MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Thursday, February 5, 2009

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Goldman called the meeting to order at 9:12 a.m.

A. Members Present:

Edward B. Goldman, Chairperson
Norma Hagenow, Vice-Chairperson
Peter Ajluni, DO (via teleconference)
Bradley Cory
Marc Keshishian, MD
Michael A. Sandler, MD
Vicky Schroeder
Thomas M. Smith
Michael W. Young, DO

B. Members Absent:

Dorothy E. Deremo
Adam Miller

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Carrie Barr
Michael Berrios
Sallie Flanders
William Hart
Larry Horvath
Kasi Kelley
Joette Laseur
Irma Lopez
Nick Lyon
Andrea Moore
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

Commission Sandler noted that he had a potential conflict with Bone Marrow Transplant, Pancreas, and Heart/Lung/Liver Transplant Services as Henry Ford Health System is a provider of these services. Chairperson Goldman noted that he had a conflict with Bone Marrow Transplant, Pancreas, and Heart/Lung/Liver Transplant Services as University of Michigan Health System is a provider of these services.

IV. Review of Minutes – December 9, 2008

Motion by Vice-Chairperson Hagenaw, seconded by Commissioner Smith, to approve the minutes as presented. Motion Carried.

V. Bone Marrow Transplant Services

Ms. Rogers gave an overview of the public hearing comments and the Department's recommendations (Attachment A). Discussion followed.

Public Comment:

Dr. Adil Akhtar Beaumont Hospitals (Attachment B)
Dr. Joseph Uberti, Karmanos Cancer Center (Attachment C)
Robert Meeker, Spectrum Health (Attachment D)
Richard Funnell, Spectrum Health
Elizabeth Palazzolo, Henry Ford Health System (Attachment E)
Dr. Sam Silver, University of Michigan (Attachment F)
Dr. Michael Wiemann, St. John Health System (Attachment G)
Dr. John Fox, Priority Health (Attachment H)
Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment I)
Dennis McCafferty, Economic Alliance for Michigan (Attachment J)
Lody Zwarensteyn, Alliance for Health (Attachment K)

Break from 11:00 a.m. to 11:15 a.m.

VI. Heart/Lung and Liver Transplantation Services

Public Comment:

Robert Meeker, Spectrum Health
Dr. Marwan Abouljoud, Henry Ford Health System (Attachment L)
Dr. Jeff Punch, University of Michigan (Attachment M)
Dr. Rick McNamara, West Michigan Heart
Dr. Lawrence Patzelt, West Michigan Cardiac Thoracic Surgeons
Dr. Robert Hooker, Michigan State University
Dennis McCafferty, Economic Alliance for Michigan
Barbara Jackson, Blue Cross Blue Shield of Michigan

VII. Bone Marrow Transplant Services - Continued

Chairperson Goldman reviewed the Department's recommendations. Discussion followed.

Motion by Commissioner Cory, seconded by Vice-Chairperson, to approve the Department's recommendations as presented. Motion Carried 7-0. Commissioner Sandler and Chairperson Goldman abstained from the vote.

VIII. Heart/Lung and Liver Transplantation Services - Continued

Ms. Rogers gave an overview of the public hearing testimony and the Department's recommendations (Attachment N). Discussion followed.

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Smith, to accept the Department's recommendations to appoint a Standard Advisory Committee (SAC) to consider elimination of the cap, in conjunction with the task of developing a clear, facility based, need methodology; and delegate the authority to the Vice-Chairperson to appoint the members of the SAC and to work with the Department to draft and approve the charge. Additionally, the Department is assigned with the responsibility to draft technical language changes to the Standards and all language changes should be moved forward to public hearing simultaneously. Motion Carried 6-1. Chairperson Goldman and Commissioner Sandler abstained.

IX. Pancreas Transplantation Services

Ms. Rogers gave an overview of the public hearing testimony and the Department's recommendations (Attachment O).

Public Comment:

Richard Peitroski, Gift of Life (Attachment P)
Dr. Darla Granger, St. John Hospital and Medical Center (Attachment Q)
Dennis McCafferty, Economic Alliance for Michigan
Barbara Jackson, Blue Cross Blue Shield of Michigan

Motion by Commissioner Keshisian, seconded by Commissioner Young, to approve the Department's recommendations as presented. Motion Carried 7-0. Chairperson Goldman and Commissioner Sandler abstained.

X. Magnetic Resonance Imaging (MRI) Services

Ms. Rogers gave an overview of the public hearing testimony and the Department's recommendations (Attachment R).

Public Comment:

Alec Allen, Oaklawn Hospital (Attachment S)
Dr. Neel Banerji, Oaklawn Hospital
Barbara Jackson, Blue Cross Blue Shield of Michigan
Dennis McCafferty, Economic Alliance for Michigan
Jamal Hamood, Basha Diagnostics, PC
Dr. Yahya Basha, Basha Diagnostics, PC (Attachment T)

Motion by Commissioner Sandler, seconded by Vice-Chairperson Hagenow, to task the Department with the responsibility to have a Workgroup on the issues of charity care, conversion of a mobile to fixed criteria, and MRI simulator. Motion Carried.

Motion by Commissioner Sandler, seconded by Vice-Chairperson Hagenow, to task the Department with the responsibility to draft the necessary language changes, including removal of non-essential criteria, modifications to the project delivery requirements, and technical/editorial

changes to the Standards. The Department will present the proposed language to the Commission at a future meeting. Language changes for these Standards should all be moved forward to public hearing simultaneously. Motion Carried.

XI. Psychiatric Beds and Services

Ms. Rogers gave an overview of the public hearing testimony and the Department's recommendations (Attachment U).

Motion by Vice-Chairperson Hagenaw, seconded by Commissioner Smith, to accept the Department's recommendations as presented. Motion Carried.

XII. Public Comment

None.

XIII. Review of Commission Work Plan

Ms. Rogers gave an overview of the Work Plan (Attachment V). Discussion followed.

Motion by Commissioner Keshishian, seconded by Commissioner Sandler, to approve the Work Plan as presented. Motion Carried.

XIV. Future Meeting Dates

March 26, 2009
June 9, 2009
September 10, 2009
December 9, 2009

XIV. Adjournment

Motion by Commissioner Keshishian, seconded by Commissioner Ajluni, to adjourn the meeting at 1:40 p.m. Motion Carried.

Attachment A

Michigan Department of Community Health (MDCH) Comments and Recommendations for Certificate of Need (CON) Review Standards Scheduled for 2009 Review Presented to CON Commission February 5, 2009

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BONE MARROW TRANSPLANTATION (BMT) SERVICES (Please refer to MDCH staff summary of comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of BMT under CON.	Yes	MDCH recommends further discussion.	
2. Increase the number of allowed adult BMT centers.	Yes	MDCH recommends further discussion.	
3. Allow for a second adult planning area within the state.	No	None.	BMT is a highly specialized service that should use the entire state as the planning area.
4. Make technical changes and updates that provide uniformity in all CON standards, i.e., revisions to reference of online system.	Yes	Draft recommended changes.	
Recommendation: MDCH recommends further discussion to gather information/research for the Commission regarding whether there remains a need to regulate BMT services, a need to maintain the existing cap, or a need to modify the existing cap. Additional discussion items will include issues of access, stem cell research, cancer treatments, and appropriate need methodology. The information would be used by the Commission at a future meeting to determine what subsequent steps it should take to address the issue. **The Department recommends that the Commission assign the responsibility to draft any necessary technical language changes to the standards to the Department. Language changes for these standards should all be moved forward to public hearing simultaneously.**			

BONE MARROW TRANSPLANTATION (BMT) SERVICES
Summary of 10/16/08 Public Hearing Comments and Department Comments
Prepared by: MDCH

Considerations from 10/16/08 Public Hearing.	
Public Hearing Summary: The complete oral and written testimonies are included in the February 5, 2009 CON Commission meeting binders. The agencies represented were as follows: • Blue Cross/Blue Shield (Verbal and Written): Believes that there is no need to formally address the BMT standards at this time. More specifically, based on a number of reasons listed, there aren't any compelling reasons or data showing there is an increased need in additional BMT programs. Reasons given were based upon outcomes of the informal BMT workgroup and state-wide BMT service trends. • University of Michigan Health System (Written): The current standards should stand as is and there is no need to re-open them at this time. They state that current expert clinical opinion is that the current capacity in Michigan is adequate and forecasts indicate no drastic change in the number of patients needing this service. Additionally, they go on to say that replication of this high cost and low volume service at additional locations within the state could, potentially, adversely impact the quality and research potential by diluting the available patient population, yet would not yield any significant access benefits. • Karmanos Cancer Institute (Written): Supports the BMT standards as they are currently written. They state that the current standards provide for the primary tenants of CON – cost, quality, and access – to be maintained. Additionally, patient needs in Michigan are being met by the three existing BMT programs. Lastly, they state that the standards as they are written now ensure that patients have access to the highest quality BMT programs and that costs are maintained through eliminating excessive capacity. • Economic Alliance of Michigan (Verbal and Written): EAM's position is two-fold. First, they state that unless there is new compelling evidence of the need for additional transplant services, they feel, at this time, the	***Policy Issues to be Addressed*** Issues to consider for further discussion: 1. Remove the cap on allowing only t of Michigan. ▪ The number of these types centers has remained relat years (2000 to 2007). The increases or decreases. ▪ The limited number of spe proliferation of this service ▪ Removing the cap would e would make the standards ▪ There are currently no adu Removing the cap would a opened and run on this sid pediatric BMT centers, one southeast Michigan. ▪ West Michigan currently ha transplant center located a ▪ Currently, all adult bone m located in southeast Michig volume requirement of 10 2. To modify the cap requirement eith number of transplant centers in Mi • Uncertain of what the cap s increased or decreased. Th identified upon which to bas

standard is fine as is. The second part, however, goes on to state that they hold a position that there may be a need for additional geographic distribution of the BMT centers. More specifically, to mirror the pediatric transplant services, to have two planning areas, one on the west side of the state and the other on the east side. • St. John Health (Written): Would like a SAC formed to review the BMT standard and to eliminate the cap of three BMT programs in Michigan. Otherwise, St. John urges the commission to eliminate BMT from being a covered clinical service under CON. • Spectrum Health (Written): Would like to redefine the planning areas for adult BMT to mirror what pediatric planning areas are. o Spectrum has drafted potential language changes for sections 2, 3 and 4 of the standards. See written testimony for language suggestions. • Beaumont Hospitals (Written): Wants the BMT standards to be reviewed and changed in regards to the limit of only allowing three transplant centers. Would like to see a SAC formed to revise the standards or would like to see the BMT standards rescinded. Additionally, they provided rationale as to why they should be allowed to provide BMT services.	
1. Review current language on what defines a planning area. Note: Consideration from 10/16/08 Public Hearing.	
Current Standards **Section 2. Definitions** (u) "Planning area" means: (i) for an adult bone marrow transplantation service, the state of Michigan. (ii) for a pediatric bone marrow transplantation service, either: (A) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or (B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.	***Policy Perspective*** MDCH does not support modifying the plan specialized service that should use the entir There should be a single planning area for t

2. Review current requirement for the number of BMT centers in Michigan. Note: Consideration from 10/16/08 Public Hear	
Current Standards **Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service** (5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2(1)(u)(i) does not exceed three (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area. (b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2(1)(u)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(u)(ii)(B) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.	
3. Review current language on the additional requirements for applying for a BMT program. Note: Consideration from 10/1	
Current Standards **Section 4. Additional requirements for applications included in comparative reviews** Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews. (2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed	

service will be located, on the date the application is submitted to the Department, as shown in the following schedule: Number of BMT Transplant Services (adult or pediatric, as applicable) Points in HSA Awarded Two or more services 0 One service 2 No services 4 (b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following: (i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor. (ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will be awarded to each applicant pursuant to this subsection. For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project. (c) A qualifying project will have 2 points awarded if an applicant documents	

that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals. CON Review Standards for Bone Marrow Transplantation Services CON-229 Approved 9/16/08 Effective 11/13/08 Page 7 of 13	

Beaumont Testimony on Bone Marrow Transplant Standards
CON Commission Meeting – February 5, 2009
Adil Akhtar, M.D., Chief of Oncology, Beaumont, Troy

Good morning, my name is Adil Akhtar, and I am Chief of Oncology for Beaumont, Troy. I am also a John Hopkins-trained transplant physician who previously practiced at Oakwood Hospital when they performed BMTs. Thank you for the opportunity to address you today on whether the Bone Marrow Transplant standards should put on the CON Commission's work plan for review. We believe these 23-year-old standards do need to be reviewed for numerous reasons:

- The arbitrary limit of three BMT programs in the state is impeding access to life-saving cancer treatment for some patients. There are no cost, quality or access reasons for continuing to limit access to this service.

- Beaumont has submitted documentation from national organizations showing the increase in numbers of these procedures at both the state and national levels, as older patients are now receiving transplants.

- Bone marrow donor registries and cord blood banks have increased the potential supply for unrelated donors. An adult's own stem cells, or those of unrelated donors, can now be used even on an outpatient basis to successfully treat cancer.

- A BMT is no more expensive than some chemotherapy drugs, some of which have to be given for the rest of a patient's life.

- National accrediting organizations assure quality for transplant programs.

- Patients should be allowed to remain with their medical oncologist during a transplant. Capacity at existing BMT centers is not the same as access.

- BMT is one cancer treatment option that is often done in combination with surgery, chemotherapy, or radiation treatments—all of which are either not regulated by CON or regulated by institution-specific criteria. BMT should be a readily available treatment option at major cancer centers like Beaumont.

For these reasons, we urge the CON Commission to review the BMT standards so they reflect the changes in medical care and treatment options for cancer patients that have occurred since the existing standards for an experimental treatment were enacted. Our belief is that there is no justification for even continuing to regulate BMT under the CON program but, if regulation is continued, it should be based on institution-specific criteria. We would be more than willing to serve the CON Commission in any capacity to review these standards.

Thank you.

BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

Bone Marrow Transplant Certificate of Need Standards Testimony
February 5, 2009

Good Morning Commissioners. My name is Dr. Joseph Uberti and I am the Service Chief for Hematology/Oncology and Co-Director of the Blood and Marrow Stem Cell Transplant Program for the Barbara Ann Karmanos Cancer Institute. Thank you for the opportunity to present Karmanos' position on bone marrow transplant CON standards.

It is our opinion that the existing BMT standards continue to serve the needs of cancer patients in Michigan. The standards ensure that those in need of bone marrow transplants have access to three high quality FACT accredited programs, each operated by experienced physicians, nurses, physician assistants and multiple layers of support staff. None of the programs are at capacity and all are capable of increasing the number of transplants. Adding more programs will certainly increase costs with the need to purchase costly equipment required to meet FACT guidelines, such as controlled rate cryopreservation systems, liquid nitrogen freezers and HEPA filtered inpatient care areas. It will take years before any programs can match the long-standing expertise of existing BMT programs in Michigan. These programs have provided a stable environment for patients, payors and providers which leads to an ability to contain the cost of transplantation. In Michigan's tenuous economic environment it is imperative that all patients, regardless of insurance coverage, have access to BMT programs. Karmanos is **the** safety net cancer hospital in southeast Michigan. In 2008, twenty eight percent of our patient volume had either Medicaid, Medicare or no insurance. It is likely that the newer programs will focus on insured patients, while leaving those under and uninsured patients to existing programs. This would ultimately result in financial hardship for programs such as ours which have been dedicated to provide care to all patients regardless of insurance status.

As you may hear there has been an increase in the number of transplants performed in Michigan since the standards were last reviewed, especially at Karmanos. However, in the late

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info@karmanos.org | www.karmanos.org

NATIONAL CANCER INSTITUTE

1990's there was also a similar spike in the number of transplants. In fact, Karmanos performed 254 transplants in 1998 and 265 in 2008, an increase of only 11 in a 10 year period. In 1998, transplantation was being promoted as a treatment modality for breast cancer and most transplants were being performed for breast cancer. Research later indicated that patients undergoing BMT for breast cancer did not have higher survival rates than those receiving other forms of treatment.

The vast majority of increases in adult transplantation over the past two years at Karmanos have been from increases for transplant for one disease - Multiple Myeloma. Patients with myeloma are somewhat unique in that they are one of the only diseases to respond to 2 and sometimes 3 transplants. In fact, the number of allogeneic unrelated and cord blood transplants at our center have not increased over the last four years. The increase in transplantation for myeloma may be transient. As stated in the most recent NCCN guidelines the data from recently completed trials as well as new agents currently available for the treatment of myeloma may decrease the need of the use of transplantation for this disease.
There are no new diseases which are using transplant as routine therapy. Although we hear of transplantation for a number of non-cancer diseases these are all investigational studies and certainly not a standard procedure offered to any patients in our center.

It has been argued that changes in the standards for stem cell transplantation are needed to provide better continuity of care for patients. Let me assure you that all patients referred to Karmanos for BMT continue to have close contact with their referring physician. The BMT multi-disciplinary team at Karmanos is committed to developing a strong working relationship with referring physicians to help ease the patients' transition to our facility for transplantation. All pre and post treatment tests are performed by the referring physician so there is no duplicity or added burden for the patient. Patients return to their original physician as soon as possible after transplantation for additional care.

You also may hear that Karmanos has turned away patients in need of transplantation. This is true. There are patients referred to us who potentially would benefit from transplantation, however, underlying medical conditions such as heart or lung problems may not make them a viable candidate. This is in keeping with the highest standards of medical care that any credible hospital would adhere to.

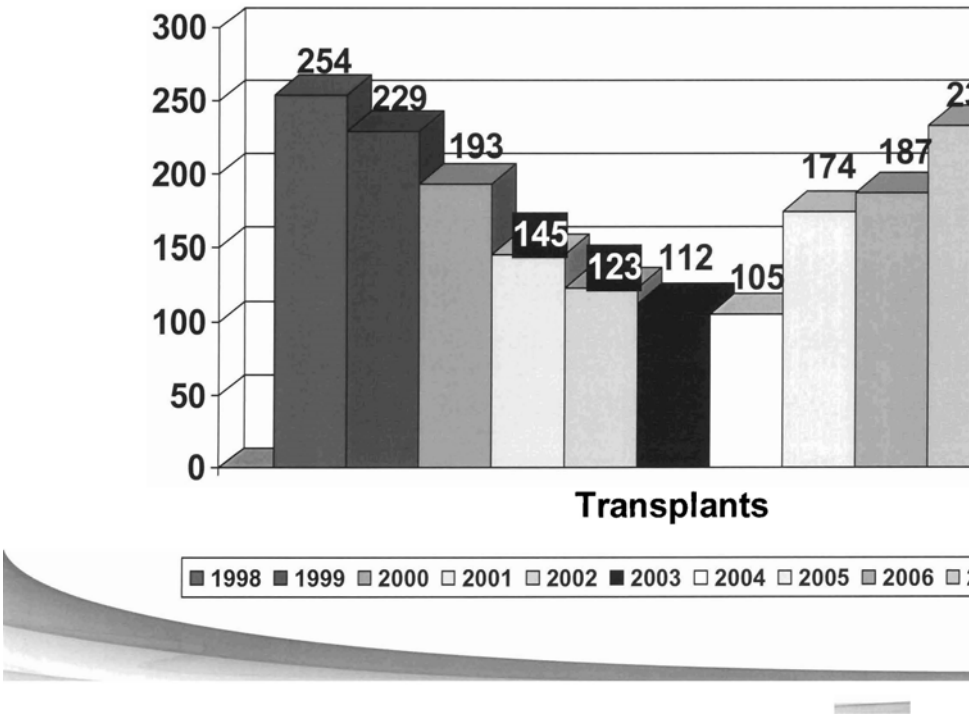
Finally, some of those advocating for additional BMT programs have focused on Michigan's new embryonic stem cell research legislation. Karmanos was one of the few hospitals in the state to actively support and endorse this legislation and we are thrilled that Proposal 2 passed by such a health margin. We firmly believe that the research conducted on embryonic stem cells has the possibility to lead to treatments and cures for numerous chronic diseases. However the new research in embryonic stem cell transplantation does not play a role in hematopoietic stem cell transplantation. These two issues should not be confused.

There are number of unique uses of hematopoietic stem cells which do not require transplant that are currently going on the area of heart disease, lung disease, and colitis or Crohn's disease. If research activities in these areas in regenerative medicine are proven to be of benefit, this type of medical care does not require hospitals to have stem cell transplant programs to administer these products.

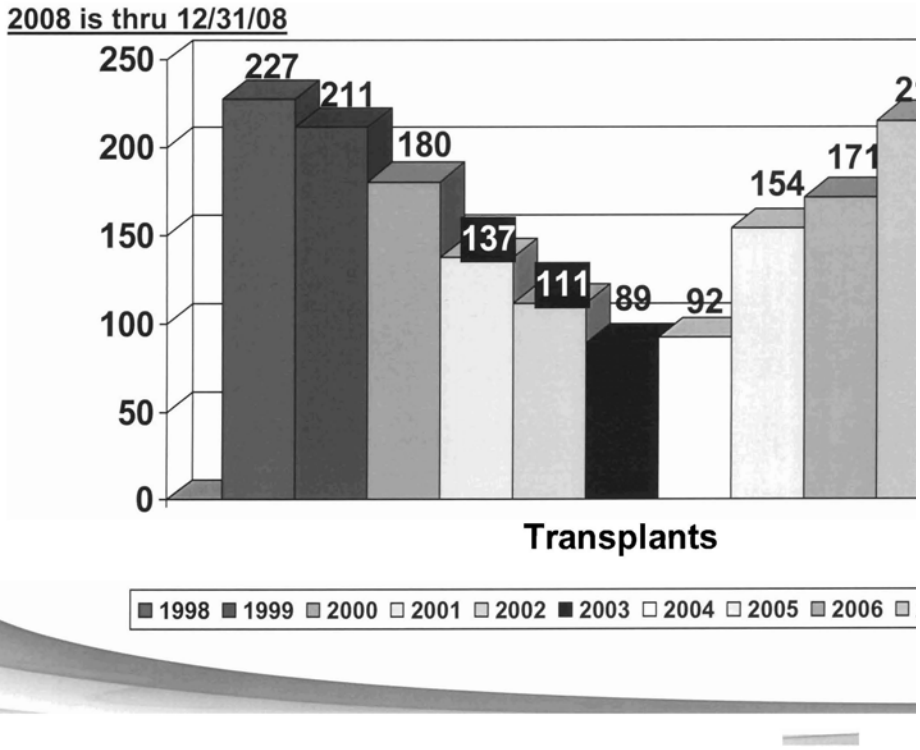
Thank you again for the opportunity to share with you Karmanos' position that the current BMT standards should remain unchanged to best ensure the tenants of CON – cost, quality, and access – are adhered to.

I'd be happy to answer any questions.

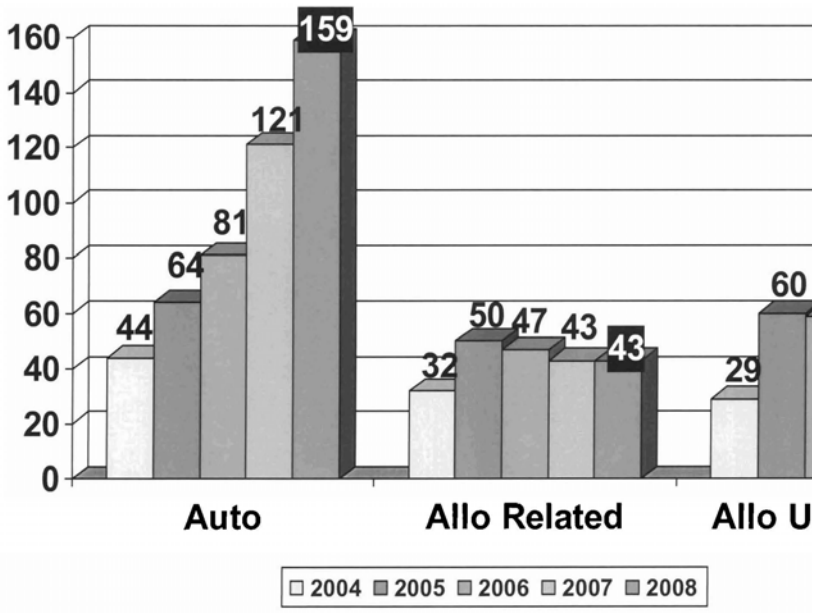
Transplants (KCI & CHM) 1998-2008



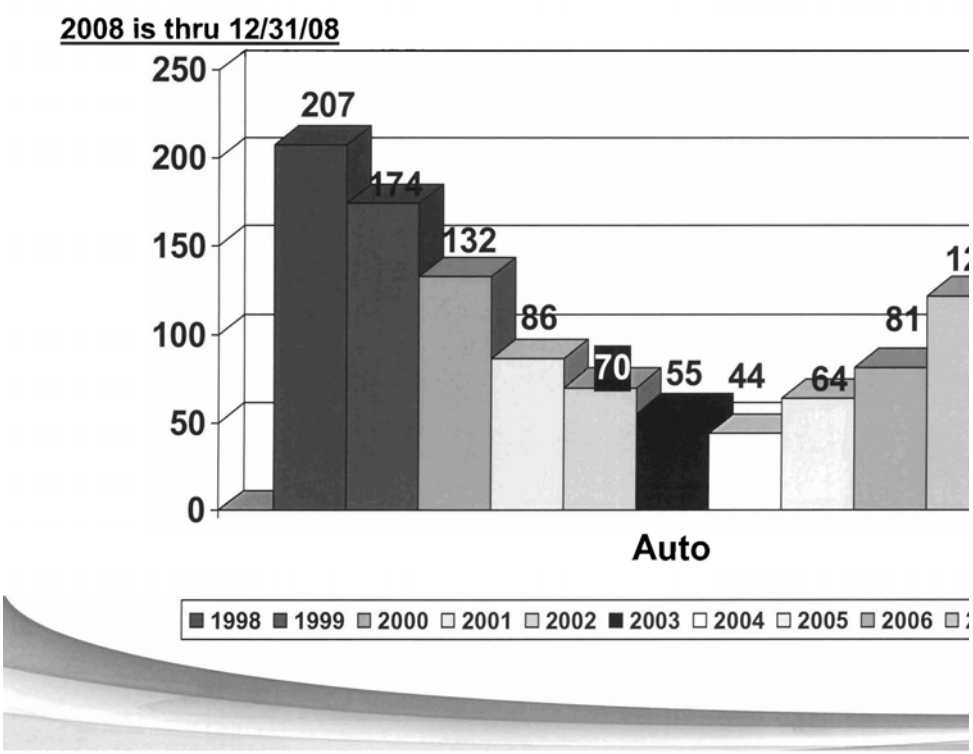
ADULT Transplants 1998-2008



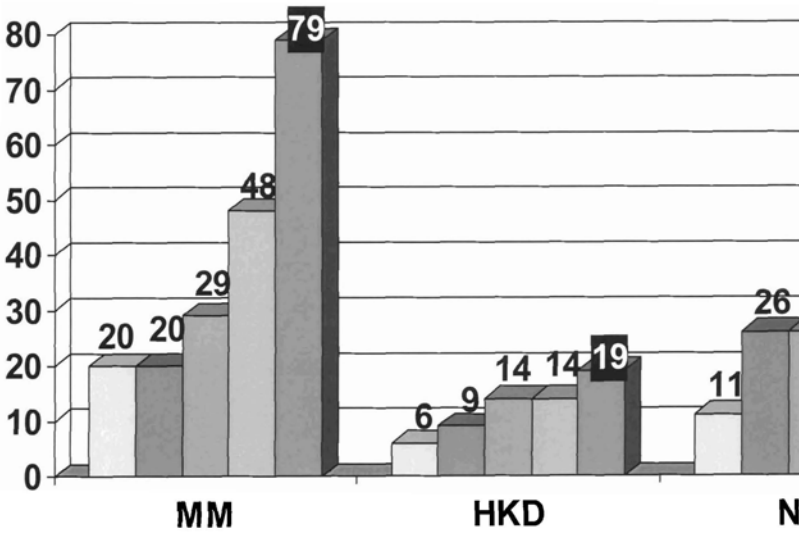
Transplants by Type (KCI & CHM)
2004-2008



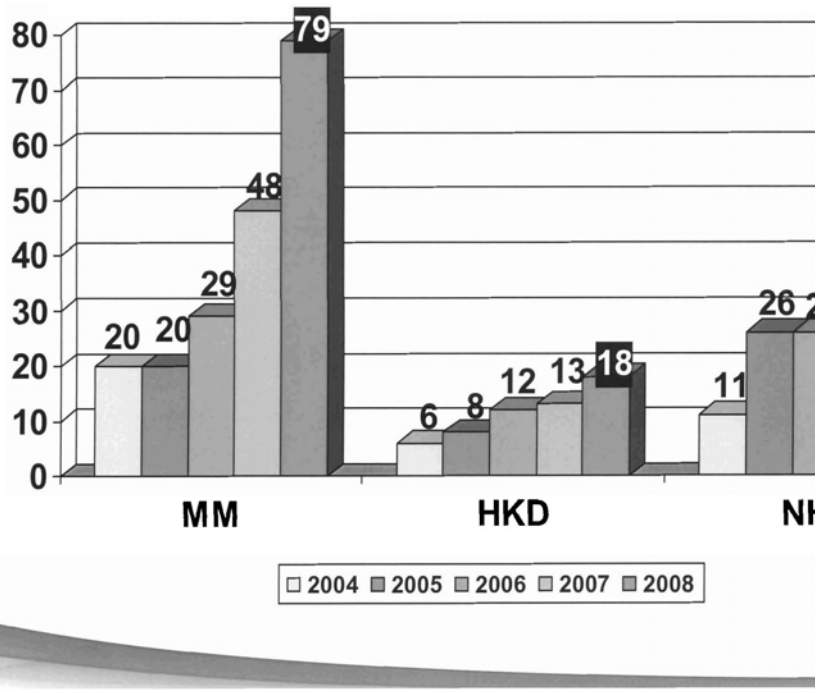
Auto Totals (KCI & CHM) 1998-2008



Transplants by Disease (KCI & CHM)
2004-2008



ADULT Transplants by Disease 2004-2008



SPECTRUM HEALTH

SPECTRUM HEALTH

Need for Solid Organ and Bone Marrow Transplant Services in Western Michigan

February 5, 2009

SPECTRUM HEALTH

Background

Transplant CON Standards Scheduled for review in 2009

Since 1986, limit of three (3) transplant programs in the state

All three (3) programs in southeastern Michigan

SPECTRUM HEALTH

Spectrum Health Position:

Revise the CON Standards for transplant services in 2009 to allow for access by residents of the western part of Michigan

Michigan

- University of Michigan
- Henry Ford Hospital
- Detroit Medical Center
  - Children's Hospital (Heart Transplant)
  - Karmanos (Bone Marrow Transplant)

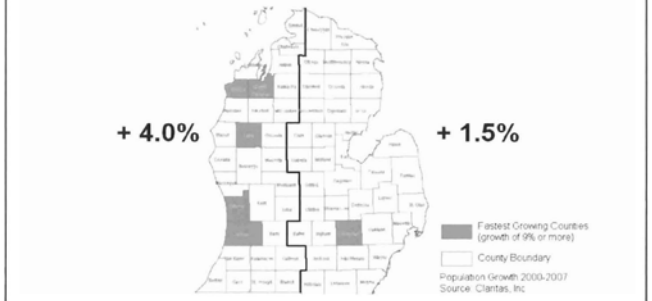
SPECTRUM HEALTH

Organ Transplant Centers in Southeast Michigan

SPECTRUM HEALTH

Population Growth in Western Michigan

Western Michigan growing more than twice as fast as East Michigan



SPECTRUM HEALTH

Continuity of Care

Physician Relationships

Knowledge of Patient's
- Disease
- Psycho-social needs
- Co-morbidities
- Management of non-transplant organ care

Management of post transplant complications
- Transplant Rejection
- Recurrence

SPECTRUM HEALTH

Patient Convenience

Average Length of Stay for BMT is approximately 25 days; for organ transplant approximately 40 days

Patients and families must uproot their lives

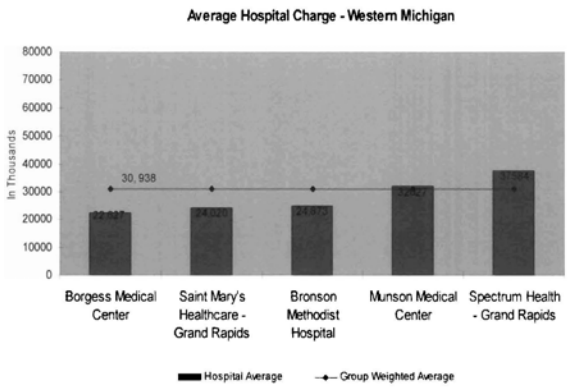
Long Distance Travel for treatment

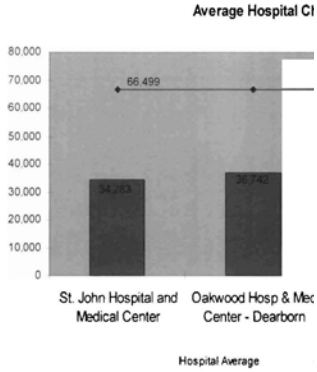
High costs – both emotional and monetary

Difficult follow-up treatment with transplant physician

Average Hospital Charges for Lymphoma & Leukemia Patients

SPE

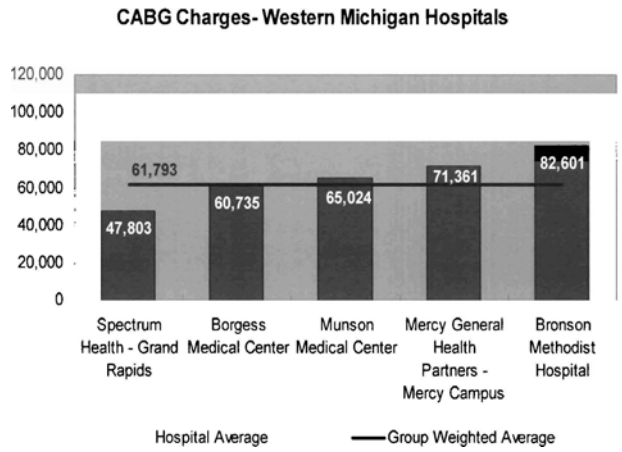


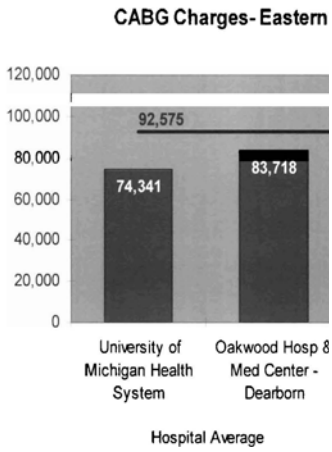


Source: MedPar, 2007.

SPE

West Michigan Hospitals have Lower Healthcare Costs for Heart Surgery





SPECTRUM HEALTH

Community Infrastructure

Van Andel Institute

Michigan State University College of Human Medicine

Health Professional Training Programs:

- Grand Valley State University
- Hope College
- Calvin College
- Aquinas College
- Ferris State University
- Western Michigan University

Rennucci Hospitality House

Ronald McDonald House

SPECTRUM HEALTH

Community Support

Strong community leadership exists in support of the effort to address access to transplant services in western Michigan

Grand Rapids Press
Grand Valley State University
Michigan State University Medical School
Meijer
C & H Holdings – Cook Holdings
Warner, Norcross & Judd
Hauenstein Neurological Center
Fifth Third Bank
Michigan Medical, P.C.
Grand Rapids Mayor Heartwell
Van Andel Institute (Craig Webb, Ph.D.)
Lakeland HealthCare
Oaklawn Hospital
Pennock Health
J.C. Huizenga
West Michigan Cardio-Thorascic Surgeons
Steelcase
RDV Corporation (Richard DeVos)
Mercy Health Partners
Spectrum Health Reed City
Holland Hospital
Helen DeVos Children's Hospital
The Right Place, Inc.
Gerber Memorial Health Services
David G. Frey
Calvin College (Gaylen J. Byker)

State Senators
Bill Hardiman
Wayne Kuipers
Mark Jansen

State Representatives:
Bill Huizenga
Dave Hildenbrand
Kevin Green
Brian Calley
Arlan Meekhof
Dave Agema
Pete Hoekstra

SPECTRUM HEALTH

Solid Organ Transplantation

SPECTRUM HEALTH

Heart Failure Patients: More and Older

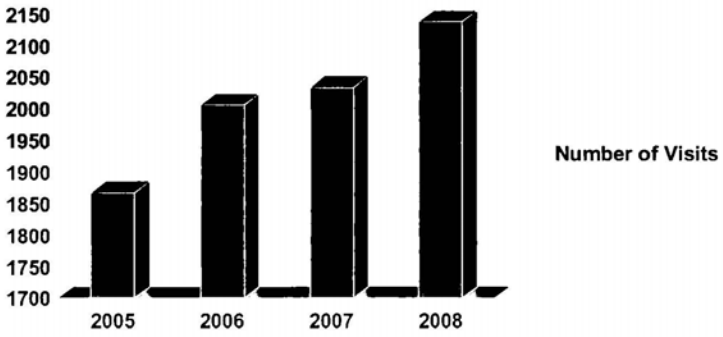
The number of patients age 65 and older who are hospitalized for heart failure has doubled since 1980.

The number of heart failure hospitalizations increased by 131% since 1980

(, Daily Briefing, 11/10/2008)

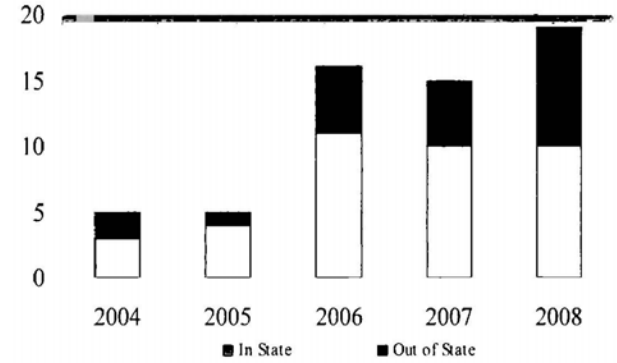
SPECTRUM HEALTH

Patient Volumes at the Spectrum Health Heart Failure Clinic



SPECTRUM HEALTH

Spectrum Health Referrals for Heart Transplant



SPECTRUM HEALTH

Quality

The Society for Thoracic Surgeons data has shown that Spectrum Health is among the highest in quality outcomes in the nation

SPECTRUM HEALTH

Existing Infrastructure for Organ Transplant

There are eight (8) open heart programs in Western Michigan

Spectrum Health

- Largest open heart program in the state performing over 1,000 adult open heart surgeries in 2007
- One of the largest organ procurement sites in the United States
- Heart Failure Clinic with more than 2,000 visits per year

Air Ambulance Services

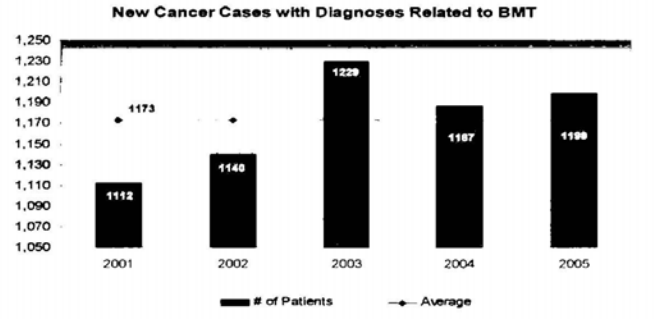
Existing Supporting Infrastructure

SPECTRUM HEALTH

Bone Marrow Transplantation

SPECTRUM HEALTH

Western Michigan Cancer Patients



Source: Michigan Resident Cancer Incidence File. Includes cases in the following categories: acute myeloid leukemia, Myelodysplastic Syndrome, Acute Lymphoblastic Leukemia, Non-Hodgkin Lymphoma, Multiple Myeloma, Hodgkin Lymphoma, and Chronic Leukemia; and processed by the Michigan Department of Community Health, Vital Records and Health Data Development Section by November 26, 2007

SPECT

Estimated Annual BMT Procedures

Diagnosis	Incidence Rate of Cancers treated w/ BMT	Northeastern NCI-CCC Experience
Acute Myeloid Leukemia	91	24%
Myelodysplastic Syndrome	75	50%
Acute Lymphoblastic Leukemia	6	25%
Non-Hodgkins Lymphoma	650	8%
Multiple Myeloma	139	28%
Hodgkins Disease	82	14%
Chronic Leukemia	156	32%
Total	1199	

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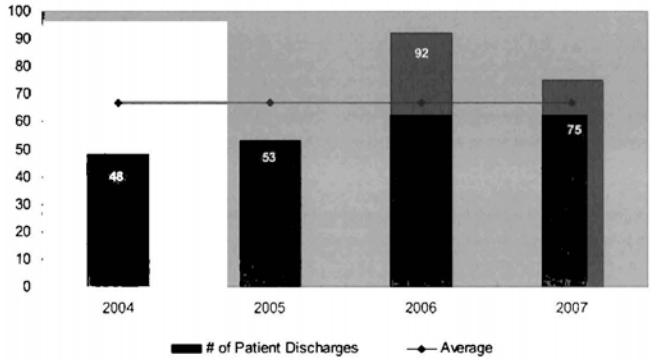
Western Michigan BMT Patient Discharges



Source: MDB fiscal years (July-June)

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Expected Growth in BMT Patients

In 2007, the National Marrow Donor Program (NMDP) realized an 18% increase in transplants it facilitated.

Source: NMDP 12/1/2008

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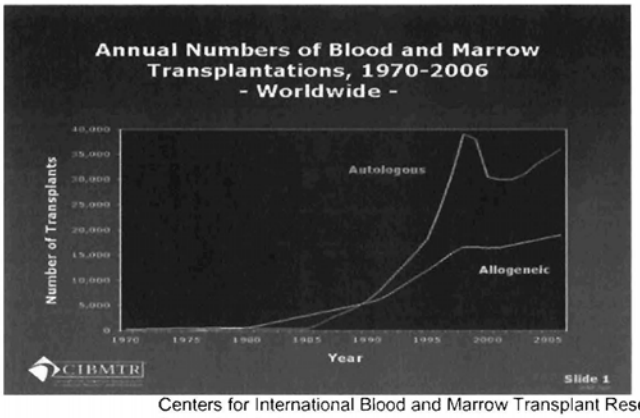
Growth Trends



Centers for International Blood and Marrow Transplant Research
December, 2007

SPECTRUM HEALTH

Existing Infrastructure for BMT

Spectrum Health
- Existing Pediatric BMT & hematopoetic cell transplantation Program
  Pediatric & Adult Trained Transplant Physician
- Three radiation oncology centers, with 8 linear accelerators

Advanced Technology Labs
- Flow cytometry
- Cytogenetics
  Engraftment analysis

Michigan Community Blood Center
  Stem cell laboratory
  Cyropreservation and storage
- T-cell depletion

Center for Molecular Biology for chimerism analysis and molecular viral testing

Established relationships with national reference and resource laboratories such as Blood Centers of Wisconsin for HLA testing

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Proposed Solution for both BMT and Organ transplant Services

Divide Michigan into two (2) planning areas – east and west

Use planning area definitions currently in place for pediatric BMT

Require at least one (1) transplant program of each type in western Michigan

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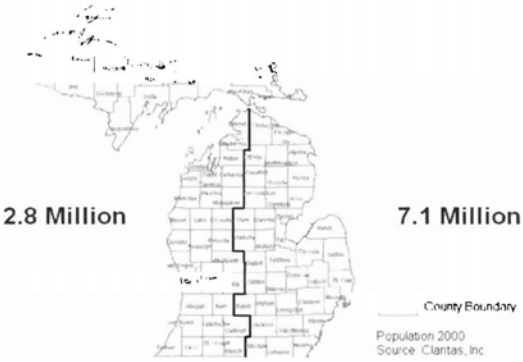
Proposed Planning Areas

Planning area boundary used in pediatric BMT Standards



Attachment D

FOR A BETTER LIFE.

Demonstration_CA_050508

HF
BMT

Good Morning. I am Liz Palazzolo and I am Director of Planning for Henry Ford Health System. Henry Ford Hospital has been providing adult bone marrow transplantation services for twenty-five years, with stable leadership since the inception of the program. We are a FACT accredited institution, as are Karmanos and University of Michigan. We provide between 40 and 50 procedures annually.

A concern has been raised that patients who live outside Southeast Michigan experience hardship when they need this procedure because they must leave their family members while they are undergoing treatment. Most of our patients reside in Southeast Michigan but we do provide procedures to patients from outside that area. When we have patients who live outside our immediate area we have housing accommodations on the hospital campus where patients and their family members can stay together while the patient is in follow-up for their procedure. These accommodations are equipped with appropriate air filtration systems for the safety of the patient. In some cases, patient insurance covers travel and housing expense. In addition, our medical social workers who are assigned exclusively to BMT patients make sure that their patients are registered with appropriate agencies such as the Leukemia and Lymphoma Society that will reimburse them for their mileage expenses if they have to travel for care. If the patient needs additional support for these expenses and does not have other recourse we have a patient medical needs fund that is used to provide assistance.

As far as access and demand is concerned, bone marrow transplantation is a very low-volume service and demand has not changed much over the last several years. This is because there are new treatment options that replace the need for this grueling procedure. We are now just over 500 procedures, very close to the 498 procedures that were provided in 2001.

At the present time, patients who require this service have excellent access to service within a reasonable timeframe at existing centers. Most patients are seen for evaluation within a week. Increasing the number of centers will merely spread the limited number of BMT patients over more facilities, resulting in most facilities performing lower volumes with the potential to raise costs and lower quality and potentially lost current contracts and accreditation.

Finally, the Commission may recall that, in addition to the three programs that currently are operating, other providers have been unable to provide a

sustainable service over time. Oakwood Hospital closed its adult BMT program in 2006 due to low volume and high cost. St. Mary in Grand Rapids held a Certificate of Need for two years and failed to initiate the program due to recruitment issues. Both of these underscore the difficulty in starting and continuing a program unless it is built on a genuine and demonstrated community need for the service.

On behalf of Henry Ford Health System I appreciate the opportunity to make these comments. We believe that three adult bone marrow transplant centers in Michigan provides the appropriate balance for Michigan citizens between cost, access and quality. I would be glad to respond to any questions you might have.

University of Michigan Statement: **February 4th, 2009**

Has the demand for bone marrow transplants increased in the past decade?
Over the past 5 years, the number of bone marrow transplants performed nationally has grown by 7% per year. The inclusion of patients > 60 years in age has been the primary cause of this growth. Whereas 10 years ago the average age of our transplant population was 48 years, it is now over 55 years in age. We are now transplanting patients who are < 75 years in age.

Will the demand continue to increase in the upcoming decade?
No. We have now maximized the age range to which transplantation can be performed. We, and other transplant centers, do not feel that bone marrow transplantation will be possible for patients who are in their 80's or 90's. Thus, the transplant market has peaked, at < 75 years in age. We anticipate growth rates in the range of 1-2%/year. Potential newer markets for transplant, such as growth of transplant for non-malignant diseases, are already in place in the State of Michigan. We are currently performing transplants for patients with sickle cell disease, thalassemia, systemic sclerosis, immune deficiencies and other genetic and inherited non-malignant disorders. We do not anticipate this market will grow significantly.

Can we currently service the needs of the state?
In 2007, 96.3% of patients eligible for marrow transplants in the State of Michigan underwent their transplant within the state.

At the U-M, 99% of patients are transplanted on schedule (based upon their medical condition and donor availability), without delay due to bed availability.

Are we at capacity for the number of transplants we can perform?
Not only are we currently **not** at capacity, but 2 facts will increase our capacity in the next 2 years: an increasing shift to outpatient transplantation and additional space that was planned and incorporated several years ago. The opening of our new transplant unit within the Children and Women's Hospital by 2011, creating a consolidation and expansion of capacity for both pediatric and adult BMT is envisioned to improve our economy of scale for performing transplants. The CoN for the construction of this new hospital has been approved. This new unit will have the space and facilities to potentially allow 50-100 additional transplants per year. From a purely demand point of view, there is no reason to expand the number of sites within the State.

What are the costs associated with building a bone marrow transplant facility?
There are both costs for building infrastructure and personnel costs. The infrastructure costs are significantly more than just building a transplant unit, with the required air flow units and sterile facility requirements. Four other facilities need to be considered in the development of a bone marrow transplant program: (1) HLA (Tissue Typing) Laboratory, (2) Molecular Diagnostic Laboratory, (3) Stem Cell Processing Facility, and (4) Extracorporeal Photopheresis (ECP) Facility. In many cases, some of these facilities will already be in place at institutions requesting CoN for transplantation. However, the

costs required to upgrade these facilities to serve the needs of a transplant program may be enormous.

Though our program has been in existence for 20 years now, in order to remain a 'state of the art' bone marrow transplant program the U-M recently expended $1.5 M to expand our stem cell processing lab, $500,000 to expand both the Tissue Typing and Molecular Diagnostic Labs and $500,000 to expand and equip our Extracorporeal Photopheresis (ECP) service. Moreover, operating costs will also increase to keep a BMT program abreast of current best-practices, even if not required to provide basic, entry-level standards of care. For example, total operating expenses in 2008 for the Tissue Typing /HLA lab were $4M. From a personnel standpoint, the lab has expanded from 7 to 12 technicians in the past 5 years to accommodate our program's needs. The total operating expenses for the molecular diagnostics lab in 2008 were $1.5M. ECP is an essential service for the treatment of graft versus host disease (GVHD), a common complication of BMT. In 2008, we have had to hire 8 ECP trained nurses to facilitate the expanded ECP program.

The total cost for updating and running these critically important ancillary services which are essential in the operation of an excellent BMT program, in the last year was ~**$8M.** Not an insignificant sum for a mature BMT program. These services are beyond what one usually considers for the construction of a BMT unit and clinic, but they are required to provide excellent BMT services for our patients.

Where will physicians be hired to staff new BMT units?
There are currently an estimated 1115 bone marrow transplant trained physicians in the US [American Society of Bone Marrow Transplant (ASBMT), data]. In addition, the median age of current transplant physicians is over 50 years in age. The ASBMT estimates that fewer than 100 new transplant physicians are trained in the country each year. Thus, in the upcoming decade, there is likely to be a severe shortage of transplant trained physicians to staff both existing and new BMT units.

We estimate that one transplant physician is required for every 20-25 transplants performed per year. Thus, a medical center proposing to perform 100 transplants / year will require 4-5 transplant physicians. The ability to employ physicians for new transplant programs can only come from one source - "overpaying" existing transplant physicians.

Loberiza et al (Blood 2005) published a review of transplant center factors critical to improvement in patient survival. The presence of 24/7 coverage by physicians with transplant experience (fellows and attendings) was a significant factor in this analysis. The use of non-transplant trained oncologists (often for weekend cross-coverage), or the use of medical residents / housestaff for coverage may in fact negatively impact survival. Many smaller BMT programs would need to rely on this cross coverage and resident coverage system, with a resultant negative impact on survival.

Are there issues related to the quality of care that must be considered?
Quality of Care in BMT has been determined by 2 factors:
1. Commitment to Clinical Trials and Clinical Research, and
2. The presence of experienced personnel, at all levels.

A quality BMT program actively engages in clinical research. At our own transplant center, we have noted a direct relationship between transplant outcome and the percentage of patients enrolled on clinical trials. At our own center, the impact of increased clinical trial participation and an associated improvement in patient survival (at 100 days and 1 year post-transplant) have been seen:

	Clinical trial participation	Survival (day 100)	Survival (1 year)
2001-2004	36%	72%	47%
2005-2006	84%	84%	56%

10 years ago, the U of M was selected by the NIH to be one of 16 programs nationwide to investigate important questions in BMT. Karmanos is also participating in this federally-funded clinical trial group. Thus, we feel strongly that a commitment to clinical research is the key to advancing patient survival and ultimately finding cures for their underlying diseases. With additional programs in the state accrual to these important clinical trials will certainly suffer, and thus impact overall quality of care to all the citizens of the state.

A quality BMT program requires experienced personnel at all levels: BMT physicians (who are in national short supply) as well as specially trained ancillary personnel and sub-specialty consultants. The ability to find technicians trained in stem cell processing, HLA typing and molecular diagnostic testing will be difficult. The ability to find nurses trained to care for transplant patients and specialty nurses to perform ECP therapy will be exceedingly difficult.

Are autologous transplants low risk transplants?
Nationally, the mortality rates within the first 100 days following an autologous transplant range from 5-15% in various reports. The notion that this is a "low risk" procedure is difficult to justify. In fact, there are a number of reasons to believe this procedure will become increasingly "higher risk" in the near future. For many malignant disorders, the role of double (tandem) autologous transplants, or "autologous followed by allogeneic" transplants, are gaining increasing acceptance. In addition, autologous transplants are now becoming a "vehicle" to allow for the generation of tumor vaccines, for gene therapy, and for a number of immuno-modulatory strategies for rare (and high risk) medical conditions. We strongly feel that the use of autologous transplantation for these conditions (and strategies) should be limited to medical centers with the expertise and basic science labs equipped to handle (and study) all aspects of the care required for these procedures. Granting approval for autologous transplantation to smaller centers, ultimately allows them access to performing gene therapy, tumor vaccine therapy or other novel immuno-therapies that would otherwise be confined to centers with the personnel experienced to perform such trials.

In summary, Michigan presently has an adequate number of BMT centers that address the current and future needs for our patients. Our current centers are national leaders. The cost to build and maintain these centers is substantial. Convenience should not be a metric to define where services are allowed to be granted. A bone marrow transplant is the biggest single event that a patient will ever face. The most important issue is access to the best program, not access to the closest.

Association of transplant center and physician factors on mortality after hematopoietic stem cell transplantation in the United States

Fausto R. Loberiza Jr, Mei-Jie Zhang, Stephanie J. Lee, John P. Klein, Charles F. LeMaistre, Derek S. Serna, Mary Eapen, Christopher N. Bredeson, Mary M. Horowitz, and J. Douglas Rizzo

The effect of the organization and delivery of health care at medical centers, referred to as "center effects," with clinical outcomes after hematopoietic stem cell transplantation (HSCT) is not clear. We examined the association between center and treatment provider factors and mortality after HSCT. We surveyed 163 (87% response rate) United States transplantation centers that performed HLA-identical sibling HSCT for leukemia or autologous HSCT for lymphoma between 1998 and 2000 among patients at least 18 years old. One hundred thirteen (69%) centers performed HLA-identical sibling transplantations, whereas 162 (99%) performed autologous transplantations. Factors associated with decreased 100-day mortality in the allogeneic setting include a higher patient-per-physician ratio ($P = .003$) and centers where physicians answer calls after office hours ($P = .03$). Medical school affiliation was not associated with increased 100-day mortality except in centers where students/residents are present without fellows ($P = .02$). Center effects were weaker in autologous HSCT at 1 year. Differences in 100-day mortality in patients receiving transplants in centers with favorable versus unfavorable factors were greater in allogeneic than autologous HSCT. Greater physician involvement in patient care is important in producing favorable outcomes after HSCT. To more clearly establish the role of the factors we identified, further studies are recommended. (Blood. 2005; 105:2979-2987)

Introduction

High-dose chemotherapy with or without radiotherapy followed by hematopoietic stem cell support is widely used to treat diverse malignant and nonmalignant diseases.[1-4] Hematopoietic stem cell transplantation (HSCT) carries high risks of early morbidity and mortality. Treatment-related mortality (TRM) ranges from 3% to over 50%, a considerably higher risk than other complex medical procedures.[4,5] For example, after autologous HSCT, 1-year TRM ranges from 5% to 15%, compared with 20% to 50% in allogeneic HSCT. Most treatment-related deaths occur in the first year after transplantation.

Although predictors of mortality are traditionally evaluated using clinical parameters related to the patient, the disease, or the treatment procedure, biologic paradigms do not completely explain outcome variations between patients and across treatment centers. Searching for factors related to the organization and delivery of health[6-8] when outcomes vary among patients with similar disease biology and treatment provides opportunities to improve treatment results. These center-dependent factors are referred to as "center effects."

Most studies on center effects in the medical and surgical literature, including HSCT, have focused on the association between procedure volume and survival.[9-18] Too great a focus on procedure volume, without exploration of other health care factors involved in the delivery of care, may lead to erroneous conclusions about how to improve quality of care and patient outcomes. We therefore collected transplantation center and treatment provider characteristics in the United States and examined their association with survival outcome after HSCT for hematologic malignancies.

From the University of Nebraska Medical Center, Center for International Blood and Marrow Transplant Research (CIBMTR), Medical College of Wisconsin, Milwaukee, WI; Dana-Farber Cancer Institute, Boston, MA; and Texas Transplant Institute, San Antonio, TX.

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Step 2: determining center factors associated with mortality. The second part of the analysis fitted separate forward stepwise multivariate logistic regression models to the 1426 allograft recipients and 2859 autograft recipients, using death probability within 100 days or within 1 year as the outcome of interest and considering center characteristics as potential predictor variables. The derived CSI (high risk versus low risk) was forced in the model building.

The transplant center characteristics tested can be categorized into 3 groups (Table 1): (1) physician and health care provider characteristics, (2) transplant unit activities and resources, and (3) medical center characteristics. Because of the exploratory nature of our study and the lack of previous studies including most of the center characteristics we examined, we decided to retain factors with a P less than or equal to .05. Interactions between factors in the final model were tested. To further verify if the variation in outcome can be explained by other unmeasured treatment center factors aside from what we already examined and found significant in the final model, we tested for a "fixed center effect term." Empirical estimates of the survival curves in the first 100 days were computed from the logistic model and plotted. Because all patients included had the potential of 1-year follow-up, survival at 100 days and at 1 year were compared between any 2 groups (eg, low-risk patients with favorable center factors versus low-risk patients with unfavorable center factors) using the χ^2 test. All analyses were performed using SAS version 8.2 for Unix (SAS, Cary, NC).

Results

Center characteristics

Of 187 centers, 163 (87%) responded, 6 (3%) refused to participate, and 18 (10%) were excluded because they no longer participate in the IBMTR/ABMTR. Among those that completed the survey, 113 (69%) performed HLA-identical sibling HSCT and 162 (99%) performed autologous HSCT. However, only 88 of the 113 responding allograft centers and 142 of the 162 responding autograft centers had patients fulfilling the disease and age eligibility requirements for the study.

Tables 2 and 3 show the characteristics of the transplant centers in the United States that perform HLA-identical sibling HSCT for leukemia or autologous HSCT for lymphoma that were included in this study. The proportion of high- and low-risk patients (based on CSI) was not associated with procedure volume.

Center and treatment provider factors in the allogeneic cohort

Table 4 shows results of the multivariate analyses of survival in the allogeneic cohort. The median CSI was 0.21 (range, 0.07-0.54) and 0.22 (range, 0.06-0.56) at 100 days and 1 year, respectively. As expected, high-risk (CSI > 0.21) patients were 3 times more likely to die than low-risk (CSI ≤ 0.21) patients within 100 days after transplantation. Factors associated with lower mortality within 100 days after transplantation were (1) higher patient-per-physician ratio, that is, patients undergoing transplantation in centers where physicians cared for more than 20 patients per year were 33% less likely to die than those with lower physician case loads, and (2) patients undergoing transplantation in centers where physicians answered after office hours or emergency calls were 28% less likely to die than those in centers where calls were answered by nurses or physician assistants. Affiliation of the transplantation program with a medical school was not significantly associated with 100-day survival except for centers with programs that had rotating students and residents but not hematology-oncology or HSCT fellows on the transplant service; 100-day mortality of patients having transplantation in these centers was about twice higher than in centers without medical school affiliations. At 1 year, only the clinical severity of patients and ratio of patients per physician per year were significantly associated with mortality.

Figure 1 shows overall survival probabilities stratified by factors associated with 100-day mortality. Low-risk patients undergoing transplantation in centers with one or more favorable factors (> 20:1 patient-to-physician ratio, physicians answering after office or emergency calls, and no medical school affiliation or a medical school affiliation with rotating hematology-oncology or HSCT fellows) had a 100-day survival probability of 87% (95% confidence interval [CI], 84%-89%) versus 77% (95% CI, 69%-85%) among low-risk patients receiving transplants in centers with none of the favorable factors, a 10% difference in survival probability. High-risk patients undergoing transplantation in centers with one or more favorable factors had a 100-day survival probability of 68% (95% CI, 63%-72%) versus 53% (95% CI, 42%-64%) among high-risk patients receiving transplants in centers with none of the favorable factors, a 15% difference in survival probability. The distributions of primary causes of death in centers with favorable versus unfavorable center factors were not statistically different.

Center and treatment provider factors in the autologous cohort

Table 5 shows results of multivariate analyses for survival in the autologous cohort. The median CSI was 0.27 (range, 0.13-0.62) and 0.29 (range, 0.12-0.65) at 100 days and 1 year, respectively. High-risk patients (CSI > 0.27) had a 2-fold higher risk of dying compared to low risk patients (CSI ≤ 0.27) both at 100 days and 1 year after autologous transplantation for lymphoma. Two center factors were associated with a decreased risk of dying within 100 days after autologous transplantation. Patients receiving transplants in centers with higher patient-per-physician ratios, that is, where physicians cared for more than 12 patients per year, had a 26% lower risk of mortality than patients receiving transplants in centers with lower physician caseloads. Similar to the allograft setting, medical school affiliation was not significantly associated with 100-day survival outcome except for centers with programs that had rotating students and residents but no hematology-oncology or HSCT fellows; 100-day mortality of patients undergoing transplantation in these centers was 1.8 times higher than in centers without medical school affiliations. At 1 year, only the clinical severity of patients and ratio of patients per physician per year were significantly associated with probability of mortality.

Figure 2 shows overall survival according to factors associated with 100-day mortality in the autologous setting. Low-risk patients undergoing transplantation in centers with one or more of the favorable factors (> 12:1 patient-to-physician ratio and no medical school affiliation or with medical school affiliation with rotating hematology-oncology or HSCT fellows) had a 100-day survival probability of 93% (95%, CI 90%-95%) versus 92% (95% CI, 89%-94%) among those receiving transplants in centers with unfavorable factors. The 100-day probability of survival in high-risk patients receiving transplants in centers with one or more favorable factors was 88% (95% CI, 85%-90%) versus 84% (95% CI, 81%-86) among those treated in centers with unfavorable factors, a 4% difference in survival probability.

Further analysis showed that procedure volume was associated with the ratio of patients per physician (r = 0.42 for allogeneic HSCT and r = 0.48 for autologous HSCT), but not with center experience (age of program). However, neither procedure volume or center experience were significantly associated with survival even after the removal of ratio of patients per physician in the model. Additionally, adding a "fixed center effect term" in both

Table 2. Continued

Variables	Center, no. (%)	Patients, no. (%)
Percentage of patients enrolled in IRB-approved clinical protocols		
25% or less	17 (19)	177 (12)
26%-50%	21 (24)	283 (20)
More than 50%	50 (57)	966 (68)
Full-time clinical research coordinators		
None	9 (10)	72 (5)
1 FTE	30 (34)	319 (22)
2 FTE	21 (24)	283 (20)
3 FTE or more	28 (32)	752 (53)
Units able to manage critically ill patients	29 (33)	559 (39)
Computerized order entry	67 (76)	1130 (79)
Electronic medical record-keeping	51 (58)	984 (69)
On-site stem cell processing laboratory	84 (95)	1410 (99)
Unit pharmacist present	81 (92)	1360 (95)
NCI-designated cancer center	28 (32)	
Devoted psychologist/psychiatrist present	54 (61)	824 (58)
Routine psychological screening done	75 (85)	1217 (85)
Initial contact person		
Nurses/nurse practitioners/physician assistants	18 (20)	344 (24)
Residents	28 (32)	466 (33)
Hematology/oncology or BMT fellows	37 (42)	558 (39)
Attendings	5 (6)	58 (4)
Systematic follow-up of patients	76 (86)	1234 (86)
Every 6 mo	21 (24)	422 (30)
Every year	40 (45)	608 (43)
Every other year	15 (17)	204 (14)
No systematic follow-up	12 (14)	192 (13)
Program has formal long-term follow-up program	66 (75)	1067 (75)
Has formal posttransplant immunization protocol	69 (78)	1104 (78)
Has formal protocol for screening posttransplant complications	45 (51)	733 (51)
Medical center characteristics		
Geographic location		
Urban	70 (80)	1164 (82)
Suburban/rural	18 (20)	262 (18)
Center for Excellence designation	63 (72)	1187 (83)
FACT accreditation		
No	13 (15)	196 (13)
Yes, pending	23 (26)	290 (20)
Yes	52 (59)	940 (66)

BMT indicates bone marrow transplantation; IRB, institutional review board; FTE, full-time equivalent; FACT, Foundation for the Accreditation of Cellular Therapy.

the allograft and autograft models did not indicate that factors other than CSI and the identified center factors were associated with outcomes.

Discussion

Our data show that aside from the clinical severity of the patient's condition, center factors in the allogeneic and autologous HSCT setting are associated with better 100-day mortality. In the allogeneic HSCT setting, a strong association was demonstrated between physician caseload (more patients per physician) and better 100-day mortality. The type of medical school affiliation and presence of physicians answering after hours calls were weakly associated with 100-day mortality. In the autologous HSCT setting, a weak association was seen between caseload and medical school affiliation and 100-day mortality. In both HSCT settings, physician caseloads have a weak association with 1-year mortality. These findings suggest that the most important center characteristic affecting outcomes aside from clinical severity is the activity level and role of transplantation physicians and senior trainees.

Although other reports[9-18] in the medical and surgical fields have shown a direct relationship between procedure volume and survival, it is unknown whether procedure volume directly affects outcome (eg, by increasing experience of personnel) or whether this is a surrogate for unmeasured factors that are associated with both improved outcomes and larger volumes. This distinction has policy implications. One can make a strong case for restricting certain complex procedures to large-volume centers if volume per se is the important parameter. However, if volume is a surrogate for other factors that are more common in large versus small centers, but which could be introduced to small centers, the appropriate course of action would be to institute these factors at all centers. Although our findings deserve further study, they suggest that there are center characteristics that may be adopted by small-volume centers that may improve survival outcomes.

Our study evaluated 2 types of HSCT that have different degrees of medical sophistication and risk. The lack of association between procedure volume (total number of transplants per year, allogeneic or autologous transplants) and center experience (number of years centers have been performing HSCT) with survival in our study contrasts with published reports in the general medicine

Table 3. Continued

Variables	Centers, no. (%)	Patients, no. (%)
Full-time clinical research coordinators		
None	23 (16)	205 (7)
1 FTE	67 (47)	800 (28)
2 FTE	26 (18)	612 (21)
3 FTE or more	26 (18)	1242 (43)
Units able to manage critically ill patients	38 (27)	940 (331)
Computerized order entry	100 (70)	2240 (78)
Electronic medical record-keeping	74 (52)	1911 (67)
On-site stem cell processing laboratory	107 (75)	2593 (91)
Unit pharmacist present	121 (85)	2633 (92)
NCI-designated cancer center	30 (21)	1153 (52)
Devoted psychologist/psychiatrist present	84 (59)	1663 (58)
Routine psychological screening done	117 (82)	2531 (88)
Initial contact person		
Nurses/nurse practitioners/physician assistants	31 (22)	756 (27)
Residents	1 (< 1)	3 (< 1)
Hematology/oncology or BMT fellows	35 (25)	1089 (38)
Attendings	75 (53)	1011 (35)
Systematic follow-up of patients done	122 (86)	2434 (85)
Every 6 mo	45 (32)	709 (25)
Every year	57 (40)	1293 (45)
Every other year	20 (14)	432 (15)
No systematic follow-up	20 (14)	425 (15)
Program has formal long-term follow-up program	87 (61)	1694 (59)
Has formal posttransplant immunization protocol	105 (74)	2275 (80)
Has formal protocol for screening posttransplant complications	56 (39)	1310 (46)
Medical center characteristics		
Geographic location		
Urban	107 (75)	2317 (81)
Suburban/rural	35 (25)	542 (19)
Center for Excellence designation	93 (65)	2433 (85)
FACT accreditation		
No	33 (23)	333 (12)
Yes, pending	40 (28)	761 (27)
Yes	69 (49)	1765 (62)

setting. The reason for this is unclear, but one possible explanation could be the relatively small and homogenous subset of stem cell transplantation population we used to examine the relationship between procedure volume/experience and survival.

When we computed the ratio of annual procedures to physicians, representing an index of average caseload or physician experience or both, we found a decreased risk of 100-day and 1-year mortality associated with higher caseloads. This ratio may be identical for a large center with many physicians caring for many patients and a small center with fewer physicians and patients. It may also be similar for a center with one predominant full-time clinician among several clinicians attending "part-time" and a center of similar size where each attending is on service for 1 month. However, this ratio must also be distinguished from the

Table 4. Center factors associated with 100-day and 1-year mortality after HLA-identical sibling transplantation among patients with acute or chronic leukemia

Variables	No.	100-d mortality odds ratio (95% CI)	P	1-y mortality odds ratio (95% CI)	P
Clinical severity index					
Lesser or equal to median (low risk)	905	1.00		1.00	
Greater than median (high risk)	521	3.16 (2.44-4.11)	< .001	4.21 (3.21-5.32)	< .001
Physician-patient case load/y					
20 patients or fewer/MD	762	1.00		1.00	
More than 20 patients/MD	664	0.67 (0.51-0.88)	.003	0.78 (0.63-0.98)	.03
Initial contact for after office or emergency calls					
Non-MDs (nurses, nurse practitioners, or physician assistants)	402	1.00		NS	NS
MDs (residents, fellows, attendings)	1024	0.72 (0.54-0.96)	.03	NS	NS
Medical school affiliation					
Nonmedical schools	283	1.00			
Medical schools with students and/or residents	57	2.35 (1.17-4.74)	.02	NS	NS
Medical schools with fellows	390	1.43 (0.92-2.22)	.11	NS	NS
Medical schools with students, residents, and fellows	696	1.43 (0.98-2.09)	.06	NS	NS

NS indicates not significant.

for the early care of patients and thereafter care is transferred back to the referring oncologist.

On the other hand, our study failed to show an association between factors that would be expected to correlate with superior outcomes, such as Foundation for the Accreditation of Cellular Therapy (FACT) accreditation, National Cancer Institute (NCI) Cancer Center designation, or Center for Excellence designation. The current study should encourage further exploration of factors necessary for high-quality care including confirmation of those found in this study. Additional outcomes, such as patient satisfaction and measures of morbidity, should also be addressed.

Our study has several limitations. First, the final sample used in the multivariate analysis of the allograft cohort included only 88 of the 113 centers surveyed. The median procedure volume of the 113 centers was 50 transplants per year; the sample studied had larger annual volumes. However, 39% of the centers included in the study performed fewer than 60 transplants per year. We feel there was ample representation of the small-volume centers. Additionally, prior experience suggests centers not registering to the IBMTR are more likely to be nonacademic centers, implying that they are likely to be doing more autologous transplants, are not involved in research, and do not have trainees. Procedure volume and center experience are probably the same as those registering to the IBMTR/ABMTR. Second, the characteristics of the centers were retrospectively collected. Because the questionnaire was sent in 2001, respondents may not have had an accurate recollection of their center's clinical practice in 1998 to 2000. However, it seems unlikely that the center factors we examined drastically changed within the relatively short interval studied. Third, the outcomes we studied did not include disease recurrence or disease-free survival. We feel these outcomes are more likely determined by dis biology and are not primarily affected by center factors, but t extent that they influence overall survival, they could be mas center effects. However, we compared the relapse rates a center by procedure volume and found no statistically signif differences. Fourth, our findings may not be applicable in pedi HSCT where procedure volume is generally lower. Lastly, derived CSI may not have adjusted completely for the pa disease, and transplant-related factors known to affect trans outcome. However, the factors included in the CSI are consi with other studies reporting outcomes adjusted for pa characteristics.

Despite the exploratory nature of our study and the lac complete understanding of the processes involved as to hov various center factors we identified contribute to better surviv appears that the greater involvement of properly trained physi is associated with better early outcomes, particularly in allogeneic HSCT and autologous HSCT for high-risk patients should be encouraged. We recommend that further studies, pr ably prospective in design, be done to establish a more definit for the factors we identified as affecting mortality after HSCT.

Acknowledgment

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On behalf of St. John Health, I appreciate the opportunity to address you and urge your support for a review of Michigan's Certificate of Need Standards on Bone Marrow Transplantation. I am Dr. Michael Wiemann, Executive Vice President, West Region, St. John Health and President of Providence Hospital. Prior to serving in administrative roles at St. John Health and at St. Vincent Hospitals and Health Care Center in Indianapolis, my clinical practice was as a medical oncologist with a specialty in bone marrow transplantation. I received my training in bone marrow transplantation at the Johns Hopkins School of Medicine in Baltimore, Maryland. I subsequently established the Bone Marrow Transplant Program at the Brown University School of Medicine in Providence, Rhode Island, and served as it Medical Director for ten years. After moving to St. Vincent Hospital in Indianapolis, Indiana, I established the Bone Marrow Transplant Program at that institution and served as its Medical Director for twenty years.

Collectively, St. John Health's cancer facilities (which include Providence Hospital Cancer Centers, Van Elslander Cancer Center at St. John Hospital, Webber Cancer Center at St. John Macomb Hospital, and our cancer programs at St. John Oakland and St. John River District) diagnose more than 4,400 cancer cases annually.

St. John Health strongly believes that members of this Commission should seek a review of the current BMT standard to ascertain whether this service should continue to

common malignant conditions, such as non-Hodgkin's lymphoma. This is no longer a rare or esoteric treatment but is now an essential part of routine care for patients with certain malignant conditions. Indeed, for many of these patients, their only opportunity for cure of prolonged remission is through the technique of hematopoietic stem cell transplantation. The necessary technology and expertise for this procedure are now widely available and there are numerous accredited programs throughout the country. For example, in my previous home city of Indianapolis, there are four accredited and busy bone marrow transplant programs. It is vital that all appropriate patients have ready access to this treatment without the undue hardship or expense of travel or transfer to another institution. St. John Health submitted comments to this effect at your October 16, 2007, hearing on the need to review a number of CON Standards including Bone Marrow Transplantation.

To summarize St. John Health's concerns as they relate to Access, Cost, Quality which are all goals of the CON program.

Access

- Limiting the number of transplant centers impedes access to patients who might otherwise be eligible for stem cell transplantation as it greatly limits the visibility of this option among community oncologists, and can impact the timely referral of their patients;
- A transplant team on-site is much more likely to advocate for this procedure to colleagues within their institution and do so early in the course of the disease when the procedure is most effective;
- Continuity of Care is maintained for patients who have developed a relationship with an oncologist in the community and can influence a patient's decision to pursue this course of treatment over alternative treatment modalities.

Quality

- An arbitrary cap on the number of programs does not on its own represent the most appropriate measure of quality rather;
- All transplant programs are required to apply for certification to the Foundation for Accreditation of Cellular Therapy. Accreditation is based on international standards in the field of cellular therapy.

Cost

- Alternative therapies can be as expensive and are frequently more expensive than Bone Marrow/Stem Cell Transplantation and do not offer the patient the opportunity for cure;

- Initiation of a BMT program at sites with a well developed oncology programs does not result in significant incremental costs;
- Bone Marrow Transplantation is sufficiently different from other technologies regulated by CON, which have a greater potential to proliferate.

Since the introduction of Bone Marrow Transplantation in the late 1960's as an experimental procedure, there have been significant advances in the field of Stem Cell Transplantation therapy that have resulted in a steady increase in the number of transplants for eligible patients in all age groups over the past decade or more. This increase in utilization is occurring both nationally and in Michigan as demonstrated by statistics compiled by the National Marrow Donor Program and data gathered by the Department of Community Health. This has occurred despite assertions several years ago when the CON Commission contemplated modifying these standards that BMT utilization was decreasing. St. John Health has distributed to each of you a document that seeks to outline the advancements in BMT/Stem Cell Transplantation since the first successful allogeneic bone marrow transplant procedure was performed in 1968 to present day. This chronology includes the establishment of the National Marrow Donor Program, advent of Umbilical cord stem cell transplantation, standardization of harvesting hematopoietic stem cells from blood and implementation of reduced intensity conditioning allogeneic transplantation.

Similarly, when BMT was first introduced it was an expensive procedure. Two major developments have contributed to put the cost of BMT in context: First, relentless

advancements in the BMT procedure and management of complications have included cost efficiencies and second the high cost of alternative therapies. The St. John Health document that was given to each of you also includes a number of alternative therapies and the estimated cost of each. It is noteworthy that several of these therapies require an annual cost as patients are kept on this therapy for an extended period of time.

In conclusion, St. John Health asserts that BMT/Stem Cell Transplantation is now a safe, routine procedure that should be available at tertiary medical centers with advanced oncology programs that can demonstrate need, expertise, appropriate facilities, and who meet national standards. Arbitrarily limiting this procedure to only three centers in the state ignores the evolution of this technology from an experimental procedure to one that is the standard of care in today's healthcare delivery environment.

Again, thank you for the opportunity to address you today. I would be happy to answer any questions or address any concerns regarding my comments or more generally on the subject of Bone Marrow/Stem Cell Transplantation

SCT 2009

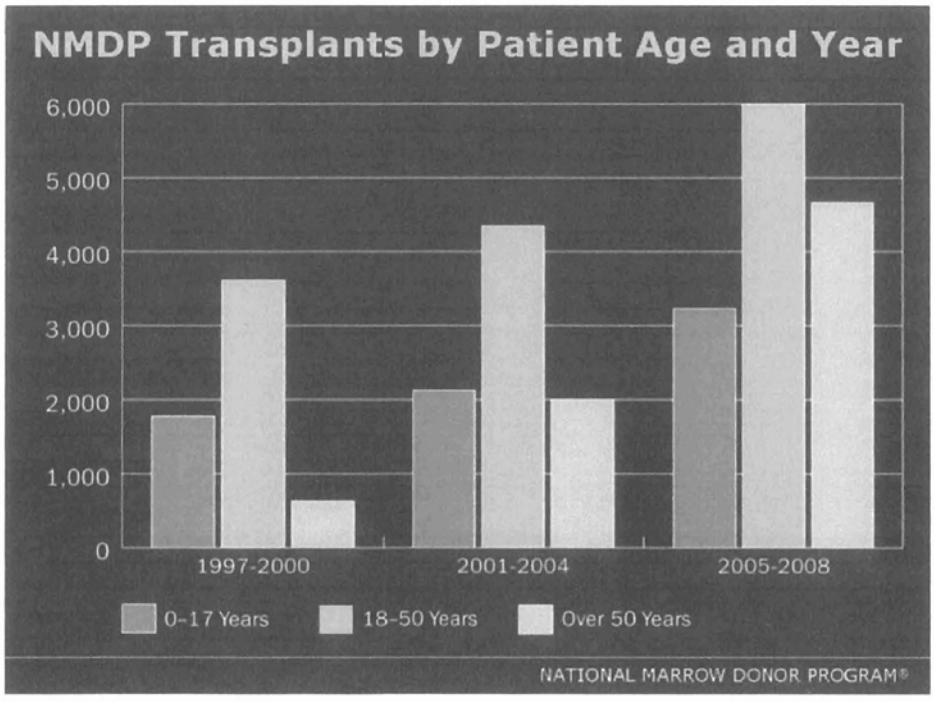
St. John Health

Introduction: The arguments used by opponents of opening up BMT to new health care systems in Michigan used 3 key words as basis for their arguments: **Quality, Cost and Access.** Careful analysis of the dynamics of delivering cancer care since the introduction of BMT reveals significant changes that should call for reevaluation of the CON strategy by the State government. Summary of key points is shown in this document:

I. **QUALITY:** In this context, quality refers to BMT as a highly specialized experimental procedure that should be limited to academic research centers. This was certainly true at the inception of BMT (1968, see below) but is by no means true in 2009. The procedure is now considered routine, standard of care for many diseases due to the advances made in its refinement as shown by the chronology below:

1968 The first successful allogenic bone marrow transplant procedure was conducted at the University of Minnesota.

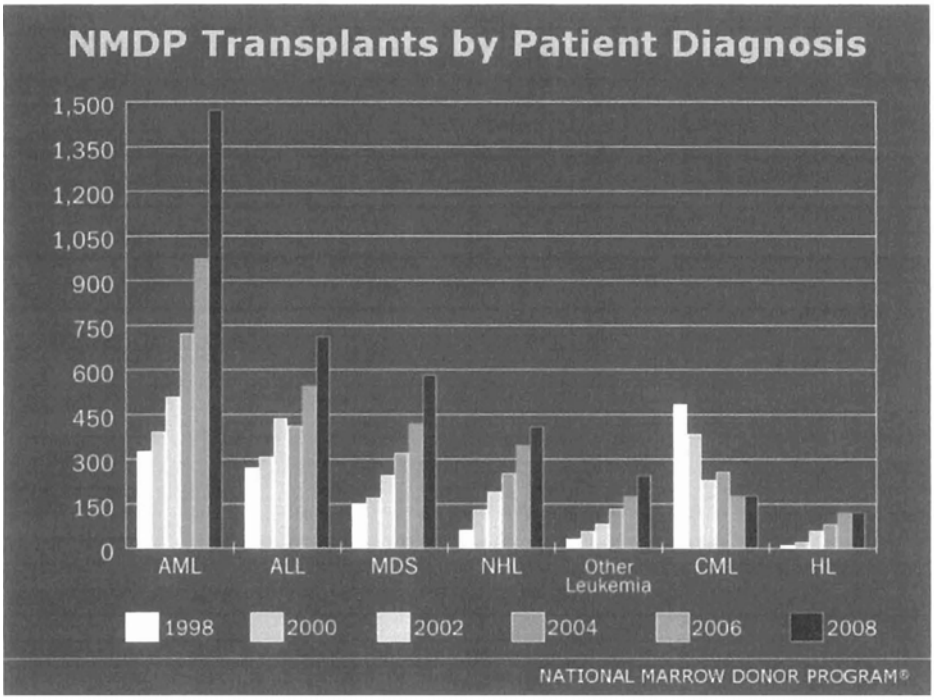
1973 First matched unrelated donor transplant done at Memorial Sloan-Kettering Cancer Center in New York. The procedure gains popularity over the ensuing years and the number of transplants has been steadily increasing for all age groups (Figure below). Statistics from Michigan department of community health showed increases in the state similar to national trend.



SCT 2009

St. John Health

1986 The National Marrow Donor Program (NMDP) is established to manage and coordinate banking and registries of bone marrow donors. As of 2006, there were more than 5million donors in transplant registries world-wide. The number of transplantations has been steadily increasing over the past 10 years except for chronic myelogenous leukemia (CML) (due to introduction of a new drug, Imatinib [Gleevec]) (Figure blow)



1988 Umbilical cord stem cell transplantation: Umbilical cord blood (UCB) hematopoietic stem cells (HSC) from a related sibling were transplanted successfully into a 5-year-old child with Fanconi anemia by Gluckman and colleagues. Once considered a 'medical waste', the cord blood is a rich source of hematopoietic stem cells that can be used for transplantation. As a result, the number of UCB transplantations (UCBT) being performed has increased dramatically (see Barker Figures 1A and 1B below). UCB has the clear benefits of rapid availability and a reduced stringency of requirement for HLA match. The latter attribute has the potential to extend the donor pool, which is of great importance for racial and ethnic minorities. In this regard, it is important to note that St John Hospital and Medical Center is among the top in the nation in collecting cord blood stem cells from ethnic minority patients.

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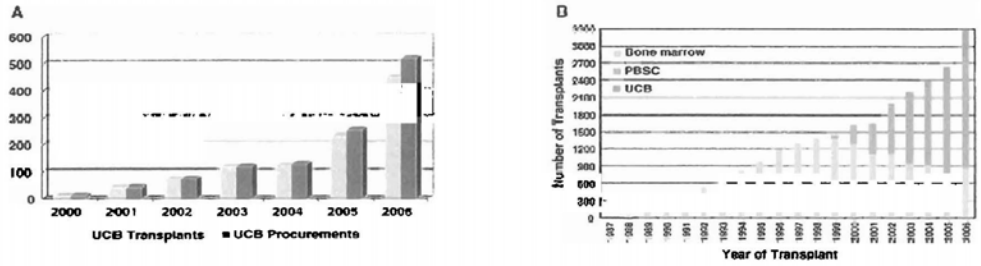
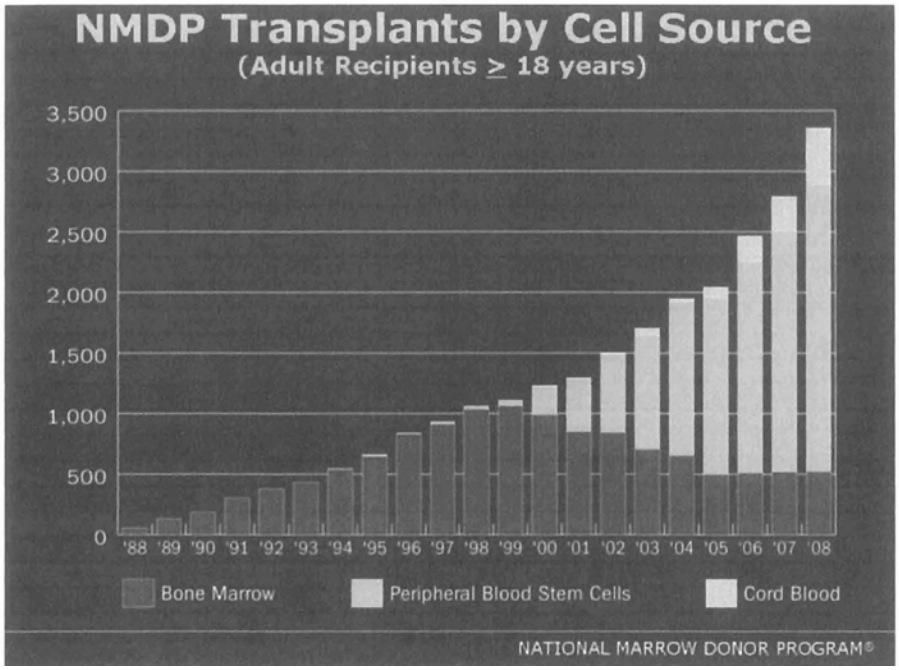


Barker Figures 1A and 1B. Umbilical cord blood (UCB) unit procurements and UCB transplants facilitated by the National Marrow Donor Program (NMDP) by year (1A): NMDP facilitated transplants by year according to hematopoietic stem cell (HSC) source (1B). (Slides courtesy of Dr Dennis Confer. NMDP).

1990's Harvesting hematopoietic stem cells from blood (rather than bone marrow) becomes standard. It was discovered that hematopoietic stem cells are present in significant numbers in the blood enough to support engraftment. Until this discovery, stem cells were harvested from the bone marrow in the operating room under general anesthesia requiring hospitalization. Harvesting stem cells from blood had great impact on reducing cost and shortening period of engraftment, ie. Peripheral blood stem cell transplantation (PBSCT) is cheaper, safer and better than bone marrow stem cell transplantation (ref #??). As a result, most of stem cell transplantations nowadays are done as PBSCT (Figure below).



SCT 2009

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1990's Reduced intensity conditioning (RIC) allogeneic transplantation. Reduced intensity conditioning (RIC) regimens have been investigated for more than 10 years as an alternative to traditional myeloablative conditioning regimens. RIC regimens are being commonly used in older patients as well as in disorders in which traditional myeloablative conditioning regimens are associated with high rates of non-relapse mortality. Hodgkin disease, myeloma, and low-grade lymphoid malignancies have been the diseases most impacted by RIC regimens. RIC regimens are shown to be safe and effective in older patients as well as patients with co-morbidities. RIC regimens are associated with lower rates of severe toxicity and non-relapse mortality.

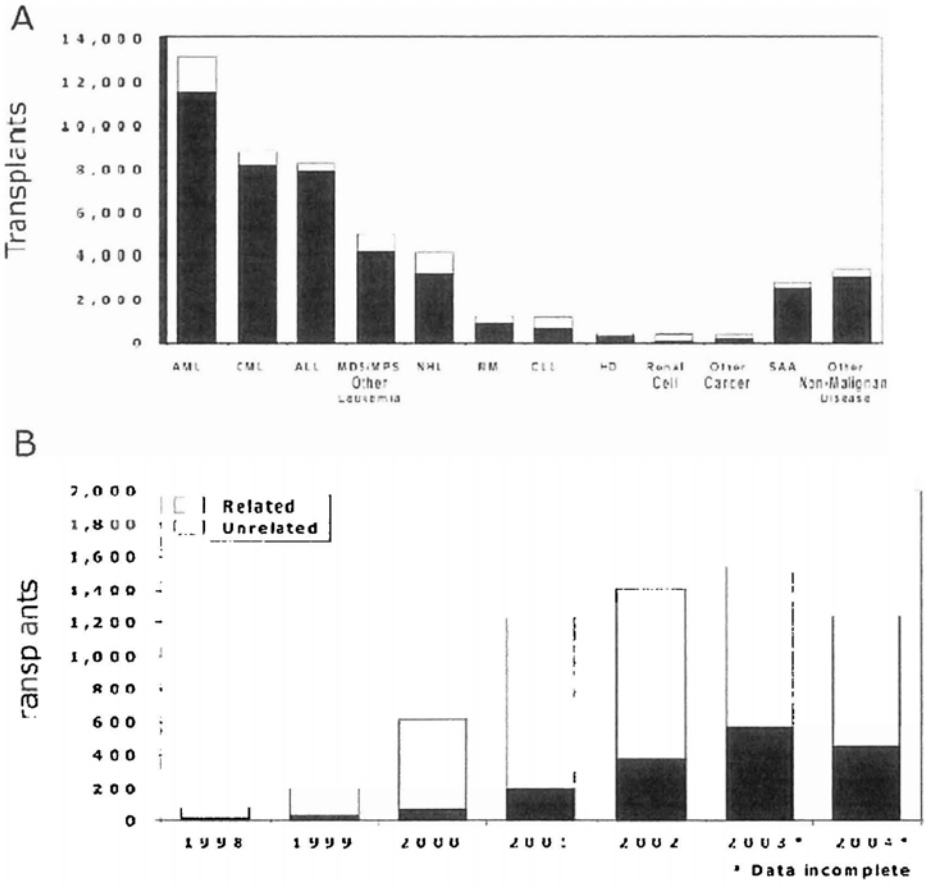

Figure 1. Use and indications for reduced-intensity conditioning regimens as reported to the Center for International Blood and Marrow Research (CIBMTR)

Abbreviations: ALL acute lymphocytic leukemia; AML acute myeloid leukemia; CLL chronic lymphocytic leukemia; CML chronic myeloid leukemia; HD Hodgkin disease, MCL mantle cell leukemia; MDS myelodysplastic syndromes; MM multiple

SCT 2009

St. John Health

myeloma; MPS myeloproliferative syndromes; NHL non-Hodgkin lymphoma; NRM non-relaps mortality; OS overall survival; SAA severe aplastic anemia; TBI total-body irradiation.

In summary, BMT (SCT) is now a safe routine procedure that should available at community centers that can demonstrate need, expertise, appropriate facility and meet national standards. The strongest opponents to opening new centers in Michigan would agree that autologous SCT is no more complicated medically than managing induction chemotherapy for acute leukemia. Skills of physicians and ancillary staff, therefore, for institutions like SJH should not be a concern.

II. Cost: It is true that in the beginning, BMT was an expensive procedure. Limiting it to few centers was appropriate to contain cost for the society. However, since then, two major developments have completely changed the outlook today. One is the relentless advancements in the BMT procedure that included cost efficiencies and second, the continued increase in the cost of alternative therapies. These two factors have made SCT a very cost-effective treatment modality. Some examples supported by published data are shown below to illustrate these observations:

1. Cost of Imatinib (Gleevec) as new alternative therapy to transplant for CML: Allogeneic SCT is the only proven curative treatment for CML. Until the introduction of Imatinib, chemotherapy was the most commonly used alternative option for treating patients with CML. Imatinib is a new drug that is specific for CML and works by exploiting the genetic abnormality in this disease, ie the translocation between chromosomes 9 and 22. It is available in pill form that patients have to take every day. After few months of therapy, majority of patients achieve complete remission. When to stop the drug is not known. Given its efficacy and tolerability, the standard of care nowadays is to keep patients on therapy for years, 3, 5…etc. The cost of Imatinib per year is $30K (see reference #2 in separate 'Literature' file). Adding the cost of this drug therapy over the years makes it even more expensive than SCT.

2. Cost of hematopoietic growth factors: These are drugs that stimulate production of red blood cells (Procrit or Aranesp) or granulocytes (granulocyte colony stimulating factor [G-CSF] like Neupogen or Neulasta). Like many new drugs in Oncology, they are very expensive. A 10 day course of neupogen (or one injection of Neulasta) costs > $2000. They are often used after each cycle of standard cytotoxic chemotherapy hence increasing the overall cost. In one study, G-CSF was used in conjunction with induction chemotherapy for elderly patients with acute myelogenous leukemia (AML) in a randomized trial (see reference #3in separate 'Literature' file). Results showed that G-CSF had 'some clinical benefits but did not reduce the duration of hospitalization, prolong survival or reduce the overall cost of supportive care'. The cost of induction therapy with G-CSF was $50,593. In best case-scenario, patients who achieve complete remission with first cycle of induction chemotherapy will undergo at least 2 additional

cycles of 'consolidation'. The total cost of chemotherapy for AML is, therefore no less than SCT (see below).

3. Cost R-hyper CVAD regimen for the treatment of Mantle Cell Lymphoma (MCL): This regimen is considered standard of care for MCL, it consist of combination of cytotoxic chemotherapy (with recent addition of Rituximab) given in 2 blocks, A and B alternating every 3 weeks. A full course of therapy involves total of 8 treatments (4 A and 4 B) (see reference #4). All therapy is done as inpatient. Part A requires hospital stay for a minimum of 4 days and Part B requires average inpatient stay of 5 days. Total inpatient days for therapy without any complications or re-admissions is (4x4)=16 days for part A + (5x4)=20 for part B; total =36 days which is more than average hospital stay for a transplant patient. If one adds the cost of rituximab ($4000 per cycle) which is now used in conjunction with this regimen plus use of growth factors (G-CSF) and re-admissions for complications, the actual cost of this regimen exceeds that of SCT.

At the same that cost of standard therapy, as alternative to SCT, has continued to increase as a result of incorporating newer, more expensive drugs, the cost of SCT had come down considerably. Example of cost of SCT is shown below:

4. Peripheral blood stem cell transplant (PBSCT) in patients with relapsed lymphoma results in accelerated reconstitution, improved quality of life and cost reduction compared with bone marrow transplantation (BMT) (Reference #5). This study was done in the Netherlands and cost was calculated in US dollars. The study concluded that: 'Total transplantation costs were significantly lower in the PSCT arm [$13,954 ($4913- 29,532) versus $17 668 ($10,170-44,083) $P < 0.05$], as a result of the reduced hospital stay and lower antibiotic costs. In summary, these results indicate that PSCT is superior to ABMT with regard to engraftment, supportive care, quality of life and cost.'

III. <u>Access:</u> During the 2006 deliberations by the SAC on BMT, there was confusion between Access and Capacity. Members of current transplant centers argued that they have 'capacity' to transplant more patients and therefore, there is no problem with 'Access'. This is obviously a one-sided viewpoint that ignores realities of Oncology practice in the community. Several factors under the present circumstances limit full access to transplant including patient-doctor relationships, referral patterns, disruption of care…etc.

REFERNCE #1:

Nature Clinical Practice Oncology (2006) **3**, 302-314
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Technology Insight: ECP for the treatment of GvHD—can we offer selective immune control without generalized immunosuppression?

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SUMMARY

Hematopoietic stem-cell transplantation remains an important curative therapy for many conditions and its use is increasing annually. Graft-versus-host disease (GvHD) is the major cause of mortality and suffering following allogeneic hematopoietic stem-cell transplantation. Conventional treatments are associated with multiple side effects and are often ineffective. New therapeutic approaches for the control of GvHD are desperately required. Extracorporeal photochemotherapy (ECP) was developed in the 1970s for the treatment of cutaneous T-cell lymphoma and was approved by the FDA as the first selective immunotherapy for a cancer. ECP has also proved an effective therapy for immune-related conditions, particularly GvHD, even in patients refractory to conventional therapies. The treatment involves the mechanical separation of circulating white cells, which are exposed to psoralen and UVA light and then returned to the patient. ECP is extremely well tolerated with minimal side effects and is not associated with the increased rates of infection or relapse of malignant disease typical of conventional immunosuppressive agents. Thus, ECP appears to offer selective immune modulation without generalized immunosuppression, but its mechanism of action remains poorly understood. This review discusses the development of ECP, its use in the treatment of GvHD, as well as current theories of its mechanism of action.

REFERENCE #2:

Nature Clinical Practice Oncology (2005) **2**, 126-127
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Is imatinib a cost-effective treatment for newly diagnosed chronic myeloid leukemia patients?

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Email

This article has no abstract so we have provided the first paragraph of the full text.

The delivery of health care gets annually more expensive, and national governments and other agencies responsible for paying are obliged to consider the cost-effectiveness of drugs already in use and of new drugs that become available. Surrogate markers (e.g. reduction of recognizable leukemia cells in the bone marrow) and short-term survival data suggest that the BCR–ABL tyrosine kinase inhibitor imatinib mesylate, first used to treat patients with CML in 1998, is an important new agent and may indeed usher in a new era of effective targeted therapy for malignant disease in general. Until recently, allogeneic stem cell transplantation was the recommended therapy for all new patients under the age of 50 who had suitable stem cell donors; today, transplants are generally reserved for those who fail initial treatment with imatinib—maybe only 30% of patients in the first year of treatment. However, treating a patient for 1 year with imatinib at the standard dosage (400 mg/day) costs about UK£17,000 or US$30,000—not trivial sums.

REFERENCE #3:

1: Cancer Invest. 2001;19(6):603-10

Economic analysis of granulocyte colony stimulating factor as adjunct therapy for older patients with acute myelogenous leukemia (AML): estimates from a Southwest Oncology Group clinical trial.

Bennett CL, **Hynes D**, **Godwin J**, **Stinson TJ**, **Golub RM**, **Appelbaum FR**; **Southwest Oncology Group**.

VA Chicago Health Care System-Lakeside, Chicago, Illinois 60611, USA.

Considerable morbidity, mortality, and economic costs result during remission induction therapy for elderly patients with acute myeloid leukemia (AML). In this study, the economic costs of adjunct granulocyte colony stimulating factor (G-CSF) are estimated for AML patients > 55 years of age who received induction chemotherapy on a recently completed Southwest Oncology Group study (SWOG). Clinical data were based on Phase III trial information from 207 AML patients who were randomized to receive either placebo or G-CSF post-induction therapy. Analyses were conducted using a decision analytic model with the primary source of clinical event probabilities based on in-hospital care with or without an active infection requiring intravenous antibiotics. Estimates of average daily costs of care with and without an infection were imputed from a previously reported economic model of a similar population. When compared to AML patients who received placebo, patients who received G-CSF had significantly fewer days on intravenous antibiotics (median 22 vs. 26, p = 0.05), whereas overall duration of hospitalization did not differ (median 29 days). The median cost per day with an active infection that required intravenous antibiotics was estimated to be $1742, whereas the median cost per day without an active infection was estimated to be $1467. Overall, costs were $49,693 for the placebo group and $50,593 for the G-CSF patients. G-CSF during induction chemotherapy for elderly patients with AML had some

clinical benefits, but it did not reduce the duration of hospitalization, prolong survival, or reduce the overall cost of supportive care. Whether the benefits of G-CSF therapy justify its use in individual patients with acute leukemia for the present remains a matter of clinical judgment.

PMID: 11486703 [PubMed - indexed for MEDLINE]

Related Articles

- A double-blind placebo-controlled trial of granulocyte colony-stimulating factor in elderly patients with previously untreated acute myeloid leukemia: a Southwest oncology group study (9031). [Blood. 1998]
- ReviewCost analyses of adjunct colony stimulating factors for older patients with acute myeloid leukaemia : can they improve clinical decision making? [Drugs Aging. 2003]
- Cost analyses of adjunct colony stimulating factors for acute leukemia: can they improve clinical decision making. [Leuk Lymphoma. 2000]
- Granulocyte-macrophage colony-stimulating factor after initial chemotherapy for elderly patients with primary acute myelogenous leukemia. Cancer and Leukemia Group B. [N Engl J Med. 1995]
- ReviewMonocyte-macrophages, granulocyte-macrophage colony-stimulating factor, and prolonged survival among patients with acute myeloid leukemia and stem cell transplants. [Clin Infect Dis. 1998]

REFERENCE #4:

Attachment G

Regimen Category	Core: Standard therapy endorsed by the Disease Site Group and a regimen widely used by most Integrated Cancer Programs in this disease site

Course A:			
CYCLOPHOSPHAMIDE	300mg/m^2	IV over 3 hours	Q12H x 6 doses Days 1, 2, and 3
MESNA may be given as an oprotectant at the same total dose as cyclophosphamide bu given by ontinuous infusion sta ting with cyclophosphamide and ending 6 hours after the last dose. (Al ough Mesna is recor mended in the cited reference (Kantarjian et al.), most RCC s usually d not administer Mesn with this dose of Cyclophosphamide.)			
METHOTREXATE	12mg	IT	Day 2
DOXORUBICIN	50mg/m^2	IV	Day 4
VINCRISTINE	2mg	IV	Days 4 and 11
DEXAMETHASONE	40mg/day	IV or PO	Days 1 to 4 Days 11-14
CYTARABINE	70mg	IT	Day 7
Course B:			
METHOTREXATE	1000mg/m^2	IV over 24 hours	Day 1
LEUCOVORI	25mg/m^2	IV 24 hours after starting Methotrexate infusion	Q6H X 6 doses
Sodium Bicarbonate	600mg	PO (starting day before Methotrexate)	TID X 4 Days
CYTAR BIN	3000mg/m^2	IV ov 2 ours	12H X 4 doses ays 2 and 3

C	CYCLE F

A total of 8 cycles is administered (4 X A. 4 X B) with the goal to give treatment as rapidly as possible.

	REMEDICATION AND SUPPORTIVE MEASURE
ANTIEMETIC REGIMENS: **HESKETH LEVEL 5**	• *With high dose Methotrexate. give hydration with Sodium Bicarbonate for 48 hours.* • *Prophylactic use of Dexamethasone 0.1% or Pred Forte Ophthalmic solution 1-2 drops q4h while awake for 7 days (during high dose Cytarabine) to prevent conjunctivitis* • *Antibiotic prophylaxis may be given (see reference)*

REFERENCE #5:

Autologous peripheral blood stem cell transplantation in patients with relapsed lymphoma results in accelerated haematopoietic reconstitution, improved quality of life and cost reduction compared with bone marrow transplantation: the Hovon 22 study.

Vellenga E, **van Agthoven M**, **Croockewit AJ**, **Verdonck LF**, **Wijermans PJ**, **van Oers MH**, **Volkers CP**, **van Imhoff GW**, **Kingma T**, **Uyl-de Groot CA**, **Fibbe WE**.

Department of Haematology, University Hospital Groningen, The Netherlands.

Br J Haematol 2001, 114(2):319-26

The present study analysed whether autologous peripheral blood stem cell transplantation (PSCT) improves engraftment, quality of life and cost-effectiveness when compared with autologous bone marrow transplantation (ABMT). Relapsing progressive lymphoma patients (n = 204; non-Hodgkin's lymphoma n = 166; Hodgkin's disease n = 38) were, after induction treatment with the DHAP-VIM (cisplatin, cytarabine, dexamethasone, etoposide, ifosfamide, methotrexate) regimen, randomly (2:1) assigned to the harvest of granulocyte-macrophage colony-stimulating factor-mobilized stem cells after the second DHAP course or autologous bone marrow cells before the second DHAP course. These stem cells were reinfused following high-dose myeloblative chemotherapy. After induction, 118 patients obtained a partial or complete response and were eligible for randomization. In the PSCT arm (n = 76) significantly faster engraftment of neutrophils [> or = 0.1 and > or = 0.5 x 10(9)/l: 10.7 d (7-36, median, range), 15 (9-45) versus 13 (8-25) and 26 (14-80), P <

0.01] and thrombocytes [> or = 20 x 10(9)/l: 13 d (7-51) versus 18 (11-65), P < 0.01] were observed. In addition, significantly fewer transfusions of red blood cells [6 (0-23) versus 8 (2-24), P < 0.01] and platelets [4 (0-60) versus 8 (2-55), P = 0.01] were required in the PSCT arm. These findings were associated with a significant reduction in the median days of intravenous antibiotics in patients with fever [8.5 (0-30) versus 14 (0-34), P = 0.04] and hospital stay [27 (8-51) versus 34 (24-78), P < 0.05]. Quality of life demonstrated a significant difference in favour of the PSCT arm. Total transplantation costs were significantly lower in the PSCT arm [$13,954 ($4913- 29,532) versus $17 668 ($10,170-44,083) P < 0.05], as a result of the reduced hospital stay and lower antibiotic costs. In summary, these results indicate that PSCT is superior to ABMT with regard to engraftment, supportive care, quality of life and cost.

2002 - YTD 2009 2002 YTD 2009 Transplants	BMTBMT Autologous	BMT Related Allogeneic	BMT Unrelated Allogeneic	Heart	Kidney	kidney/pkidney/pancreas					
Cedars Sinai Medical Center					1						
Children's Hospital					1						
Children's Memorial - Chicagog				11							
Duke University			1								
Fairview University Med. Center			2								
Froedtert Memorial Lutheran			1			1					
Henry Ford Health System											
Indiana University y	11										
Karmanos	8	5	10								
Loyola University	1	2	2	1							
Mayo Clinic	9		2		4						
Mayo Clinic of Florida											
Northwestern Memorial Hospital p	33										
Pennslyvania Hospital	1										
Rochester Methodist					1						

Hospital											
Spectrum Health	4	8	13		5						
St. Mary's Hospital (GR)					99						
Univeristy of Iowa Univeristy						11					
University Medical Center			1								
University of Chicago					2						
University of Michigan	29	22	34	4	14	2					
University of Wisconsin					2	1					
unknownunknown	22										
West Penn Hospital	1										
	59	**37**	**66**	6	**129**	5					

Blue Cross
Blue Shield
Of Michigan

600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Commission Meeting
February 5, 2009

I'd like to thank the Commission for this opportunity to testify on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents. This role is even more significant based on the current turbulent economic conditions.

Over the past few months, BCBSM/BCN administrative and clinical staff members have met with many of the organizations interested in addressing the Bone Marrow, Pancreas, Heart, Heart/Lung and Liver Transplant CON review standards. So far, consistent with our previous testimony, none of these discussions have convinced us that there is a need for any more transplant programs in Michigan. Additionally, 2000-2007 state-wide heart, liver, lung and bone marrow transplant data generally shows stable individual program volumes with limited evidence of increased demand. BCBSM/BCN continues to have concerns regarding transplant program expansions based on potentially negative ramifications to our stakeholders in terms of cost, quality and access to care.

The Psychiatric Beds and Services CON review standards were significantly revised in 2007. BCBSM/BCN would support some technical language modifications to make this standard simpler to understand and easier to administer.

Again, reiterating our previous testimony, BCBSM/BCN continues to support the review of CON standards in terms of cost, quality and/or access concerns. We urge the CON Commission to perform an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM/BCN will continue to be an open-minded, active participant in these endeavors. We recommend the following approaches to address these CON review standards based on the current array of issues, prioritization of required resources and time frame for output:

- Convene Standard Advisory Committees
  - Bone Marrow Transplant
  - Heart, Heart/Lung and Liver Transplant
- Convene Work Groups
  - Pancreas Transplant
  - MRI Services
- Modify Technical Language
  - Psychiatric Beds and Services

As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

Attachment J