MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) MEETING

Wednesday, July 29, 2009

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

APPROVED MINUTES

I. Call to Order

Chairperson VeCasey called the meeting to order at 9:01 a.m.

A. Members Present:

Paul Adams, MD, Vice-Chairperson, Self
Aly Abdel-Mageed, MD, Spectrum Health
Adil Akhtar, MD, Beaumont Hospitals
Grant Grace, UAW (called in at 10:10 a.m.)
Nalini Janakiraman, MD, Henry Ford Health System
Mary Marks, Alliance for Health
Thomas Ruane, MD, Blue Cross Blue Shield/Blue Care Network
Elna Saah, MD, Michigan State University
Joseph Uberti, MD PhD, Barbara Ann Karmanos Cancer Institute
Amy Vanderwoude, MD, Cancer & Hematology Centers of West Michigan
Donald VeCasey, Chairperson, consumer Health Care Coalitiion
Michael Wiemann, MD FACP, St. John Health System (left at 10:50 a.m.)

B. Members Absent:

Samuel Silver, MD, University of Michigan Health System
Jeffrey Trent, PhD, VanAndel Research Institute

C. Michigan Department of Community Health Staff Present:

Jessica Austin
Michael Berrios
Sallie Flanders
Bill Hart
Kasi Kelley
Irma Lopez
Andrea Moore
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

No conflicts were noted for the record.

III. Review of Agenda

Motion by Ms. Marks, seconded by Dr. Abdel-Mageed, to move item VII B to Item V on agenda.
Motion Carried.

Motion by Ms. Marks, seconded by Dr. Ruane, to approve agenda as modified.
Motion Carried.

IV. Review of Minutes July 8, 2009

Motion by Dr. Ahktar, seconded by Ms. Marks, to accept the minutes as presented.
Motion Carried.

V. Determination of Access Issues for Outside of Southeast Michigan

Mr. Funnell, Spectrum Health, gave an overview of West Michigan Access issues.

Discussion followed.

Motion by Dr. Abdel-Mageed, seconded by Dr. Uberti, to recommend that there is an access issue outside Southeast Michigan.

Public Comment:
Bob Meeker, Spectrum Health

Discussion followed.

Public Comment:
Steve Szelag, University of Michigan Health System on behalf of Dr. Sam Silver (Attachment A)

Motion Carried.

VI. BMT CON Standards

Dr. Uberti gave an oral and written presentation (Attachment B)

Discussion followed.

VII. Facility Based Methodology Presentation

Dr. Akhtar, and Dr. Wiemann gave an oral and written presentation (Attachment C).

Discussion followed.

Break at 10:50 a.m. – 11:10 a.m.

VIII. Determination of Access Issues for Southeast Michigan and Discussion of Cap Based Methodology

Discussion on Access Issues in the Southeast Region of Michigan.

Motion by Dr. Adams, seconded by Dr. Saah, to recommend that there are no access issues within southeast region for Bone Marrow Transplantation (BMT).
Motion Carried.

Discussion followed.

Motion by. Dr. Abdel-Mageed, seconded by Ms. Marks, to create two planning areas that mirror the pediatric requirements and to allow at least one adult BMT program in the new planning area.
Motion Carried.

Dr. Ruane abstained.

IX. Public Comment

None.

X. Future Meeting Dates

August 28, 2009
September 24, 2009
October 22, 2009
November 18, 2009

XI. Next Steps

The group will look at the Comparative Review Criteria to address if any changes need to be made.

XII. Future Meeting Dates

August 28, 2009
September 24, 2009
October 22, 2009
November 18, 2009

XIII. Adjournment

Motion by Dr. Saah, seconded by Vice-Chairperson Adams, to adjourn the meeting at 12:04 p.m.
Motion Carried.

Attachment A

University of Michigan
Health System

University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
BMT Standards Advisory Committee
July 29, 2009

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments on behalf of Dr. Samuel Silver who is unable to attend today's CON Standards Advisory Committee meeting.

UMHS believes that determining the need for BMT programs based upon the potential number of BMT candidates in a hospital's local catchment area, as opposed to state-wide needs assessment is not the correct way to determine the need for the number of BMT programs. First and foremost, the current programs continue to meet the need for patients in the State of Michigan and have excess capacity. In addition, unlike radiation oncology, where the population-based need for radiation oncology services has remained stable for many years, the need for BMT services is a moving target. As has been discussed during these meetings, the diagnoses that require or have received BMT services have varied extensively over the past 15 years. Breast cancer was formerly the major diagnosis for autologous stem cell transplantation, but is now rarely used. Multiple myeloma has now taken its place as the predominant service for which autologous stem cell transplantation is performed. However, with the advent of new chemotherapy and immunomodulatory therapies, the role of BMT is being debated.

As quoted from an article to be published in Heme/Onc Today, "The question that has yet to be answered, however, is whether transplant confers further benefit on patients who achieve very good responses with the novel agents alone. Kenneth C. Anderson, MD, director of the Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute in Boston, said that an international trial is scheduled to begin soon that will try to answer this question." and ""New therapies are improving the treatment [of myeloma]," said Bill Bensinger, MD, a researcher at the Fred Hutchinson Cancer Research Center in Seattle. "We think, at least preliminarily, that it makes a difference with these new therapies in terms of how patients do with a transplant. But the question is, do you need a transplant for some patients and not for others? We don't know.""

With such wide potential swings in the diagnoses for which BMT is employed, using small silo populations in hospital catchment areas, could potentially lead to the establishment of unneeded units and an increase in unnecessary State-wide spending on infrastructure costs. I do not see this as a reasonable methodology to adjudicate BMT units.

Thank you for according us this opportunity to makes these comments today.

Attachment B

BONE MARROW TRANSPLANT CON STANDARDS

July 29, 2009

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Wayne State University

Attachment B

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Joseph Uberti, M.D., Ph.D.

Professor of Medicine

Chief, Division of Hematology and Oncology-WSU School of Medicine

Co-Director, Blood & Marrow Stem Cell Transplant Program, KCC

Attachment B

CON Standards

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- BMT is NOT the only standard with a cap in the number of programs.
  - Heart Transplant – 3
  - Liver Transplant – 3
  - Lung Transplant – 3
- BMT standards were determined by a panel of experts, much like the composition of the current SAC.
- Why regulate hematopoietic stem transplantation?

Attachment B

FDA Requires Regulations- Based on 5 public health and regulatory concerns of HSCT

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1. Prevention of the transmission of communicable diseases.
2. Assurance that necessary processing controls exist to prevent the contamination of cells and tissues and to preserve their integrity and function.
3. Assurance of clinical safety and effectiveness.
4. Assurance of necessary product labeling including permissible promotion of or proper product use.
5. Establishment for a mechanism for FDA to communicate with the cell and tissue industry.

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Stem cell transplant = Organ transplant Regulation Now Part of Federal Register

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- Federal Register, FDA 21 CFR 1271--Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments -requires FDA registration yearly.

- Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing through CLIA- Clinical Laboratory Improvement Amendments, Requires registration for certificate of accreditation every 2 years.

- National Marrow Donor Program (NMDP), accreditation to receive unrelated products every year.

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Current regulatory agencies

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- Government regulation federal state level.
- FDA regulates human cells tissues and cellular and tissue based product/Facilities registered with the FDA.
- CBER-Center for Biological Evaluation and Research.

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Do we need more state regulation/limits?

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- "Government regulation of HC therapy at the state level is fragmented, often voluntary and, in the opinion of the FDA inadequate to prevent transmission of disease. Many states have little specific regulation."

- In order to overcome this

  "Some states have adopted mechanisms of qualifying HCT programs and facilities such as the Certificate of Need Process."

Hematopoietic Cell Procurement, Processing and Transplantation:Regulation and Accreditation Warkentin et al in Hematopoietic Stem Cell Transplantation--2003

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Why regulate/limit stem cell transplant?

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- Prevent indiscriminate, unsafe use of stem cells
- High mortality
- Limited stem cell availability
- High risk of infectious disease transmission
- Expense

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Transplant Mortality Remains High

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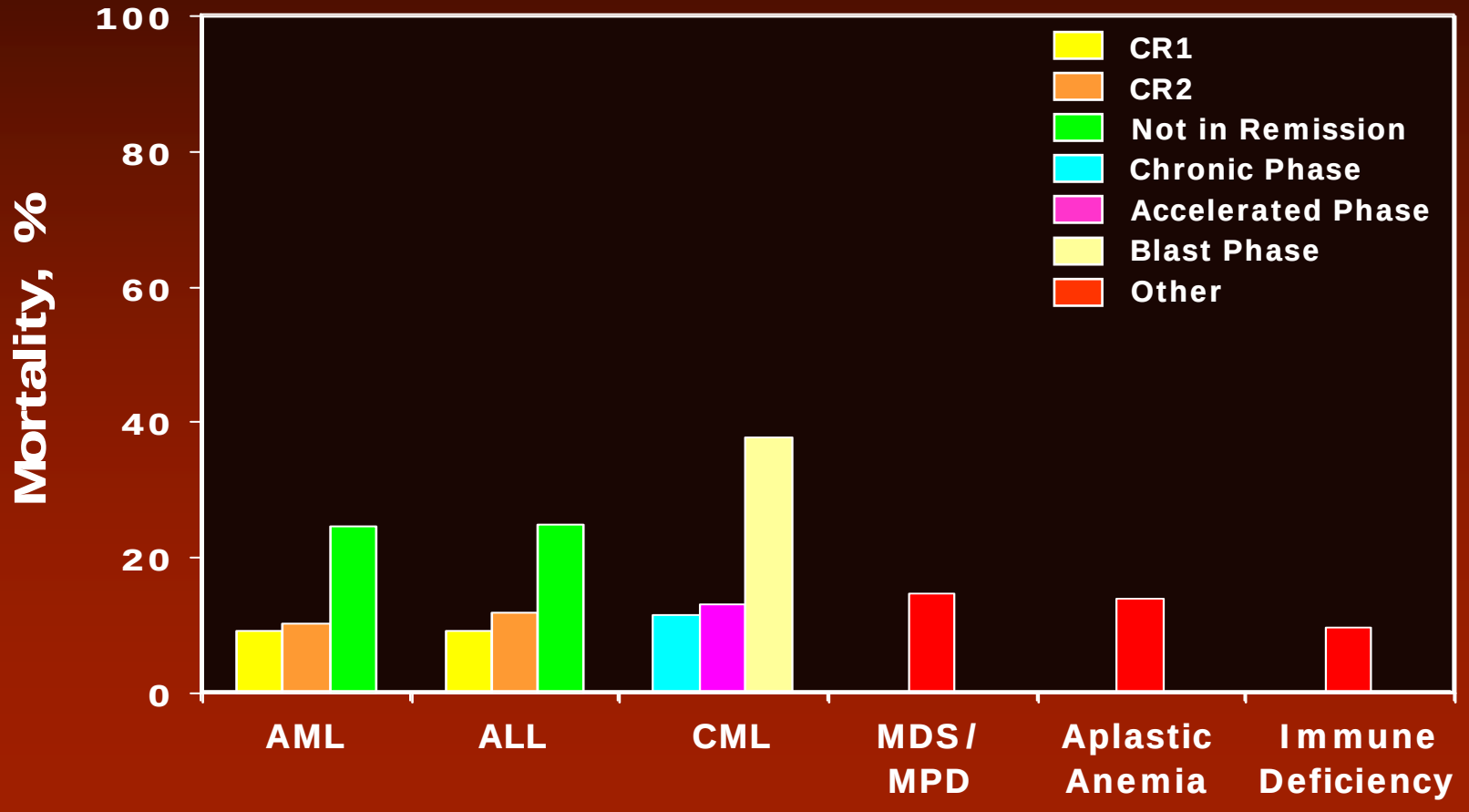
- 100 day mortality is taken as a marker for toxicity of transplantation
- Stem cell transplantation mortality and outcome is worse than solid organ transplantation
- Reduced Intensity Transplants have high mortality

100-day Mortality after HLA-identical Sibling Transplantation, 2004-2005



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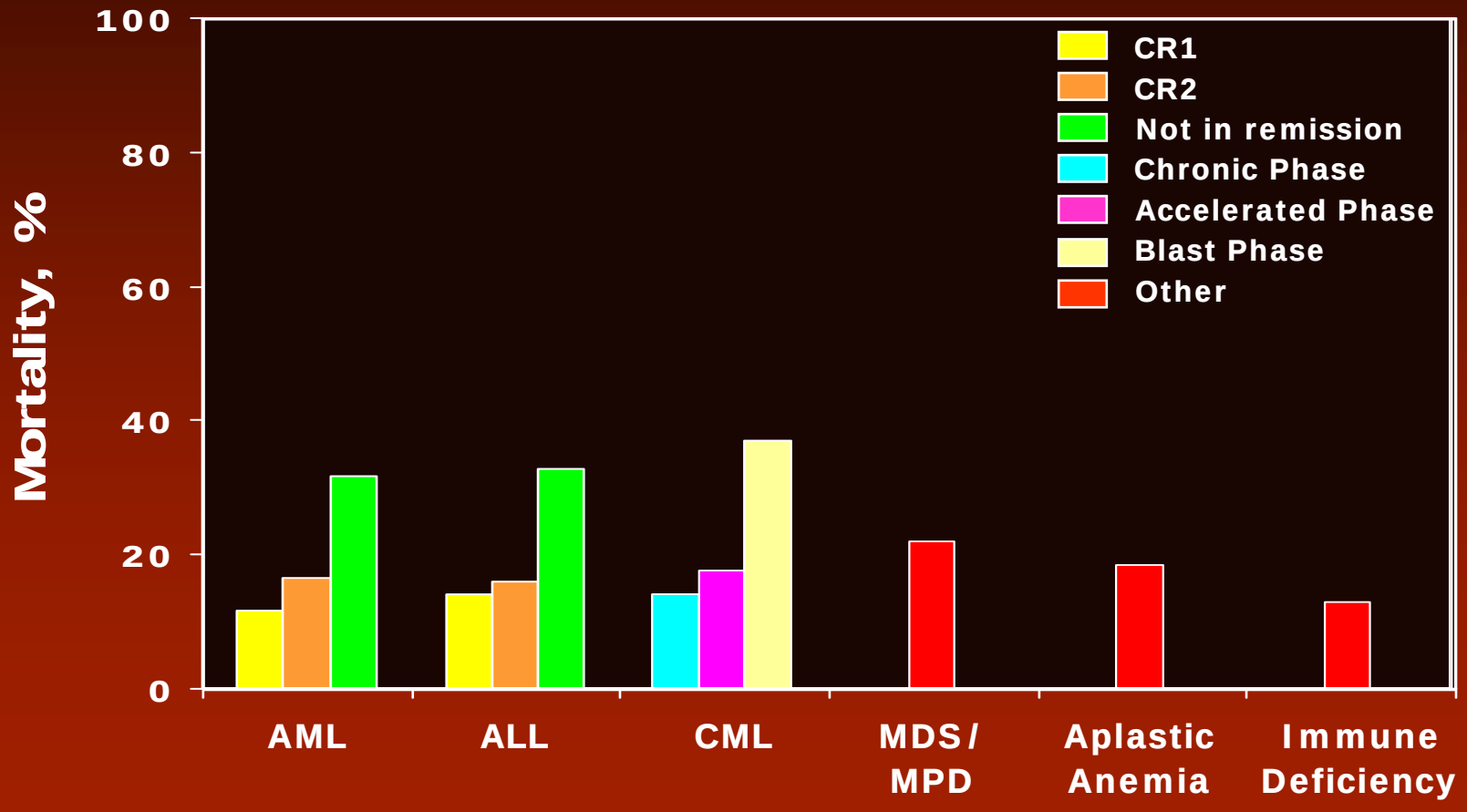
100-day Mortality after Unrelated Donor Transplantation, 2004-2005



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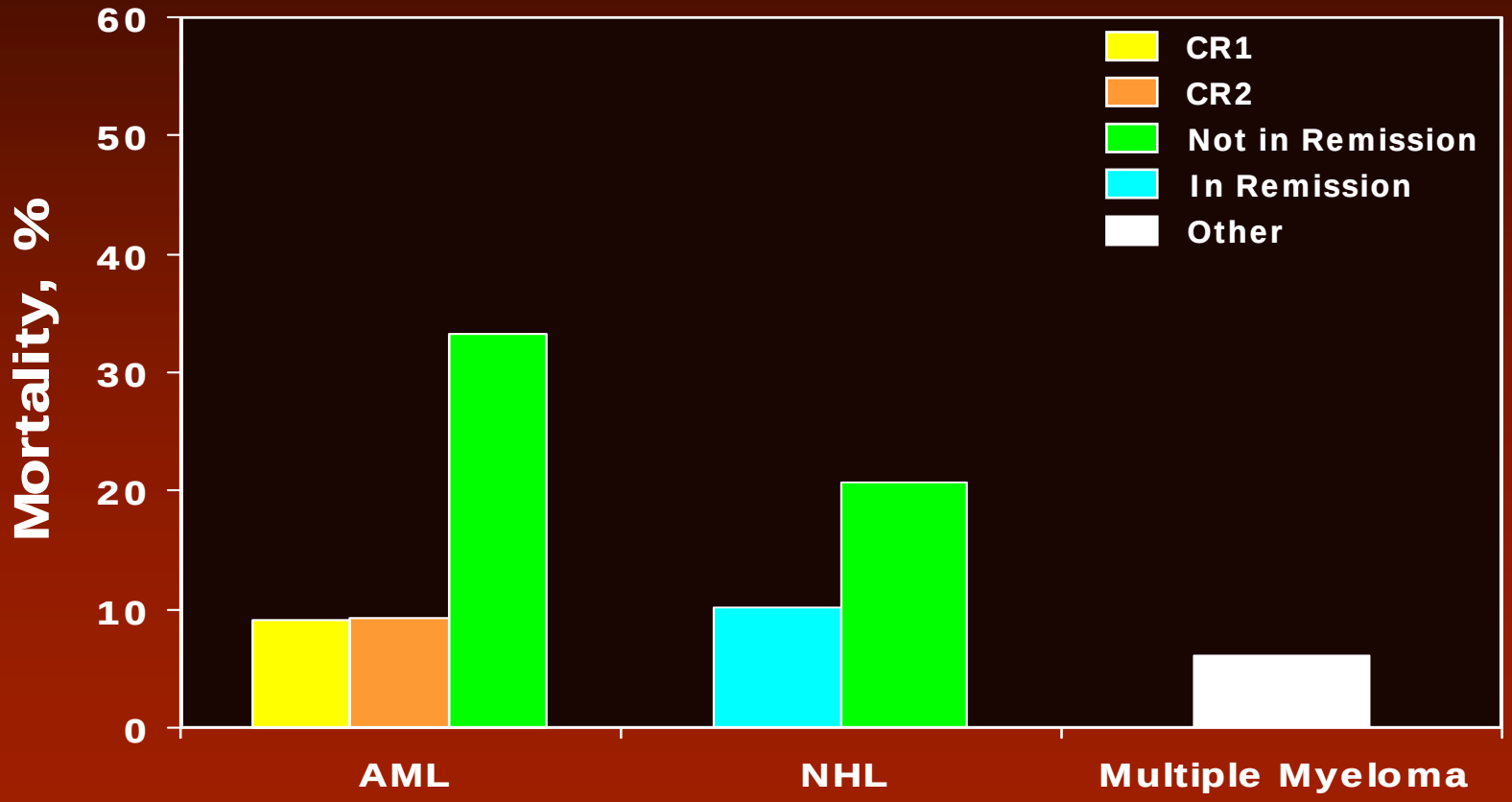
100-day Mortality after Related Donor Transplantation with Reduced Intensity Conditioning, 2004-2005



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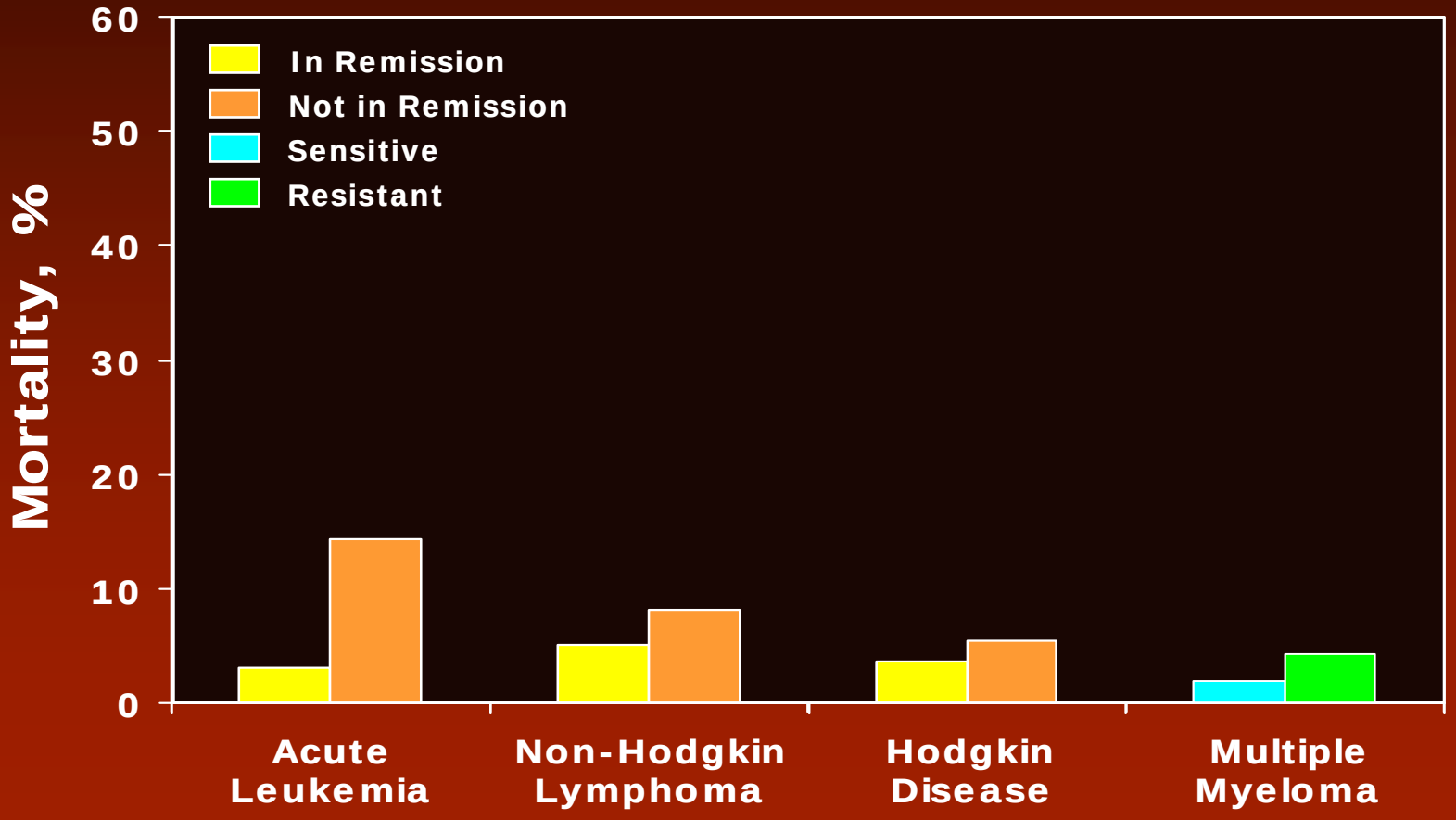
100-day Mortality after Autologous Transplantation, 2004-2005



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Outcome of organ transplants superior to outcome of stem cell transplants

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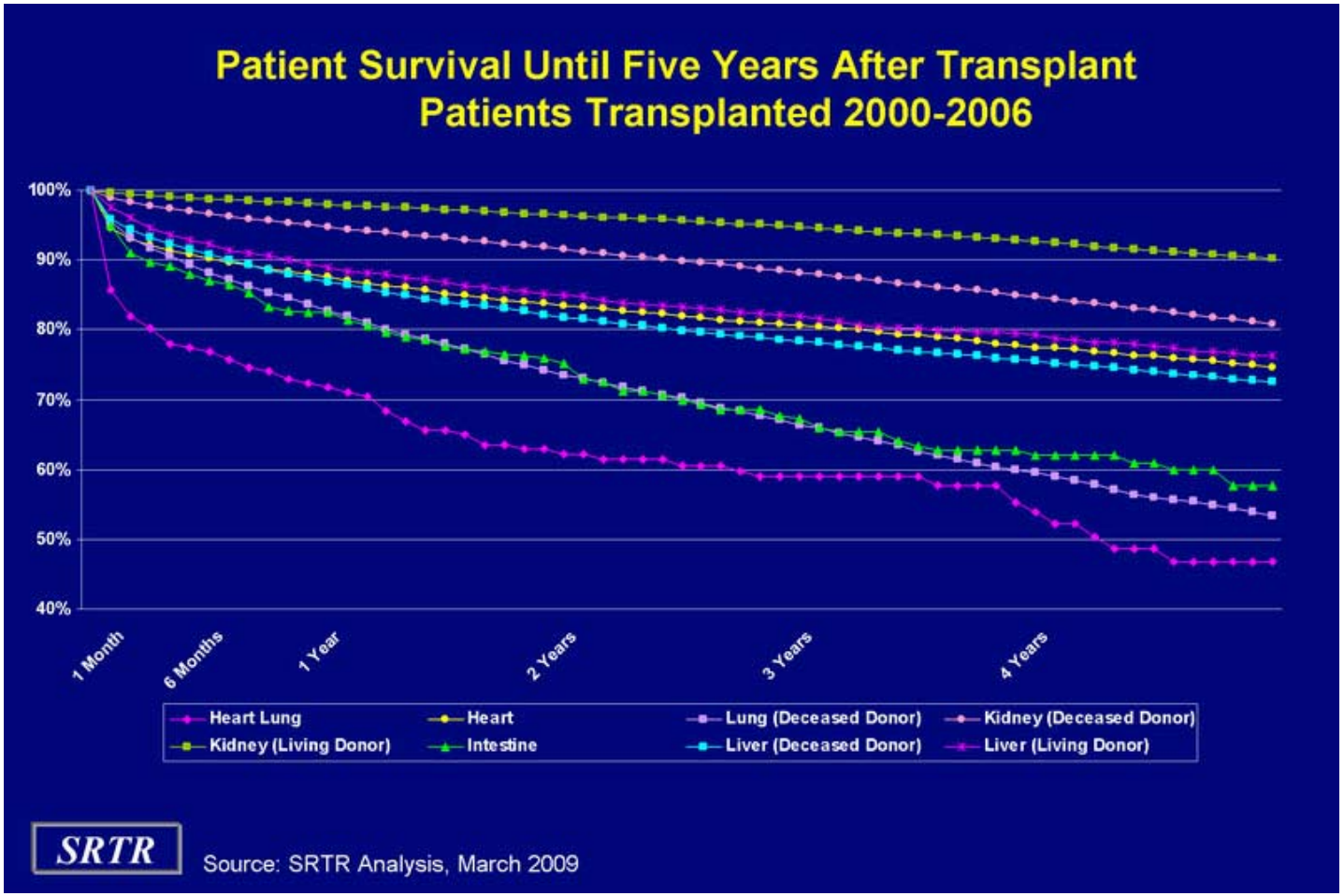

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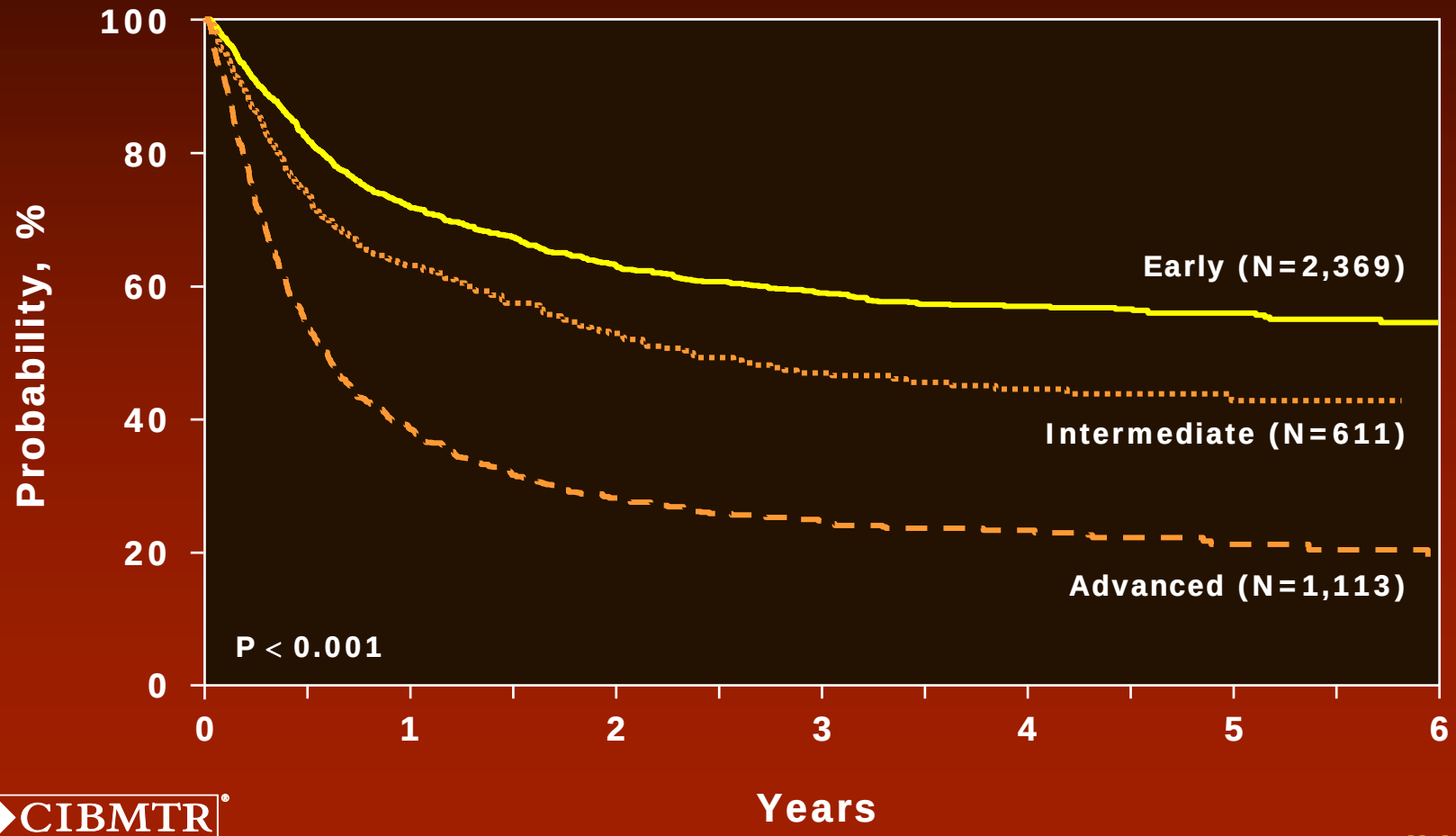
Probability of Survival after HLA-identical Sibling Transplants with Myeloablative Conditioning for AML, Age ≥20 Years, 1998-2004
- by Disease Status -



CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

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Limited Stem Cell Availability

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"Opportunity for life saving treatment with BMT is not limited by a finite number of available organs as with other transplants"

- **Currently over 25 patients at Karmanos are searching for donors for stem cell transplantation—No donors are found**
- **Numbers are not higher because patients die due to lack of donors**
- **GAO estimated that over 10,000 patients each year in the United States should receive an unrelated hematopoietic cell transplant but do not due to lack of donor availability.**
- **Increasing donor registry above current level of 11,000,000 not cost effective way to increase the number of patients who could be transplanted.**
- **To increase the number of transplants by 1% we would need to add 7,000,000 more donors to the registry.***

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Use of a needs based methodology to increase transplant units

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- **Depends on accurate estimation of patients who require transplant.**
- **Needs to take into account the age of patient performance status of the patient as well as underlying disease characteristic.**
- **Beaumont/St. John estimated based on a consultant what percentage of patients with a new diagnosis of cancer would require a transplant. They estimated that**

  "Beaumont Patients alone should generate Over 100 BMTs"

- **However, number of new cancer cases may not be accurate as most patients do not undergo transplant until they relapse or fail several therapies.**

  "This methodology could serve as a basis for institutional based methodology."

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Primary Site	MI Actual 2005*		Est. Total Transplants/disease /2005**	Beaumont Volume projection
Acute Myeloid Leukemia	455		103	227 (50%)
Myelodysplastic Syndrome	296		31	98 (33%)
Non-Hodgkin Lymphoma	2277		125	523 (23%)
Multiple Myeloma	642		113	321 (50%)
Total	3670		372	1169

*Source : Michigan Resident Cancer Incidence File. Includes cases diagnosed in 2004 - 2006 and processed by the Michigan Department of Community Health, Division for Vital Records and Health Statistics by December 29, 2008.

**Estimated total transplants based on KCI performance of 35% of total 438 Adult Transplants in MI in 2005 per the Annual Hospital Statistical Survey

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Using Beaumont Methodology how many patients would require a transplant in US

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Myeloma	20,000 new cases x 50%	=	10,000
ALL	5,760 new cases x 50%	=	2,800
NHL	65,000 new cases x 23%	=	15,000
Hodgkins	8,510 new cases x 9%	=	765
AML	12,810 new cases x 50%	=	6,400
CML	5,050 new cases x 10%	=	500

TOTAL TRANSPLANT in USA (Beaumont Method) 35,464

TOTAL TRANSPLANT in USA (2005) 15,000

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Needs Based Methodology

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- Changes in practice patterns affect needs for transplant
- Numbers fluctuate dramatically
- Examples Transplants/year Karmanos

			2009
Breast Cancer	152	to	1
CML	15	to	1
Myeloma	15	to	80

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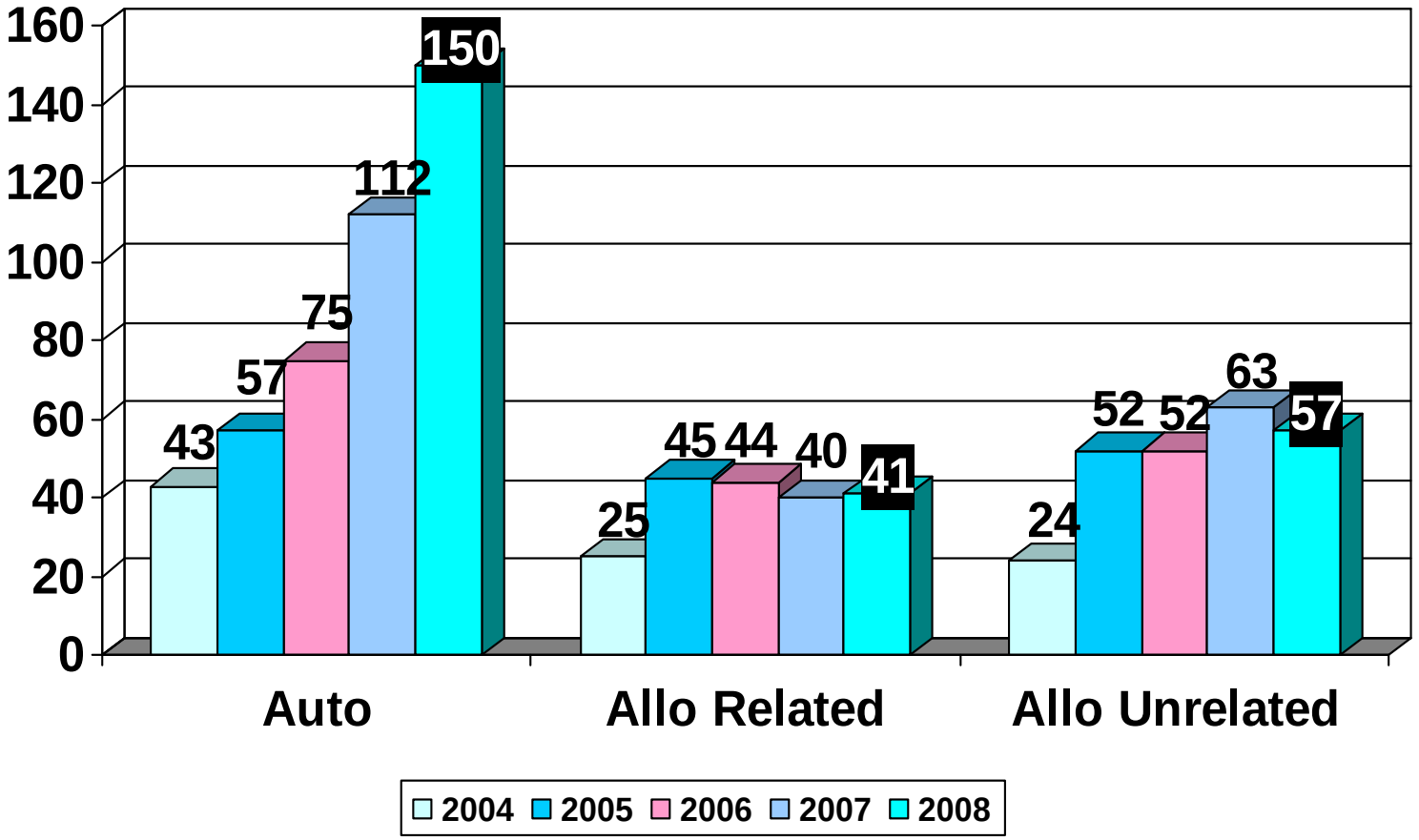
2008 is thru 12/31/08



Transplants by Disease (KCI & CHM)

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2004-2008

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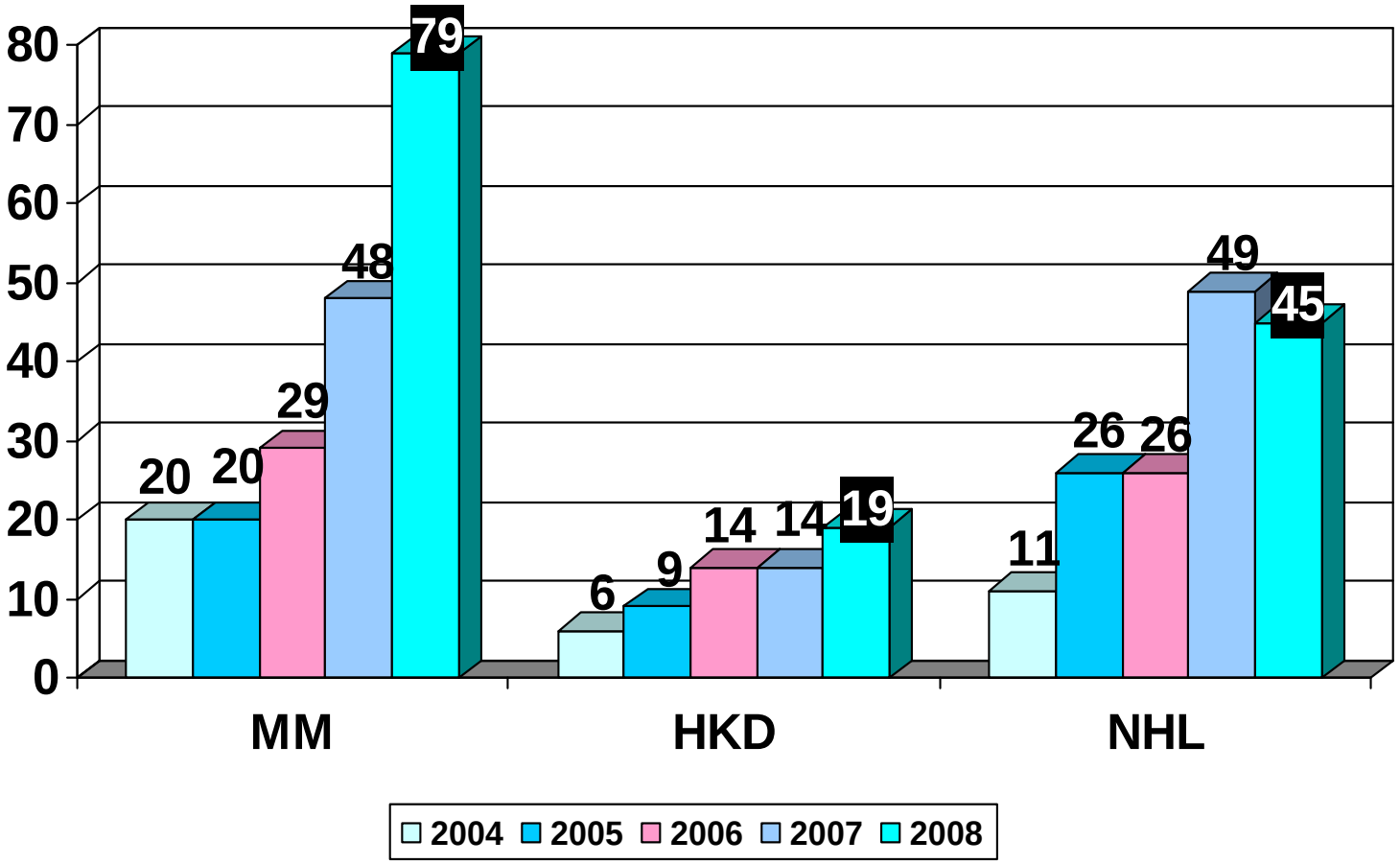

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Guidelines for the Treatment of Multiple Myeloma

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- Some believe the availability of newer agents with unique mechanisms of action may change the treatment algorithms for all patients with multiple myeloma.

- "To date, stem cell transplantation provides the best long term survival benefit. However, novel agents such as the IMiD's, bortezomib and pegylated doxorubicin have raised speculation that HDT for myeloma may become obsolete. "

[1] Siddiqui et al : The role of high dose chemotherapy followed by peripheral blood stem cell transplantation for the treatment of multiple myeloma. Leukemia & Lymphoma August 2008

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Quality

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- Needs based methodology has to ensure quality and patient safety

"No Correlation Between 1 Year Survival and Annual BMTs/Program"

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5 Studies have shown Correlation between Outcome Size/Experience of Programs

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• **Horowitz, et al Blood 1992**	**Procedure Volume**	**Significantly affected TRM and DFS**
• **Hows, et al BMT 1993**	**Procedure Volume**	**Significantly affected survival**
• **Frassoni, et al Lancet 2000**	**Procedure Volume**	**Significantly affected survival and transplant related mortality**
• **Matsuo, et al BMT 2000**	**Procedure Volume**	**Affected 100 day survival Disease free survival and survival**
• **Apperly, et al Blood 2000**	**Procedure Volume Center Experience**	**Correlated with overall Survival TRM**

Attachment B

Review: Transplant Center Characteristics and Clinical Outcomes After Hematopoietic Stem Cell Transplantation: What Do We Know, Loberiza, et al, Bone Marrow Transplantation 2003

- Studies on Center Experience and Volume on Outcome Suggest the Following:

1. Although a threshold for what is considered “high procedure volume’ has not been consistently defined, the relation between high volume and superior clinical outcomes is replicable.
2. Outcomes associated with center effect (mainly procedure volume) include TRM, treatment failure and survival but not relapse.

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Association of Transplant Center and Physician Factors on Mortality

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- Studies in <u>experienced well established transplant</u> centers have not shown an effect on volume and survival.

- Defined by median of <u>70 transplants/year and a median of 11 years of center experience</u>.

- "Appears that the greater involvement of properly trained physicians is associated with better early outcomes, particularly in the allogeneic HSCT and autologous HSCT for high-risk patients, and should be encouraged.

Lobrezia et al Blood 2005

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Quality

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- "Arbitrary" BMT standards have produced outstanding programs in Michigan

  - Highly skilled professionals with extensive training in BMT.
  - All programs have FACT Accreditation- x 3 cycles
  - Karmanos rated "Outstanding"
  - Insurance companies use our programs as Centers of Excellence:

    AETNA Blue Distinction Centers for Transplant, Cigna/Lifesource, Humana/HTN

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Years of Experience among Karmanos BMT Team

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Name	Role	Experience
Joseph Uberti, MD, PhD	Co-Director	22 years
Voravit Ratanatharathorn, MD	Co-Director	25 years
Lois Ayash, MD	Physician	20 years
Muneer Abidi, MD	Physician	8 years
Lawrence Lum, MD	Physician	27 years
Zaid AL-Kadhimi, MD	Physician	7 years
Anne Marie Campbell, BSN, RN, OCN	Coordinator	13 years
Stacey Prieur, BSN, RN	Coordinator	8 years
Amy Beck MSW	Clinical Social Worker	17 years
Cheryl Grey-Gilliard, MSW	Clinical Social Worker	2 years
Ann Zdilla-Dejonckheere	Patient Finance Mgr	18 years
Stephanie Bower, RN, CCRP	Manager	12 years
Alanna Kurosky R.N. ANP-BC	Nurse practitioner	20 years
Stephanie Mellon-Reppen RN MSN ACNP	Nurse practitioner	12 years
LaDonna Hinch, RD	Clinical Dietitian	6 years
TOTAL YEARS EXPERIENCE		**217 years**

Attachment B

Cost

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- Average Sized BMT Unit $1,300,000 start up and maintenance- Advisory Board March 10, 2009
- Equipment
  - Controlled rate cryopreservation systems
  - Liquid nitrogen freezers
  - HEPA filtered inpatient care areas
- Does not take into account training and experience of staff
  - Annual nursing/patient care expense of:
    - Allogeneic Patient Unit - $3,046,000
    - Autologous Patient Unit - $1,554,000
    - BMT Coordinators and NPP's - $2,580,000

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Access

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- Are transplants increasing in MI?
- 2001 498 transplants
- 2008 533 transplant
- 2007 536 transplants
- Over 8 years transplant numbers have gone up by 35 patients < 1% increase/year

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Access

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- No center has reported a bed shortage
- No referring center has reported lack of access to a transplant center
- No potential BMT candidate was denied service because of lack of capacity.
- No potential BMT candidate should have died because they weren't referred to an existing program.

Attachment B

Conclusions

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- Adding more BMT programs in Southeast Michigan would be like REARRANGING THE DECK CHAIRS:
  - Diluting the patient base among more hospitals, thereby increasing cost.
  - Diluting highly skilled personnel throughout the region, thereby harming quality.
  - Creating no appreciable improvements in access.

Attachment B

Conclusions

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- Eight Mile is NOT a geographical barrier.
- No Capacity issues
- Increase in transplant numbers due to myeloma but changes in treatment strategies may lesson the need for transplantation for this disease.

Attachment B

Conclusions

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- Level of experience of current transplantation programs makes it impossible to duplicate the quality of care now provided to patients in new programs.
- There is no duplication of expensive tests (despite claims to the contrary).
- Requirement for new services, equipment, and personnel will increase cost.
- The current BMT CON Standards meet the needs of patients in Southeast Michigan.

Attachment C

Proposed Language for BMT
For Discussion at July 29, 2009 BMT SAC

Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service

Sec. 3. (1) An applicant proposing to initiate a bone marrow transplantation service shall specify in the application whether the proposed service will perform either or both adult and pediatric bone marrow transplant procedures.

(2) An applicant shall specify the licensed hospital site at which the bone marrow transplantation service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.
(ix) neurology.
(x) oncology.
(xi) pathology, including blood banking experience.
(xii) pulmonary medicine.
(xiii) radiation oncology.
(xiv) radiology.
(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric bone marrow transplant procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.
(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed bone marrow transplantation service.

(5) (a) An applicant proposing to initiate an adult Bone Marrow Transplant (BMT) program shall project an operating level of at least 30 adult projected BMTs based on the methodology used in Section 6. ~~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.~~

(6) (a) An applicant proposing to initiate an adult bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate an adult bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

Attachment C

Proposed Language for BMT
For Discussion at July 29, 2009 BMT SAC

(c) An applicant proposing to initiate both an adult and a pediatric bone marrow transplantation service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed hospital site at which the proposed bone marrow transplantation service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in Children Oncology Group (COG)

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in bone marrow transplantation or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10) (a) An applicant proposing to initiate either a new adult or pediatric bone marrow transplantation service shall submit, in its application, a written consulting agreement with an existing bone marrow transplantation service, that meets each of the requirements in subsection (b).

(b) The written consulting agreement required by subsection (a) shall specify the term of the agreement and the roles and responsibilities of both the existing and proposed service, including at least the following:

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform bone marrow transplant procedures.

(ii) One or more representatives of the existing bone marrow transplantation service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.

(B) infection control.

(C) nutritional support.

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(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

(iv) Specify a schedule of site visits by staff of the existing bone marrow transplantation service that, at a minimum, includes:

(A) 6 visits during the first 12-months of operation of the proposed service.

(B) 4 visits during each the second 12-months and third 12-months of operation of the proposed service.

(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:

(A) a review of the number of patients transplanted.

(B) transplant outcomes.

(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.

(D) all deaths occurring within 100 days from transplant.

(E) each of the requirements of subdivision (iii).

(vi) Specify that a written report and minutes of each site visit shall be completed by the existing bone marrow transplantation service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).

(vii) Specify that the existing bone marrow transplantation service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.

(viii) Specify that the existing bone marrow transplantation service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.

(c) For purposes of subsection (10), "existing bone marrow transplantation service" means a service that meets all of the following:

(i) currently is performing and is Foundation for Accreditation of Cell Therapy (FACT) accredited in, the types of transplants (allogeneic or autologous; adult or pediatric) proposed to be performed by the applicant;

(ii) currently is certified as a National Marrow Donor Program; and

(iii) is located in the United States.

(d) An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c).

Attachment C

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Section 6. Documentation of projections

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(a) Retrieve from the tumor registry the number of adult cancer cases for Non-Hodgkin's (morphology codes M95903-M95913 and M96703-M97393), Hodgkin's (morphology codes M96503-M96673), Acute Lymphocytic Leukemia (morphology codes M98353-M98373), Acute Myelogenous Leukemia (morphology codes M98403-M98743 and M98913-M99203), Chronic Myelogenous Leukemia (morphology codes M98633, M98753-M98763 and M99453), Chronic Lymphocytic Leukemia (morphology codes M98233), Multiple Myeloma (morphology codes M97313-M97343), and Myelodysplastic Syndrome (morphology codes M99803-M99893) for the most recent report full-year of tumor registry data.

(b) Multipy the number of adult cancer cases recorded in subsection (6)(a) above by the estimated probability that a specific type of cancer will require a Bone Marrow Transplant.The estimated probabilities are as follows: Non-Hodgkin's (0.23), Hodgkin's (0.09), Acute Lymphocytic Leukemia (0.5), Acute Myelogenous Leukemia (0.5), Chronic Myelogenous Leukemia (0.1), Chronic Lymphocytic Leukemia , Multiple Myeloma (0.5), and Myelodysplastic Syndrome (0.33).

(c) Combine the results calculated in subsection (6) (b) above to determine the total number of projected adult BMTs.

~~Sec. 7. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.~~