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

Thursday, March 10, 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 Jennifer Barish, National Bone Marrow Transplant LINK (participated via phone) 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 (participated via phone) Gregory Yanik, MD, University of Michigan Health System

B. Members Absent:

None

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

#### IV. Review of Minutes from February 11, 2016

Motion by Dr. Uberti, seconded by Dr. Chu, to accept the minutes as presented.

#### V. Review of Cost, Quality, Access Charts for Charges 1, 2 and 3 Completed Via E-mail

Chairperson Carl gave an overview of the charts (see Attachment A).

Discussion followed.

A sub-committee was formed to make each bullet more explicit as necessary, determine column appropriateness, and decide how to revise the frame and format if needed. The sub-committee will consist of Dr. Chu, Dr. Akhtar, and Dr. Uberti.

#### VI. Follow-up on Methodology Reviewed by MDHHS

Chairperson Carl reviewed Dr. Delamater's paper (see Attachment B) on BMT methodologies.

Discussion followed.

#### VII. Review and Discussion of Charge 3

A. Dr. Akhtar gave a presentation (see Attachment C) of BMT data by planning area in 2012 and 2014.

Discussion followed.

The SAC recessed at 10:42 a.m. and reconvened at 10:58 a.m.

B. Dr. Yanik gave a presentation (see Attachment D) on a methodology proposal for a working group.

Discussion followed.

A sub-committee of the SAC was formed to begin work on a possible methodology for determining need for the SAC to consider at a future meeting. The sub-committee will consist of Dr. Williams (chairperson), Ms. Barrish, Chairperson Carl, Dr. Akhtar, and Dr. Yanik.

#### VIII. Next Steps

#### IX. Future Meeting Dates – April 7, 2016; May 12, 2016

#### X. Public Comment

David Newman, Economic Alliance for Michigan

#### XI. Adjournment

Motion by Dr. Akhtar, seconded by Dr. Momin, to adjourn the meeting at 12:09 p.m. Motion Carried.

#### How Does Continued CON Regulation of Allogeneic BMT Services Impact, Cost, Quality And Access either Positively or Negatively?

	Negatively?					
	Positively	VOTES	Negatively	VOTES		
	Standardization for implementing all required standards for facilities already approved and operating a program	8	Start-up costs associated with facility and personnel if new programs were to open	5		
	Continuity of care - product at the center already if the patient relapses	5	FACT Accreditation	6		
	Reports showing that CON states have lower BMT costs	7	Maintenance costs for maintaining current program	2		
	No proliferation will occur if BMT cap is removed	3	Change in the field for immuno-based therapies and trials	8		
Cost	Large volume facilities can bundle hospital and drug charges	9	Compared to other CON services the amount spent on BMT is very low	3		
ပိ	Complexity of treatment	7	7 BMT is often no more costly than non-CON regulated chemotherapy drugs.			
	Donor issues	4	Testing is often repeated when patients are referred from one center to another BMT			
	Cost of developing and maintaining an HLA lab and molecular diagnostic	6	No potential for excessive utilization	2		
	More programs will increase costs to consumers	3				
	Transplant related costs will increase if BMT is deregulated due to outbidding of state and capital costs of new programs	6				
	Positively	VOTES	Negatively	VOTES		
	Continuity of care will be maintained	6	Specialization and ancillary staff would become under utilized	4		
	Continuing education of staff	5	More trained personnel in the field	2		
	Keeping up with the standards as well as the indications of transplant	5	BMT outcomes are not impacted by CON regulations	3		
	Specialized physicians and ancillary staff	7	No correlation between on year survival rates and the BMT volume of the program	2		
	Existing centers provide high quality care	10	BMT quality is being monitored by FACT	5		
>	Transplant care is optimized if provided 24/7/362 by a transplant trained provider	7	Stem cell therapies will be tried in non-cancer indications, limited programs will limit research	4		
Quality	Volume of transplant patients improves treatment of patients and improves the knowledge and practice of treatments	6	Michigan BMT programs have better than national average outcomes	8		
ď	Outcomes of trials have proven that BMT volume does matter	6	FACT Accreditation is not a means of licensing and does not recognize outcomes	4		
	There is a shift in healthcare teams regardless if its from within the same facility	2	Poor patient selection and unnecessary fixed costs to purchasers in non-CON covered states			
	In addition to competent BMT staff, a program requires access to specialized consultative services that are familiar with BMT related complications	7	Non-BMT intense cancer treatments are being done in other healthcare systems, so why not BMT?	2		
	As more BMT patients are alive, long term follow up care provided by the BMT team along with the community physicians is extremely important	7				

How Does Continued CON Regulation of Allogeneic BMT Services Impact, Cost, Quality And Access either Positively or Negatively?

	Positively	VOTES	Negatively	VOTES
	No issue with access and capacity is in fact, underutilized, including southeast and northern Michigan	5	Hard to quantitate access	1
	Adding new centers will not improve access	5	Patient preference	4
	Access is determined by issues other than center location including socio-economic and other demographic factors	8	Excess capacity does not equal access	4
S	Patients do not want convenient care, they want optimal care	6	Unmet need for BMT	3
Acces	Adding programs will not address the barriers already affecting access	7	Volume of the transplant continues to increase	4
Ac	Patient has to spend more time at the center after they undergo the transplant	1	Timely referral of patients for transplant, especially minority populations who continue to be under served	5
	Geographic access in Michigan is better than most states in the U.S.	7	Patients are looking for convenience of care with optimal care	3
			Large healthcare systems with large patient volume should not have to displace their patients from their primary are of residence and primary care teams	4

How Does Continued CON Regulation of Autologous BMT Services Impact, Cost, Quality And Access either Positively or Negatively?

	Negatively?				
	Positively	VOTES	Negatively	VOTES	
	Standardization for implementing all required standards for facilities already approved and operating a program	6	Start-up costs, facility and personnel	3	
	Continuity of care - product at the center already if the patient relapses	4 FACT Accreditation		2	
	Reports show that CON states have lower BMT costs	6 Maintenance costs for maintaining current program		1	
Cost	No proliferation will occur if BMT cap is removed	3	Changing in the field for immuno-based therapies and trials		
ö	Large facilities can bundle hospital and drug charges	6	Compared to other CON services the amount spent on BMT is very low	2	
			BMT is often no more costlier than non-CON related chemotherapy drugs		
			Testing is often repeated when patients are referred from one center to another for BMT	3	
			No potential for excessive utilization	1	
	Positively	VOTES	Negatively	VOTES	
	Continuity of Care	4	Specialization and ancillary staff would become under utilized	3	
	Continuing education of staff	5	More trained personnel in the field	1	
	Keeping up with the standards as well as the indications of transplant	4	4 BMT outcomes are not impacted by CON regulations		
	Specialized physicians and ancillary staff	7	7 No correlation between one year survival rates and the BMT volume of the program		
Ţ	Existing centers provide high quality care	8	BMT quality is being monitored by FACT		
Quality	Transplant care is optimized if provided 24/7/365 by a transplant trained personnel	6 Stem cell therapies will be tried in non-cancer indications, limiting programs will limit research		2	
	Volume of transplant patient improves treatment of patients and improves the knowledge and practice of treatment	Michigan BMT programs have better than national average outcomes		3	
	Outcomes of trials have proven that BMT volume does not matter	3	FACT accreditation is not a means of licensing and does not recognize outcomes	1	
			Poor patient selection and unnecessary fixed costs to		

#### How Does Continued CON Regulation of Autologous BMT Services Impact, Cost, Quality And Access either Positively or

Negatively?							

	Positively	VOTES	Negatively	VOTES
	No issues with access and capacity is in fact under utilized including southeast and northern Michigan	6	Hard to quantitate access	2
	Adding new centers will not improve access	6	Patient preference	5
SS	Access is determined by issues other than center location including socio-economic and other demographic factors	8	Excess capacity does not equal access	2
Acce	Patients don't want convenient care - they want optimal care	7	Unmet need for BMT	2
	Adding programs will not address the barriers already affecting access	7	Volume of BMT continues to increase	3
			Timely referral of patients for transplant, especially minority populations who continue to be underserved	3

	Positively	VOTES	Negatively	VOTES
	Standardized services	9	More competition means lower costs	2
	regulation of costs across programs - bundling of charges	6	Cost in relation to total cancer care is low	
	Regulation keeps cost low among other states	6	6 Promotes monopoly of programs - anti-competitive	
ب	Large volume programs have the ability to bundle pharmacy and other program components	6 CON does not impact cost of service		2
Cost	Cost of developing and maintaining programs is large	7 Dilution of talent leads to increase in personnel costs		4
U	Healthcare costs per capita are highest in areas with duplicity of resources	6 Animosity between systems		2
			More facilities does not lead to lower costs for purchasers	
			Cap does not force current programs to examine costs, resources	5
	Positively	VOTES	Negatively	VOTES
	CON regulation has improved the quality of current transplant programs compared to national programs	6	More trained personnel from current pool of personnel would be able to train better quality personnel	2
	Management of post-transplant care would be highly specialized	2	Increase of current BMT workforce	
>	All current centers are performing at high quality	9	No relationship between program size and outcomes	2
Quality	Care is optimized by 24/7/365 by transplant trained personnel at all levels; transplant physicians, nursing staff, supporting specialists and ancillary staff	No conclusive study showing better outcomes in MI programs are a direct result of CON regulations		2
σ	Programs that have been established have higher quality and are experienced	5	5 No reason to assume a new program would not also have high quality	
	Experienced transplant physicians are limited; increasing # of programs dilutes number of experienced physicians	7	Removing cap could entice more physicians to become transplant physicians	2
	Positively	VOTES	Negatively	VOTES
	CON does not affect access	2	More centers will improve access	2
S	Current CON regulation has maintained access	6	More centers will give consumer additional options; allow for second opinions	3
Access	Access is not an issue for oncologists out-state/outside SE MI	5	More centers would provide greater access of transplant services	2
ACC	Patients currently have options and can get a second opinion	7 A methodology would give an objective ability to look at access		6

How Does Maintaining a Cap on BMT Services Impact Cost, Quality, and Access either Positively or Negatively?

#### Bone Marrow Transplantation: Review of Need Methodology

March 8, 2016

Paul L. Delamater  $^{*,a}$  and Ashton M. Shortridge  $^{b}$ 

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#### **General Observations**

Bone Marrow Transplantation (BMT) is an extremely specialized service. According to the CON Annual Survey, only 633 adult (Age 21+) BMTs were performed in Michigan in 2014 on an adult population of more than 7 million. As a result, applying the need methodologies from other CON-regulated services (especially those for equipment, e.g., PET) may not be appropriate for BMT. Further, many of the other CON-regulated services' need methodologies contain either implicit or explicit assumptions regarding the regional or local "geography" of service utilization and/or need. Given the small total number of statewide BMTs each year, assessing regional variation may present difficulties due to small numbers and unstable rates.

- We note that the other transplantation services regulated by CON, Heart/Lung and Liver (HLL) Transplantation, also contain a provision to cap the number of services in Michigan. The HLL Standards cap the number of services at 3 for the entire state.
  - Implementing a hard cap as a means to regulate the supply of services is not an especially appealing approach. It is certainly not data-driven. However, the caps that are currently in place for both regulated transplantation services (BMT and HLL) may be a result of the complexity of the services themselves, signaling limited confidence in the ability to accurately predict unmet need for these highly-specialized services.

Given our past experience with CON, we believe population-based need methodologies are generally preferable over facility-based or facility-specific methodologies. Population-based need methodologies (those calculated for the entire state) provide all stakeholders (as well as the CON Commission and MDHHS CON Program) with an opportunity to assess the potential regional or local variations in utilization and/or unmet need across the state.

• However, population-based need methodologies can be much more difficult and time-consuming to develop (and implement), as they often require multiple data sources and broad-scale modeling assumptions about trends in service utilization or changes in the underlying population. When developing a population-based need methodology, finding an agreement on the model "assumptions" can be the most difficult part of this process, as it requires service-specific experts (representing all stakeholders) to work in tandem to develop an acceptable data-driven approach.

- Besse et al. (2015) provide an example of a population-based methodology to predict unmet need for BMT services. Although their approach is a generalized method applied to large service areas across the US, the authors do offer a basic blueprint for what this type of approach may potentially look like (with the important caveat that any methodology would have to be modified and specialized for BMT services in Michigan).
  - If georeferenced tumor registry data and cancer incidence data were made available for small areal units for the entire state (e.g., counties or zip codes), we believe that this information could be integrated with BMT MIDB utilization data and population (sociodemographic, e.g., age, gender, race/ethnicity, health insurance) data to develop a statewide predictive model of BMT need. The predicted BMT need data could be compared to the BMT utilization data and would represent an "expected vs. actual" approach to identifying unmet need.
  - An alternate approach would be to identify a proxy variable that signals a missed opportunity for BMT and can thus be used to estimate unmet need for this service. The proxy must be a non-BMT treatment mode (or a specific service use) that functions as an alternative to BMT, when BMT is the most appropriate treatment for the patient, but not utilized due to a lack of accessibility or availability. In this approach, the non-BMT treatment essentially functions as the proxy variable for unmet BMT need. This is the fundamental approach in the UESWL (lithotripsy) Standards, where an inpatient hospitalization for a kidney stone signals a missed opportunity for lithotripsy.

Geographic access to BMT does not appear to be lacking in Michigan when the state is compared to other states in the US (see the 2013 BMT report and Delamater and Uberti, 2016). However, for BMT, limited geographic access to services is likely trumped in importance by limited availability (population demand vs. facility supply) of services. However, one issue with BMT that causes difficulties in understanding availability is the lack of an easily quantifiable measure of the "supply" available. For other regulated services, such as acute care hospitals, the number of beds available at a particular location provides a relatively straightforward measure of the facility supply, thus occupancy rates (utilization/beds) can be used to understand if population demand is stressing the available supply of services (and thus potentially signaling potential unmet need). We are unaware of any such measure that can be used to evaluate BMT services.

From our understanding of the recent scientific literature, unmet need for BMT services is not (and will not be in the future) driven simply by a lack of facilities providing BMT, but by a lack the appropriate human resources and infrastructure necessary to provide BMT services (see Mahail et al., 2012). Hence, BMT service provision may be considered a zero-sum game, such that an increase in capacity in one place can only be gained via a decrease in capacity in another place.

#### Proposed Methodology (Dr. Akhtar)

We have reviewed the methodology provided by Dr. Akhtar (Powerpoint file) and the transcript from the BMT SAC meeting on February 11, 2016. We believe that the proposed methodology would not demonstrate need for BMT services as presented. Our most serious concern is that the methodology appears to only offer a mechanism to "transfer" BMT demand from existing BMT programs to proposed, new programs.

We present an example below to illustrate our concern. Although the example is extremely simplified, we believe that it accurately captures the fundamental approach underlying the proposed methodology. In the example, we consider BMT demand in a hypothetical state for one year. We consider a single type of cancer tumor and two hospitals in our state. In the example, only one hospital provides BMT services.

- Hospital 1 provides BMT services and Hospital 2 does not provide BMT services
  - Hospital 1 performed 10 BMTs for cancer tumors (all statewide BMTs were performed here)
- The total number of new tumor cases in the statewide registry was 50
  - 25 tumor registry cases were reported by each hospital
- To calculate the BMT factor, the proposed methodology would divide the 10 statewide BMTs by the 50 statewide tumor registry cases, reporting that 20% of all tumor cases resulted in a BMT
  - Hospital 2 could then multiply their 25 tumor registry cases by 0.2 (for 20%) and report that their new BMT service could generate 5 BMTs
  - However, the overall statewide demand would remain at 10 BMTs and the 5 BMTs at Hospital
    2 would not represent a new or unmet demand for BMT services, but simply existing demand
    transferred from Hospital 1 to Hospital 2

We also express concerns over the lack of any "geography" in the proposed methodology. Importantly, the methodology does not consider whether BMT services are already available in the region of a proposed new facility, thus does not consider the existing supply of BMT services or the potential for duplication of services. A geographic component could potentially be added to the proposed methodology, possibly constraining the region(s) from which the cancer tumor registry cases could be drawn when applying for a new BMT service. However, even if a geographic constraint were to be added, this approach would not rectify the underlying "transfer" mechanism in the methodology.

A final concern in the proposed methodology is the use of tumor registry cases without incorporating the complex set of patient factors that are considered when determining whether BMT is an appropriate treatment option. For example, the age of the BMT patients are not considered in either the factor calculation or the need methodology. At this time, we do not have a specific recommendation to alleviate this concern, but the straightforward use of the cancer tumor registry data appears to oversimplify the potential need for BMT services.

#### References

Besse, K. L., Preussler, J. M., Murphy, E. A., Denzen, E. M., Lill, M. C., Chell, J. W., ... Williams, E. P. (2015). Estimating Demand and Unmet Need for Allogeneic Hematopoietic Cell Transplantation in the United States Using Geographic Information Systems. Journal of Oncology Practice, 11(2), e120–e130. http://doi.org/10.1200/JOP.2014.000794

Delamater, P. L., & Uberti, J. P. (2016). Geographic access to hematopoietic cell transplantation services in the United States. Bone Marrow Transplantation, 51(2), 241?248. http://doi.org/10.1038/bmt.2015.246

Majhail, N. S., Murphy, E. A., Denzen, E. M., Ferguson, S. S., Anasetti, C., Bracey, A., ... Snyder, E. L. (2012). The National Marrow Donor Program's Symposium on Hematopoietic Cell Transplantation in 2020: A Health Care Resource and Infrastructure Assessment. Biology of Blood and Marrow Transplantation, 18(2), 172–182. http://doi.org/10.1016/j.bbmt.2011.10.004

#### IMPACT OF INCREASED BMT ACCESS IN MICHIGAN

Peer reviewed journal articles have shown that BMT is an underutilized treatment and that there is unmet need across the country. There are various potential reasons for this, including availability of programs, education and outreach, socioeconomic factors, etc. There has also been debate as to whether as to whether new BMT programs could mitigate some of this unmet need. In Michigan, this can be evaluated by looking at the impact of Spectrum Health's adult BMT program that was initiated in 2013.

The current CON standards for BMT divide the State of Michigan into two Planning Areas. Planning Area 1 is the essentially the east side of the state including Southeast Michigan, and Planning Area 2 is the west side of the state which includes Grand Rapids where the Spectrum adult program began in 2013.\*

The data below shows that between 2012 (before the Spectrum program was firmly established) and 2014 (after the Spectrum program was established), the number of BMT discharges for residents living in Planning Area 2 increased 38.4%, while BMT discharges for Planning Area 1 increased only 9.6%. This is a fourfold difference between the two Planning Areas. This cannot be explained by patients from Planning Area 2 who previously went out of state, to receive BMT, since the number out-of-state transplants performed on people living in Planning Area 2 actually increased between 2012 and 2014.

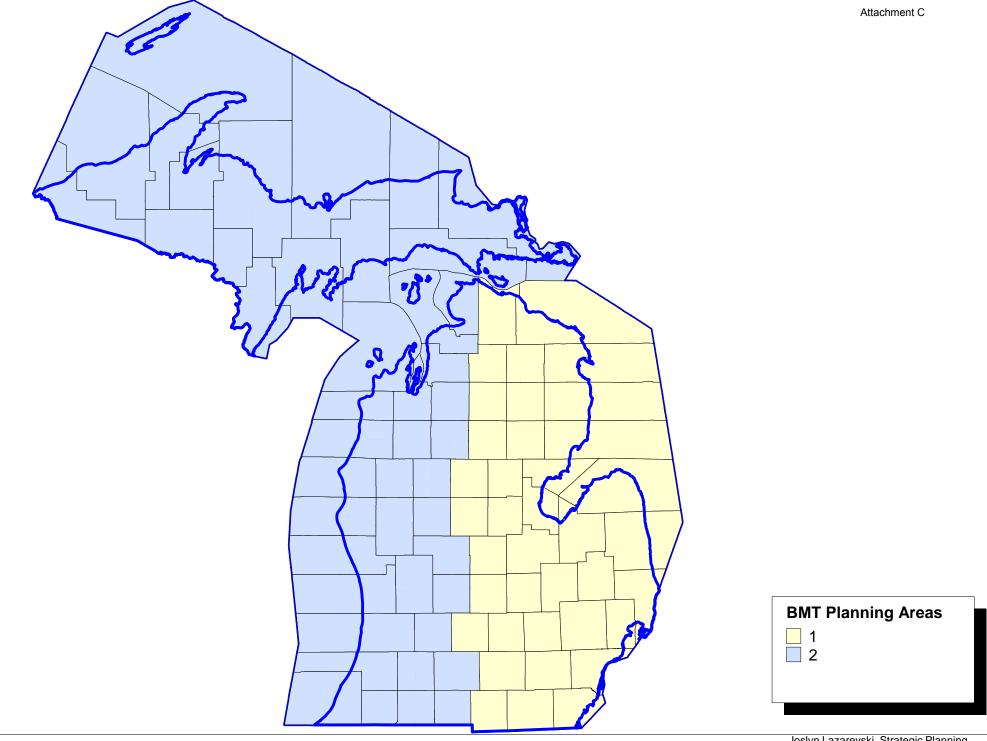
	2012 Adult BMT Discharges**	2014 Adult BMT Discharges**	# Change	% Change
Planning Area 1 Residents (East)	415	455	40	9.6%
Planning Area 2 Residents (West)	138	191	53	38.4%

#### **BMT Discharge Trend by Planning Area**

Importantly, the addition of a new adult BMT program did not result in a collective decrease in BMT cases in the three existing programs- in fact these programs collectively increased by 6.8% between 2012 and 2014. (source: MDHHS).

\*The Spectrum adult BMT C.O.N. was approved in 2010, but in 2010-2012 the program performed 2 or less cases per year. Source: MDHHS

\*\*Source: Michigan Inpatient Database (MIDB)



Joslyn Lazarevski, Strategic Planning h:\maps\BMT Planning Areas.wor

## Needs Based Methodology Proposal Bone Marrow Transplant Services

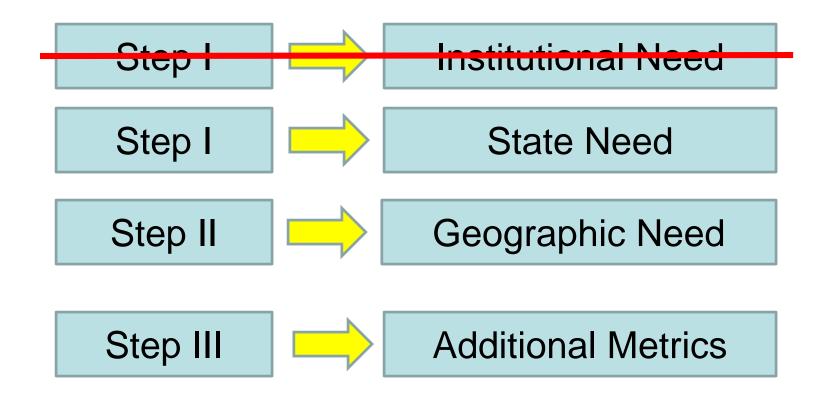
Gregory Yanik MD University of Michigan Medical Center Joseph Uberti MD Karmanos Cancer Center

# **Needs Based Methodology**

- Cannot be based solely upon incidence.
  - Easy to overestimate the need for a given procedure.
  - Diagnosis is only one part of overall evaluation of patients going to transplant.
- Methodology should take into account:
  - Co-morbidities/Disease status. Donor availability.
  - Geographic Access: To existing BMT centers. Duplicity of resources. Cost efficiency if close proximity.
  - Patient Willingness: Family resources / Socioeconomics.
- Must estimate BMT needs nationally (SEER, CIBMTR).
- Must consider trends in BMT practice.
- Must be equitable. Cannot be center specific.

# **Needs Based Methodology**

## **Potential Stepwise Option:**



# **Needs Based Methodology**

- **BMT Volume**: <u>Being able to justify a minimum</u> <u>transplant volume at your center does not establish a need</u>.
- The ability for a center to meet FACT standards (10/year) does not establish a need. The ability for a center to meet "prior" CON statement (30/year) does not establish a need.
- Should we consider Geographic Access.
  What is the reasonable distance to travel for BMT services.
  For example:

In SE Michigan: 30 miles? Outstate: 60 miles? <u>Neither</u>.

- Access is not defined by distance.
- Centers will use any distance metric to their advantage

# **Issues for Consideration**

## Should BMT Metrics be established to examine:

- **1. Availability?** Are current centers providing adequate access. Consider "Time to Referral" as possible metric.
- 2. Quality / Outcome: Risk adapted survival? 1-year?
- **3. Cost efficiency**?

For new centers: Infrastructure? Personnel? Training? For existing centers: Billable charges? Nat'l comparators?

Response: Each of these metrics has issues. Each need exact definitions. They may not be equally weighted, especially in terms of establishing need. Thus:

## Recommendation

- Organize focused "Working-Group"
- Small group. Not necessarily SAC based.
- Must Have Broad Based Representation:
  From 1 (or more) health care providers.
  From 1 (or more) health care utilizers.
  From a non-BMT center (Beaumont or St. John's)
  From an active BMT center (UM, DMC, HFH, Spectrum)
- The health care provider or utilizer cannot have an affiliation with an existing BMT or non-BMT center.

# **Working-Group: Primary Objective**

## To develop a "Consensus" Needs Based Methodology:

The committee should consider:

- a. Is there a state-wide volume estimate that warrants consideration of another program.
- b. If a volume estimate suggests the potential need, how should geographic location / access be considered?
- c. Should metrics to assess BMT services be examined? Considering availability, quality, and cost metrics.

### **Outcome: Must be equitable.** <u>Not center specific</u>.

## Working Group: Secondary Objective

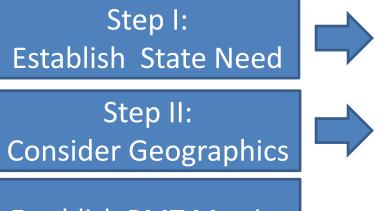
## **Goal: Improve Patient Care: Work-Flow. Education.**

- Develop strategies for optimizing transitions between referring and BMT centers.
  - a. For primary referral.
  - b. For post-transplant care.

c. To develop patient care guidelines for referring oncologists and primary care-givers, thereby increasing their care capabilities, and ultimately allowing less dependence on primary BMT center.

• Should this be a primary objective.

# **Methodology Model: Summary**



Population based. SEER and CIBMTR data.

Must be reasonable. For Patients. State. Cost efficient. Prevent Duplicity of services.

Establish BMT Metrics

### For:

- Availability/Timeliness
- Outcome analysis
- Cost efficiency

### Should we focus on:

- Transitions-in-Care between centers.
- Education: Referring MD / Caregivers.

