliferative Diseases
CML = Chronic Myelogenous Leukemia

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[1] http://www.leukemia-lymphoma.org/all_page?item_id=6989

[2] http://www.cancer.org/docroot/CRI/content/CRI_2_2_2x_What_Causes_Multiple_Myeloma.asp?sitearea=

[3] Ibid.

Staff Summary

While acute myelogenous leukemia accounts for the majority of allogeneic transplants, the vast majority of autologous transplants, and overall highest number of transplants, are performed on multiple myeloma patients. Nationally, aside from a substantial increase in the number of patients diagnosed between 2006 and 2007, the number of new multiple myeloma patients, while increasing, has remained fairly level. A review of the numbers of new diagnoses in Michigan reflects the same trend.

Issue #6

Do the National Cancer Institute's guidelines require BMT services to be considered a comprehensive cancer center? Are other standards for these centers addressed?

NCI-designated Comprehensive Cancer Centers
Bone Marrow Transplant Status

Cancer center	Affiliation	City	State	Offers BMT?	State regulation of BMT
UAB Comprehensive Cancer Center	University of Alabama at Birmingham	Birmingham	AL	Yes – at the University of Alabama at Birmingham Hospital	Organ transplants regulated through Alabama CON program; not sure if it covers BMT
Arizona Cancer Center	University of Arizona	Tucson	AZ	Yes	No CON program
Chao Family Comprehensive Cancer Center	University of California at Irvine	Orange	CA	Partners with UCLA for actual transplant; Chao provides pre- and post-transplant services	No CON program
City of Hope National Medical Center	Beckman Research Institute	Duarte	CA	Yes	
Jonsson Comprehensive Cancer Center	University of California at Los Angeles	Los Angeles	CA	Yes	
Rebecca and John Moores UCSD Cancer Center	University of California at San Diego	La Jolla	CA	Yes	
UCSF Helen Diller Family Comprehensive Cancer Center	University of California at San Francisco	San Francisco	CA	Yes – At the University of California at San Francisco Medical Center	

USC/Norris Comprehensive Cancer Center	University of Southern California	Los Angeles	CA	Yes – At the University of Southern California University Hospital and Children's Hospital Los Angeles	No CON program
University of Colorado Cancer Center	University of Colorado at Denver & Health Sciences Center	Aurora	CO	Yes	No CON program
Yale Cancer Center	Yale University School of Medicine	New Haven	CT	Yes	Organ transplants regulated through Connecticut CON program; not sure if it covers BMT
Lombardi Comprehensive Cancer Center	Georgetown University	Washington	DC	Yes	Organ transplants regulated through DC CON program; not sure if it covers BMT
H. Lee Moffitt Cancer Center & Research Institute	University of South Florida	Tampa	FL	Yes	Regulated by the Certificate of Need program at the Florida Agency for Health Care Administration
Holden Comprehensive Cancer Center	University of Iowa	Iowa City	IA	Yes	Organ transplants regulated through Iowa CON program; not sure if it covers BMT

Robert H. Lurie Comprehensive Cancer Center	Northwestern University	Chicago	IL	Yes	Not regulated under IL's CON program
University of Chicago Cancer Research Center	University of Chicago	Chicago	IL	Yes, at the Duchossis Center for Advanced Medicine (University of Chicago Hospitals)	
Dana-Farber/Harvard Cancer Center	Dana-Farber Cancer Institute	Boston	MA	Yes, through Dana-Farber/Brigham and Women's Cancer Center	Organ transplants regulated through Massachusetts Determination of Need (DON) program; not sure if it covers BMT
Sidney Kimmel Comprehensive Cancer Center	Johns Hopkins University	Baltimore	MD	Yes	Regulated by Maryland CON program
Barbara Ann Karmanos Cancer Institute	Wayne State University School of Medicine	Detroit	MI	Yes	Regulated by Michigan's CON Commission
University of Michigan Comprehensive Cancer Center	University of Michigan	Ann Arbor	MI	Yes	
Mayo Clinic Cancer Center	Mayo Clinic Rochester	Rochester	MN	Transplant services at all 3 Mayo Clinic Locations (Rochester, MN; Jacksonville, FL; Scottsdale, AZ)	No CON program in MN or AZ; regulated in FL

Masonic Cancer Center	University of Minnesota	Minneapolis	MN	Yes – At the University of Minnesota Medical Center	No CON program
Siteman Cancer Center	Washington University School of Medicine	St. Louis	MO	Yes	Not regulated under Missouri's CON program
Duke Comprehensive Cancer Center	Duke University Medical Center	Durham	NC	Yes	Regulated through North Carolina CON program
UNC Lineberger Comprehensive Cancer Center	University of North Carolina at Chapel Hill	Chapel Hill	NC	Yes – At the North Carolina Clinical Cancer Center	
Wake Forest Comprehensive Cancer Center	Wake Forest University	Winston-Salem	NC	Yes	
Norris Cotton Cancer Center	Dartmouth-Hitchcock Medical Center	Lebanon	NH	Yes	Not regulated under New Hampshire CON program
Cancer Institute of New Jersey	Robert Wood Johnson Medical School	New Brunswick	NJ	Yes	Regulated through New Jersey CON program
Herbert Irving Comprehensive Cancer Center	Columbia University	New York	NY	Partners with New York-Presbyterian Hospital for transplant services	Regulated under New York CON program
Memorial Sloan-Kettering Cancer Center	n/a	New York	NY	Yes	
Roswell Park Cancer Institute	n/a	Buffalo	NY	Yes	

Case Comprehensive Cancer Center	Case Western Reserve University	Cleveland	OH	Yes, through Taussig Cancer Center and Ireland Cancer Center	Not regulated under Ohio's CON program
Ohio State University Comprehensive Cancer Center	Ohio State University	Columbus	OH	Yes	
Abramson Cancer Center	University of Pennsylvania	Philadelphia	PA	Yes	No CON program
Fox Chase Cancer Center	n/a	Philadelphia	PA	Partners with Temple University Cancer Center for transplant services	
University of Pittsburgh Cancer Center	University of Pittsburgh	Pittsburgh	PA	Yes – Through a partnership with the University of Pittsburgh Medical Center Cancer Centers	
St. Jude Children's Research Hospital	n/a	Memphis	TN	Yes	Not regulated by Tennessee CON
Vanderbilt-Ingram Cancer Center	Vanderbilt University	Nashville	TN	Yes – At the Vanderbilt University Hospital and Vanderbilt Clinic	
M.D. Anderson Cancer Center	University of Texas	Houston	TX	Yes	No CON program
Fred Hutchinson/University of Washington Cancer Consortium	Fred Hutchinson Cancer Research Center	Seattle	WA	Yes – at University of Washington	Regulated by Washington CON program

UW Paul P. Carbone Comprehensive Cancer Center	University of Wisconsin	Madison	WI	Yes – At the University of Wisconsin Hospital and Clinics	Not regulated by Wisconsin CON

The Six Essential Characteristics of an NCI-designated Cancer Center

Facilities: Physical facilities dedicated to the conduct of cancer focused research, and to the center's shared resources, administration, and research dissemination efforts, should be appropriate and adequate to the task.

Organizational Capabilities: The center should be organized to take maximum advantage of institutional capabilities in cancer research, and to appropriately plan and evaluate center strategies and activities.

Transdisciplinary Collaboration and Coordination: Substantial coordination, interaction, and collaboration among center members from a variety of disciplines should enhance and add value to the productivity and quality of research in the center.

Cancer Focus: A defined scientific focus on cancer research should be clear from the center members' grants and contracts, and from the structure and objectives of its formal Programs.

Institutional Commitment: The center should be recognized as a formal organizational component with sufficient space, positions, and discretionary resources to insure its stability and fulfill the center's objectives.

Center Director: The director should be a highly qualified scientist and administrator with leadership experience and institutional authority appropriate to manage the center and further its scientific mission and objectives.

A **cancer center** has a scientific agenda that is primarily focused on laboratory, clinical research, or population science or some combination of these components. Such centers are encouraged to stimulate transdisciplinary research. All areas of research should be linked collaboratively. Cancer centers with clinical components are *expected* to initiate and conduct investigator-initiated, early phase, innovative clinical trials and to provide leadership for, and participate in, the NCI cooperative groups.

A **comprehensive cancer center** demonstrates reasonable depth and breadth of research activities in *each* of three major areas: laboratory, clinical, and population-based research, with substantial transdisciplinary research that bridges these scientific areas. A comprehensive cancer center is expected to initiate and conduct investigator-initiated, early phase, innovative clinical trials and to provide leadership for, and participate in the NCI cooperative groups. An NCI-designated Comprehensive Cancer Center must also demonstrate community service, outreach, and dissemination; and education and training of biomedical researchers and health care professionals**.**

Quoted directly from: http://cancercenters.cancer.gov/documents/CCSG_IGuide9_08.pdf

Staff Summary

While the application guidelines for comprehensive cancer centers do not address BMT services as a requirement for designation, all of the 39 programs identified either perform transplants on-site or partner with an affiliated hospital for services. The standards also do not address geographic proximity or number of centers in a specific location.

Issue #7
Who are Michigan and national sources of expertise in BMT?

Michigan

Facilities currently providing BMT services
Barbara Ann Karmanos Cancer Institute
University of Michigan
Henry Ford Transplant Institute
Spectrum Health System (pediatrics)

Facilities proposing to provide BMT services
St. John Health
Beaumont Hospital

Other
Genesys Health System

National

Neal Flomenberg, MD, Physician at the Kimmel Cancer Center at Jefferson

Richard J. O'Reilly, MD, Chair, Department of Pediatrics; Chief, Pediatric Bone Marrow Transplant Service at Memorial Sloan-Kettering Cancer Center

Marcos de Lima, MD, Associate Professor, University of Texas MD Anderson Cancer Center

34 remaining comprehensive cancer centers

Note: MDCH staff have met with representatives of Spectrum Health System, Beaumont Hospital, University of Michigan, and St. John Health as part of the information gathering process.

Issue #8
Other Issues for Consideration

- Blood/HLA typing – Impact on patients and other facilities
- Complete data regarding how many patients travel outside of Michigan to receive BMT services/how many patients travel to Michigan to receive BMT services