

**MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES
BONE MARROW TRANSPLANTATION SERVICES
STANDARD ADVISORY COMMITTEE (BMTSAC) MEETING**

Thursday, May 12, 2016

Grand Tower Building
235 S. Grand Ave.
Lansing, Michigan 48933

APPROVED MINUTES

I. Call to Order and Introductions

Chairperson Carl called the meeting to order at 9:36 a.m.

A. Members Present:

Muneer Abidi, MD, Spectrum Health Hospitals
Adil Akhtar, MD, Beaumont Hospitals
Bruce Carl, MD, Chairperson, UAW Retiree Benefits Trust
Roland Chu, MD, Children's Hospital of Michigan
Joan Herbert, PharmD, MidMichigan Health
Feroze Momin, MD, Oakwood Hospital- Dearborn
Edward Peres, MD, Henry Ford Health Systems
Joseph Uberti, MD PhD, Barbara Ann Karmanos Cancer Institute
Michael Wiemann, MD, St. John Providence
Felicia Williams, MD, BCBSM/BCN
Gregory Yanik, MD, University of Michigan Health System

B. Members Absent:

Jennifer Barish, National Bone Marrow Transplant LINK

C. Department Staff Present:

Tulika Bhattacharya
Sallie Flanders
Amber Myers
Beth Nagel
Tania Rodriguez
Brenda Rogers

II. Declaration of Conflicts of Interests

None.

III. Review of Agenda

Motion by Dr. Herbert, seconded by Dr. Momin, to accept the agenda as presented. Motion Carried.

IV. Review of Minutes from March 10, 2016

Motion by Dr. Akhtar, seconded by Dr. Momin, to accept the minutes as presented.

V. Sub-committee Follow-up on Cost, Quality, and Access Charts for Charges 1, 2, and 3

Dr. Chu gave an overview (see Attachment A).

Discussion followed.

Motion by Dr. Herbert, seconded by Dr. Uberti, to accept the document as presented. Motion Carried.

VI. Methodology Sub-committee Update

Dr. Akhtar gave an overview of the methodology that he presented at the February 11, 2016 meeting (see Attachment B) along with additional data (see Attachment C).

Discussion followed.

Dr. Yanik gave a presentation for a new methodology to consider by the SAC (see Attachments D and E).

Discussion followed.

SAC recessed at 11:00 a.m and reconvened at 11:12 a.m.

Discussion continued.

Public Comment

Patrick O'Donovan, Beaumont Health System
Dennis McCafferty, Economic Alliance of Michigan (EAM)

Motion by Dr. Akhtar, seconded by Dr. Wiemann, to adopt a needs based methodology – a hybrid of the methodology presented by Dr. Akhtar and tier 3 of the methodology presented by Dr. Yanik. Motion Failed in a vote of 3 - Yes, 8 - No, and 0 - Abstained.

Motion by Dr. Williams, seconded by Dr. Uberti, to adopt the needs based methodology as presented by Dr. Yanik (see Attachment E). Motion Carried in a vote of 9 - Yes, 2 - No, and 0 - Abstained.

VII. Next Steps

Chairperson Carl will provide the final report of the BMTSAC to the CON Commission.

The Department stated that draft language will not be ready to present for proposed action at the June Commission meeting.

VIII. Public Comment

None.

IX. Adjournment

Motion by Dr. Akhtar, seconded by Dr. Momin, to adjourn the meeting at 11:55 a.m. Motion Carried.

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

CON REGULATION OF BMT SERVICES:**COST:**

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT regulated cost:

- 1) Regulating the number of programs, allows lower costs due to economy of scale of more patient volumes allowing facilities to bundle hospital and drug charges.
 - a. Opposing point of view states that there is no data to support that economy of scale lowers cost.
- 2) CON regulation of BMT services minimizes cost by limiting the expense of a BMT allogeneic program by preventing too many hospitals from starting BMT programs. These include:
 - a. BMT trained staff (physicians, nurses, stem cell lab personnel)
 - b. Facilities: renovation to meet BMT standards, HLA laboratory, Apheresis center, Stem cell processing lab. This includes the cost of implementing and maintaining these services.
 - c. Personnel to maintain quality standards: Clinical Nurse Specialist to maintain policies for FACT accreditation, data managers, BMT coordinators, social worker.
- 3) There are publications showing that CON regulated services have lower costs than states with no CON regulated services.
 - a. Opposing point of view states that there is no specific cost comparison data specific to BMT.
- 4) The complexity of BMT treatment is complex and high risk, higher mortality than standard chemotherapy. By regulating BMT services, cost is minimized due to having experienced staff (e.g. nurses, BMT dedicated physicians, subspecialists comfortable with BMT related complications) who can navigate the BMT issues and thus minimize waste due to inexperience.
 - a. Opposing point of view states that this argument can be made for all complex healthcare services, not just for BMT.
- 5) Deregulation will increase cost to the state and systems due to the cost of new programs and not having economy of scale to help with recouping cost.
 - a. Opposing point of view argues that de-regulation should increase competition which could lower costs.
 - i. This has worked on a business level, but has not always worked that way in healthcare.

These were the top factors that the SAC felt discontinuing CON regulation of allogeneic and autologous BMT services would NEGATIVELY impact cost:

- 1) The number of active clinical trials may reduce the need of BMT related services. These include the promising field of immune-based therapies for acute leukemias and multiple myeloma.
 - a. If the number of programs is not regulated, new BMT facilities (nursing, physicians, ancillary staff, lab and stem cell processing facilities) could be created

- with a potential for decreasing BMT needs, thereby wasting healthcare dollars that could be used for other needed services.
- b. Opposing point of view states that it is too early to know if these newer therapies will alter the need for BMT.
 - c. Opposing point of view argues that there is no data to support that states that do not regulate BMT have higher costs compared to CON states.
 - i. University of Michigan has data to show that BMT costs are lower than national average. Since majority of states are NOT CON regulated states, University of Michigan and Karmanos Cancer Center argue that CON regulation in MI has contributed to lower costs.
- 2) The cost of maintaining FACT (Foundation for Accreditation of Cellular Therapeutics) accreditation, cost of renovating and building infrastructure for BMT services, and personnel with BMT experience is not trivial. Without, the volume of BMT patients, this could be significant expenditure of health care dollars that can impact taking away health care dollars that can be spent on much needed services for the community.
 - 3) Compared to other BMT regulated services, the cost of BMT is low. BMT chemotherapy is no more costly (and sometimes less) than non-CON regulated cancer drugs.
 - 4) As the indications for BMT are small, there is less concern for potential for excessive utilization and thus cost can be managed without CON regulation.

Quality:

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT improved quality:

1. Data from the existing BMT centers show that state of MI provides high quality care. Outcomes exceed national averages.
 - a. It is felt that CON regulation has helped with maintaining high volumes and that is why state of MI outcomes exceed national averages.
 - b. There are publications that show that outcomes are directly proportional to volume of BMT patients.
 - c. Opposing point of view feels that non-regulated BMT states can also demonstrate high quality of care.
2. CON regulation helps maintain the proper volume of patients:
 - a. Volume of patients keeps all staff experienced with recognizing BMT complications. This is also important in not only the BMT staff, but all staff in the hospital who need to understand the complexity of BMT patients. This includes the other subspecialists who need to be experienced to care for BMT related complications. This improves the experience and familiarity of these treatments which translates to high quality of care.
 - i. Dissenting point of view argues that FACT only requires 10 transplants in allogeneic HSCT and 10 autologous HSCT to apply for accreditation?. State of MI CON requires 30 transplants.

Commented [HB1]: CON regulation maintains the volume by continuing to limit access.

1. Disagreement that a minimum level of these transplants will ensure high quality, that only doing small numbers will not ensure that people are familiar with BMT.
3. Transplant care is optimized if provided 24/7/365 by transplant trained providers.
 - a. There is a national shortage of transplant trained physicians.
 - i. This is an extra year of training, lack of trainees entering these training programs.
 1. Another new program will potentially cannibalize from existing programs to staff new HSCT center thus putting the stress on the existing program and jeopardizing the high quality that currently exists in the state of MI.
 - ii. Extending coverage with other hematology/oncology providers may not allow recognition of BMT complications in a timely manner.
 - iii. Opposing point of view states that many specialties have shortages and that it should not be considered in CON consideration of a new program as long as other requirements are met.
4. Volume of patient is also important to keep physicians and facilities experience in providing long term follow up care as more patients are surviving BMT.

These were the top factors the SAC felt discontinuing CON regulation of allogeneic and autologous BMT services could NEGATIVELY impact quality.

- 1) By diluting patient volumes, this could impact the quality of current outcomes demonstrated by the BMT programs compared to national averages.
 - a. Opposing point of view argues that opening 1-2 new programs will not put current programs on falling below 30 BMT patients (or whatever new minimum volume if set).
 - i. Disagreement in that volume is needed to see all types of complications in BMT on a REGULAR frequency. With small volumes, high risk complications will not be seen as frequently, and physicians and staff will lose familiarity since more time will lapse between rare or serious complications.
- 2) As FACT accreditation ensures the program has a process to maintain quality, some SAC members felt this has been what will maintain the quality of the BMT programs in the state of MI.
 - a. However, programs that have been through FACT has demonstrated that it does NOT take outcomes into account with maintaining accreditation
- 3) Discontinuing CON regulation and increase in the number of BMT programs will negative impact the experience and specialization of staff due to underutilization.
 - a. Opposing point of view states that we currently do not collect data to support this concern
 - i. Spectrum (Grand Rapids) opened a program and it did not adversely impact the numbers of the other Michigan BMT programs

- ii. However, discussion was raised that Grand Rapids is a completely different geographic area. There are currently 3 BMT programs that service southeastern MI all at 50% capacity, averaged.
- 4) By allowing other BMT programs, continuity of care will improve patient's experience as they will be familiar with the facility and ancillary staff.

ACCESS:

These were the top factors that the SAC felt CON regulation of allogeneic and autologous BMT improved access:

- 1) Access is determined by issues other than geographic distance.
 - a. Unable to identify a suitable HLA donor.
 - b. Lack of caregivers to support the patient through BMT
 - c. Economic pressures of unemployment due to medical leave.
 - d. Timely referral and evaluation of BMT eligibility.
 - i. Discussion if there really is an issue with timely referral as the BMT centers have stated that there is no wait for an initial consultation. This suggests that the delay may be on lack of education/awareness of referring physicians.
 - ii. Discussion if determination of BMT eligibility (I.e. sending blood in for HLA typing) is also delaying or impairing access.
 1. Some of what is needed is driven by insurance to determine BMT approval process (repeating of tests)
- 2) Adding programs to existing programs will not improve these access barriers.
 - a. Data was presented that when BMT program opened in western Michigan, more patients living in western MI received BMT, no decline in cases for SE Michigan, improving access.
 - i. Total number of cases appeared to grow in state of MI suggesting that patients on that side of the state who may have gone to Indianapolis, or Chicago are able to receive BMT in MI.
 - ii. Suggesting improved access
- 3) Comparing geographic access in Michigan compared to other states, distance to a BMT program in Michigan is comparable or better than most states in the US.
 - a. The CON process helped with opening a program in Grand Rapids to improve access on the West side of Michigan which was underserved. Those patients were driving to Southeastern Michigan or other states to receive BMT.

These were the top factors the SAC felt CON regulation of allogeneic and autologous BMT services had NEGATIVELY affected access:

- 1) Minority and lower socioeconomic status patients may be negatively impacted by CON regulation as these patients are required to travel for BMT services.
- 2) Excess capacity does not equate to equal access.
- 3) Large systems with large volumes of patients should not have to displace their patients from their primary area of residence and primary care teams

- 4) Despite articles showing that MI has better geographic access, National Marrow and Donor Program has published there are still unmet BMT needs, including Michigan.
- 5) BMT volumes continue to increase, thus CON regulation may not be needed as more patients could be transplanted if access was improved by allowing the opening of other BMT programs.

Maintenance of a Cap on BMT services:

Cost:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has maintained costs:

- 1) The Cap has allowed standardization of services therefore minimizing costs.
- 2) Cost of developing and maintaining a program is large
- 3) Healthcare costs per capita are highest in areas with duplicity of resources.
- 4) Regulation keeps cost low compared to non-CON regulated states.
 - a. Opposing point of view states that this is not specific to BMT services.
- 5) Limiting programs allow bundling of costs (including drug charges)
- 6) More facilities in health care has not shown lower costs to purchasers of health care.

These were the factors the SAC felt that maintaining the Cap NEGATIVELY impacts cost:

- 1) The Cap does not force current programs to examine costs and resources.
 - a. This is done locally at the system level as the hospital administration is what pays attention to the financial benefit of BMT services.
- 2) By removing the Cap, there is a concern that dilution of talent could lead to increase in personnel costs as programs compete to retain staff.
- 3) BMT costs in relation to total cancer care is LOW.
- 4) Free market forces should mean that more BMT facilities should increase competition a thus lower costs.

Quality:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has maintained quality:

- 1) All BMT centers are performing at high quality with better outcomes than the national average.
 - a. This is due to the CON Cap in the state of MI limiting BMT programs and thus having patients go to an experienced center.
 - i. Risk adjusted.
 - ii. Opposing point of view argues that there are non regulated states with just as good outcomes.
- 2) Experienced transplant physicians are limited, and thus increasing the number of BMT programs will dilute the number of experienced physicians.
- 3) Care is optimized by 24/7/365 coverage by transplant trained personnel at all levels.

These were the top factors the SAC felt that maintaining a Cap on BMT services has NEGATIVELY affected quality:

- 1) There is no reason to assume a new program would not also have high quality.
- 2) Removing the cap could entice more physicians to become transplant physicians
 - a. Financial incentive as non-academic centers traditionally pay more, some prefer a non-academic environment, more competition may increase financial incentive.
- 3) Having more programs could increase current BMT workforce.

Access:

These were the top factors that the SAC felt that maintaining a Cap on BMT services has affected access:

- 1) With 3 centers in SE Michigan, and Grand Rapids, the patients currently have options and get a second opinion.
- 2) Oncologists outside SE Michigan (Mid- and Northern MI) do not perceive a lack of access for current BMT services.
- 3) Current CON has maintained access by increasing the cap when lack of access is identified.
 - a. Opening a program in Grand Rapids to improve access in Western Michigan.
 - b. Opposing point of view is that the Cap has failed to recognize lack of access.
 - i. A Cap is not a methodology
 - c. There is no current methodology to assess when a new BMT center is needed in the state of MI

These were the factors the SAC felt that maintaining the Cap on BMT Services has NEGATIVELY impacted access.

- 1) There is no established methodology that can reliably and objectively look at access and when a new program is needed.
- 2) Cap limits access by needing, as patients may have to travel.
- 3) More centers will improve access
- 4) More centers will give consumers additional options.

BMT Need Methodology

BMT SAC

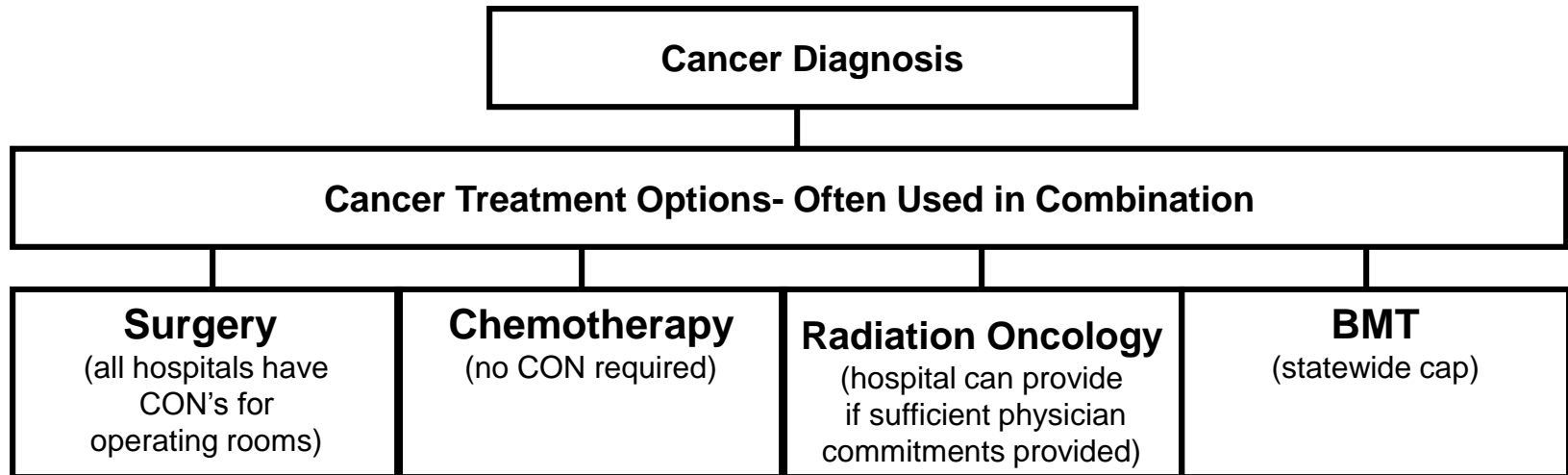
February 11, 2016

Overview

- SAC has voted to continue CON regulation of BMT (Charges 1 & 2)
- SAC must now recommend a CON need methodology for BMT (Charge 3)
 - Recommended methodology must take into account “consistency of CON approach” between BMT and other CON covered services (Charge 4)
 - CON trend in Michigan has been toward institution-specific methodologies (vs. caps)

BMT is the Only Cancer Treatment Option with Program Limit

Attachment B



Consistency of CON Approach to Need

PET*	based on	tumor registry cases
ESWL*	based on	urological discharges
Open heart	based on	cardiac discharges
Radiation oncology	based on	physician commitments
BMT	based on	cap

*Cap removed in favor of institution specific need methodology

Proposed BMT Methodology

- Starts with Statewide Tumor Registry Cases for cancers for patients age 20+ most often requiring BMT (sources: Michigan Cancer Surveillance Program; Centers for Disease Control & Prevention)
- Each “cancer category” is multiplied by a “factor” (percentage) of cases likely to result in BMT. For the “base year” (2012- most recently available statewide tumor registry data), the factor is calculated by dividing the total Statewide BMT cases (from the Michigan Inpatient Data Base) by the Statewide Tumor Registry Cases.
 - This need methodology is very conservative because it does not take into account unmet need- the total “need” for the State is simply the total number of BMT’s performed.

BMT Need Methodology

Calculation of Factors (2012)

(A) Diagnosis	(B) 2012 State Registry Cases*	(C) Factor (Estimated % receiving BMT)**	(D) 2012 Statewide Volume**
Non-Hodgkins	2197	5.5%	121
Hodgkins	238	11.7%	28
Acute Leukemia (ALL/ AML)	515	21.6%	111
Chronic Leukemia (CML)	178	4.5%	8
Multiple Myeloma	702	27.1%	191
Myelodysplastic Syndrome	519	6.2%	32
Other	<u>629</u>	3.6%	<u>23</u>
Total	4978	10.3%	514

* Source: Michigan Cancer Surveillance Program; Centers for Disease Control

** Source: Michigan Inpatient Data Base (totals match closely with CON Annual Survey totals)

*** Calculated Field (D/B)

Proposed BMT Methodology (continued)

- Applicants for a new BMT program demonstrate need by applying their institutional tumor registry cases by cancer category to the corresponding factor, and summing the results. If the summed results meet the (TBD) “threshold”, then the applicant would demonstrate need and could initiate a program.
 - Note: the FACT minimum volumes are 10*; the current BMT CON standard minimum volume is 30
- Applicants using their own tumor registry could combine their cases from other hospitals who agree to “commit” their cases to the applicant (consistent with other CON standards)
- Tumor registry cases at existing hospitals with a BMT program could not be used to support other applications
- Once tumor registry cases from a hospital are committed to an application, those tumor registry cases could not be used again as long as the new program is operational (consistent with other CON standards)
 - This provision limits the number of new programs that can be approved

BMT Need Methodology

Calculation of Factor, 2010-2012

(A) Diagnosis	2010 Factor (Estimated % receiving BMT)	2011 Factor (Estimated % receiving BMT)	2012 Factor (Estimated % receiving BMT)
Non-Hodgkins	4.9%	5.3%	5.5%
Hodgkins	14.5%	11.9%	11.7%
Acute Leukemia (ALL/ AML)	19.4%	21.6%	21.6%
Chronic Leukemia (CML)	2.7%	4.5%	4.5%
Multiple Myeloma	25.7%	26.3%	27.1%
Myelodysplastic Syndrome	2.9%	4.9%	6.2%
Other	6.9%	5.1%	3.6%
Total	9.8%	10.3%	10.3%

Conclusions

- Current cap approach is out of date and should be replaced with a rational, data based need methodology (Charges 3, 4)
 - BMT methodology presented is consistent with need methodologies for other CON covered services
 - Proposed next step is to request the Department to review, validate and make recommendations pertaining to this methodology
-

IMPACT OF INCREASED BMT ACCESS IN MICHIGAN

BMT Discharge Trend by Planning Area (Source: Michigan Inpatient Data Base)

	2010 Adult BMT Discharges	2011 Adult BMT Discharges	2012 Adult BMT Discharges	2013 Adult BMT Discharges	2014 Adult BMT Discharges	2015 Adult BMT Discharges***
East Side Programs*						
Planning Area 1 Residents (East)	392	395	396	420	440	459
Planning Area 2 Residents (West)	130	123	122	112	107	64
Total East Programs	522	518	518	532	547	523
West Side Programs**						
Planning Area 1 Residents (East)	0	0	0	0	2	1
Planning Area 2 Residents (West)	2	1	2	35	61	95
Total West Programs	2	1	2	35	63	96
All MI Programs						
Planning Area 1 Residents (East)	392	395	396	420	442	460
Planning Area 2 Residents (West)	132	124	124	147	168	159
Total All MI Programs	524	519	520	567	610	619

*Henry Ford, Karmanos, U-M

**Spectrum

***Annualized based on Jan-Sept. 2015

Need Based Methodology for BMT services in Michigan

G. Yanik MD
University of Michigan Medical Center

Needs Based Methodology

- **3-Tier Model. Basic Tenets:**
- The criteria should be a composite of national and statewide data. Not based upon an individual center's data.
- The need for BMT services is determined by more than geographic distance.
- The criteria should not be viewed as favorable to any one individual center.

Needs Based Methodology: 3 Tier Model

Metrics for evaluation:

Tier 1: Center Performance

Tier 2: Center Access

Tier 3: Center Volume
(For proposed centers)



Needs Based Methodology: Tier 1

Tier 1

- Assess Performance of Existing BMT Centers vs. National Standards.
- Determine the % of Transplants in MI for a Target Disorder, compared to National Average.
- Target Disorders: AML and Myeloma

Needs Based Methodology: Tier 1

Tier 1

Requires:

- **SEER data:** Total # cases in US (for that disorder).
- **CIBMTR data:** Total # BMT in US (for that disorder).
- **National BMT rate:** # BMT (CIBMTR) / SEER incidence.
- **Michigan BMT rate:** # BMT (MI) / Total # cases in MI.
- **Proposal for Tier 1:** If the state average is 5% less than national average, then proceed to Tier 2. (The metric must be met for both target disorders identified).

Needs Based Methodology: Tier 2

Tier 2

Access at existing BMT centers.

- **Two metrics:**
Time from Referral to Consult. < 28 days
Time from Referral to receipt HLA typing. < 14 days
- **Recommendation:**
Metric should be a composite of statewide data. Existing BMT centers should meet both metrics.
- If this metric is not met, then proceed to Tier 3.

Needs Based Methodology: Tier 3

Tier 3 Justification.

- Determine New Center's ability to support BMT.
- Examine a center's tumor registry. Determine the total number of cases by target disorder.
 - Apply correction factor (% BMT) from Tier 1.
 - Summate estimated number of BMT (for each target disorder)
 - Metric: If estimate > 50 BMT/year total, a center would meet that metric.

Need Based Methodology

- All 3 Tiers must be fulfilled for new center performance.
- Tier 1: Holds existing BMT centers accountable for performance of certain level of BMT. Will account for changing trends in BMT, both overall and for particular target diseases.
- Tier 2: Holds existing BMT centers accountable for access / availability.
- Tier 3: Creates cost-efficiency. Eliminates a duplicity of resources, by preventing the opening of multiple small BMT programs within the state.

Needs Based Methodology

- Two different proposals have been presented:

Dr. Akhtar / Beaumont

Center Volume

Dr. Yanik / UM

Performance

Access

Center Volume

Needs Based Methodology: 2 views

Dr. Akhtar / Beaumont

"Unmet Need"



How will building a program at Beaumont fill this perceived need.

Are we focusing on the wrong need

Dr. Yanik / UM

Existing BMT Services are Adequate

Access is Good

High Quality (Outcome)

Cost Efficient Care

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

2011 - Present

University of Michigan Volume has declined since 2013

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

2011 - Present

University of Michigan Volume has declined since 2013

Karmanos / DMC BMT volume remained constant

BMT Transplant Volume: 2011 - 2015

	2011	2012	2013	2014	2015	2016
MICH	225	212	239	222	192	170*
DMC	275	276	260	277	274	TBD
HFH	48	53	69	78	89	TBD

2011 - Present	
University of Michigan	Volume has declined since 2013
Karmanos / DMC	BMT volume remained constant
Henry Ford Hospital	BMT volume increased by 40 cases /yr.

BMT Transplant Volume: 2011 - 2015

- UM lost transplant volume, the loss primarily from the west side of the state.

BMT Volume	2000 - 2011	2012 - 2016
West MI	31%	< 10%

- Karmanos performed the same number of transplants, on a fewer number of patients, with the patients older in age (60 years).

Second Transplants (Graft Rejection) at Karmanos				
2011	2012	2013	2014	2015
19	26	35	30	31
22 per year		32 per year		

BMT Transplant Volume: 2011 - 2015

- Henry Ford increased their transplant volume. This growth led to an overall 12.3% growth in transplants in SE Michigan between 2011 - 2015.
- Does this mean there is an unmet need?

Not necessarily. Are we focusing on the wrong need

“Building more transplant programs may not be the answer. Improving awareness of referring physicians may fill a greater need.”

Improving Awareness for BMT services in the State of Michigan

Gregory Yanik
Jennifer Barish

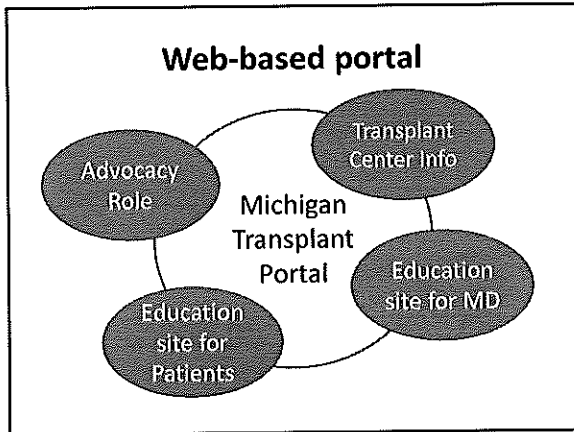
Improving Awareness

Improving Awareness:

- Of referring physicians.
- Of patients.
- Of transplant physicians.

Recommendation:

- “Establish Michigan Transplant Portal”
- Partnership of BMT centers, NBMT Link, non-BMT centers, Primary Insurers.



**Michigan Transplant Portal
Physician Information Site**

- **Web-Based Portal:** Would contain BMT site specific information for referring MD's.

BMT Site

Physician Contact:
RN Coordinator:
Clinic:
Social Work:
Financial Counsel:
HLA Instructions:

**Michigan Transplant Portal
Patient Site**

- **Patient portal. Include Site Specific:**
"Welcome videos". Directions, Parking, Location of BMT center. Contact information for key BMT personnel / Clinic / ER at each site.

**Michigan Transplant Portal
Education Site**

Referring
Physicians

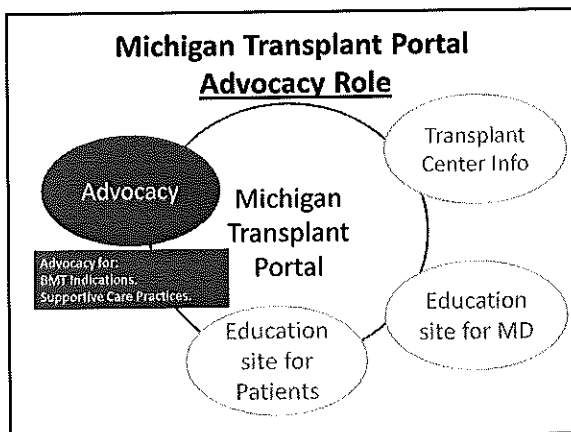
For Patients
Use NBMT Link

Clinical care resources / guides.

- Indications for BMT.
- Transplant Eval (by disease).
- Post-BMT Vaccination.
- Long Term Follow-Up.
- Post-BMT disease monitoring.

Patient Resources / Public's

- Frequently asked BMT?
- GVHD Guide
- Caregiver's Guide
- Survivorship Guide
- GVHD Phone Support Group.
- Peer Support On-Call Programs.



**Michigan Transplant Portal:
Conclusion**

- **There is a need to better educate physicians and patients. Regarding:**
 - Indications for BMT. Timeliness of referrals.
 - How to refer patients into the system.
 - Resources for patients.
 - Resources for physician caregivers.

Proposed Need Based Methodology



- **Three Tiers, in which:**
- **Current programs:** Must be held accountable.
- **New centers:** Must be able to justify their ability to support the service.
- **Must improve awareness** of patients and MD's.

Conclusions

- There is no unmet need for BMT centers in the state of MI
- Existing transplant centers are providing high quality care in an economically responsible manner
- Timely transplant referrals are required to improve the access of patients to BMT not more transplant centers.
- A 3-Tier model should be considered.

Extra slides

Intensity of Stem Cell Transplantation Compared to Organ Transplantation

	1 Year Mortality
Heart Transplantation	10-15%
Kidney Transplantation	4-8%
Lung Transplantation	22%
Liver Transplantation	17%
Allogeneic and Unrelated Stem Cell Transplantation	40-50%

BMT Transplant Volume: 2011 - 2015

- Karmanos performed the same number of transplants, on a fewer number of patients, with the patients increasingly older in age (median 60 years).

Transplants for patients > 65 years in age at Karmanos				
2011	2012	2013	2014	2015
66	61	44	70	93

Second Transplants (Graft Rejection) at Karmanos				
2011	2012	2013	2014	2015
19	26	35	30	31

22 per year

32 per year

Needs Based Methodology:

We recommend that the SAC consider a Needs Based Methodology dependent upon a 3-tier criteria.

The criteria should be based upon a composite of statewide transplant data, and not based upon an individual transplant program's data. The criteria cannot be viewed as favorable to one center.

Tier 1: Assess the PERFORMANCE of existing transplant centers versus national standards:

Determine the composite number of transplants in our state for a target disorder, when compared to the national average for that same disorder. The target disorders would be adult AML and multiple myeloma, the two leading indications for transplant in the US. (The target disorders could be changed in future years by the CON, depending upon national trends in bone marrow transplantation,)

This metric requires analysis of:

- a. SEER Data: Total number of cases for a target disease (AML, Multiple Myeloma) in US.
- b. CIBMTR Data: Total number of transplants for a target disease (AML, Multiple Myeloma) in US.
- c. National Average: # Transplants (AML or Myeloma) in US / Total number cases in US
- d. State of Michigan Average: # Transplants (AML or Myeloma) / Total number cases in state.
- e. If the state average is $\geq 5\%$ less than the national average, **THEN:**

Tier 2: Assess AVAILABILITY of transplant at existing centers:

The availability of transplant services would be assessed by two factors: 1) Time from referral to consult. 2) Time from referral to receipt of sample for HLA typing. We recommend that the median time from referral to consult be ≤ 28 days. We recommend that the time from referral to receipt of HLA typing should be ≤ 14 days. The metric should reflect a composite of statewide transplant data, not based upon individual center performance. If existing transplant centers are unable to meet both metrics (time to referral, time to receive sample for HLA typing), **THEN:**

Tier 3: For an individual center to apply for transplant services, that center be able to adequately SUPPORT transplant for a target disorder. This metric requires examining a center's institutional tumor registry, to determine the total number of cases of AML and multiple myeloma /year within that institution (3-year average). Apply the correction factor from Tier 1 to that center's case load. If the estimated transplants for "AML + myeloma" exceeds 50, then the CON would give consideration to that center to develop a transplant program. Using a threshold of 50 transplants provides an element of cost-efficiency, as the fixed costs of establishing a program would be justified by patient volume. This also limits the duplicity of resources, limiting multiple smaller programs from opening transplant programs.

The proposed methodology focuses on the PERFORMANCE (Tier 1) and AVAILABILITY (Tier 2) of existing transplant centers, coupled with a new institution's ability to adequately SUPPORT transplant for that disorder (Tier 3). All 3 criteria must be fulfilled for a new center to open a transplant program within our state.