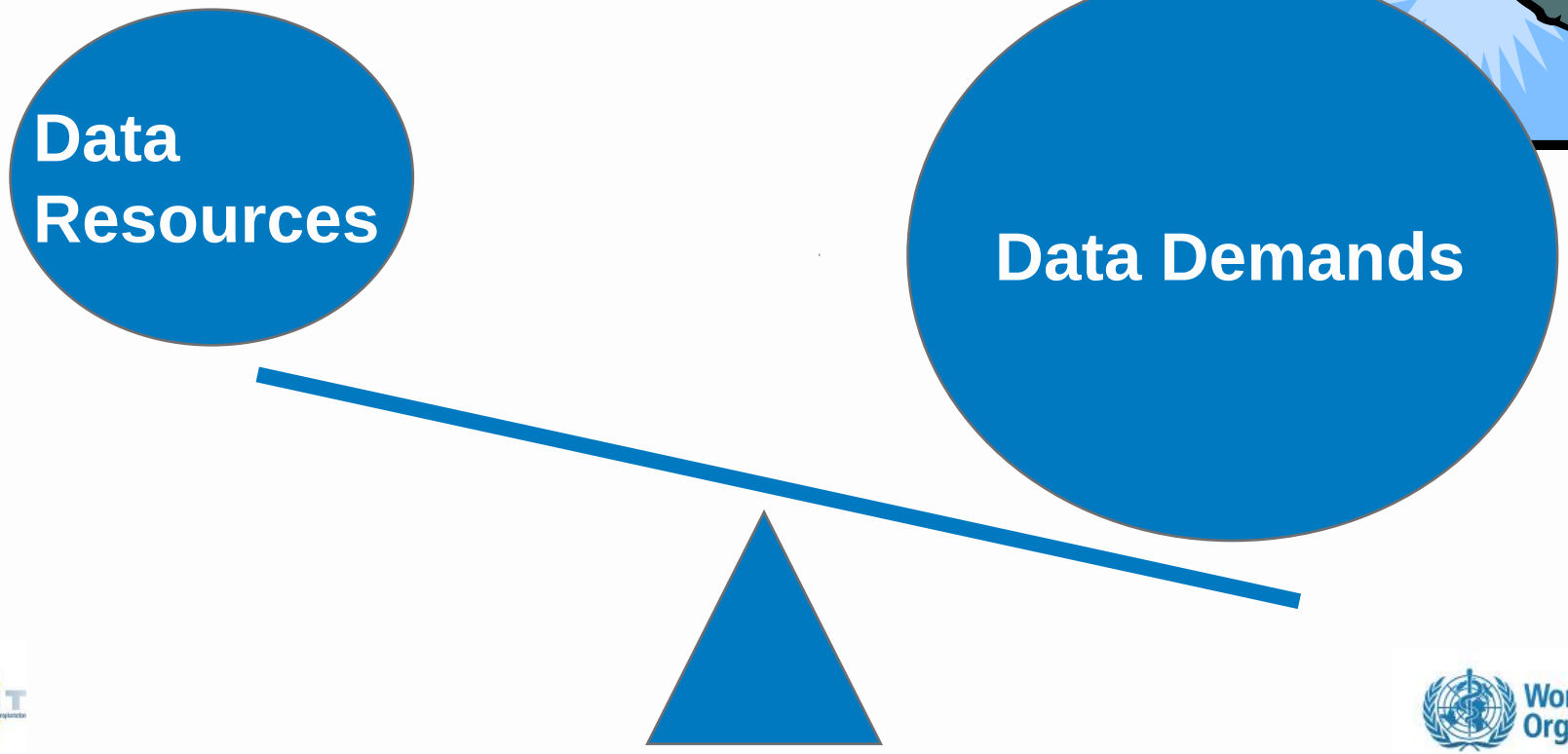
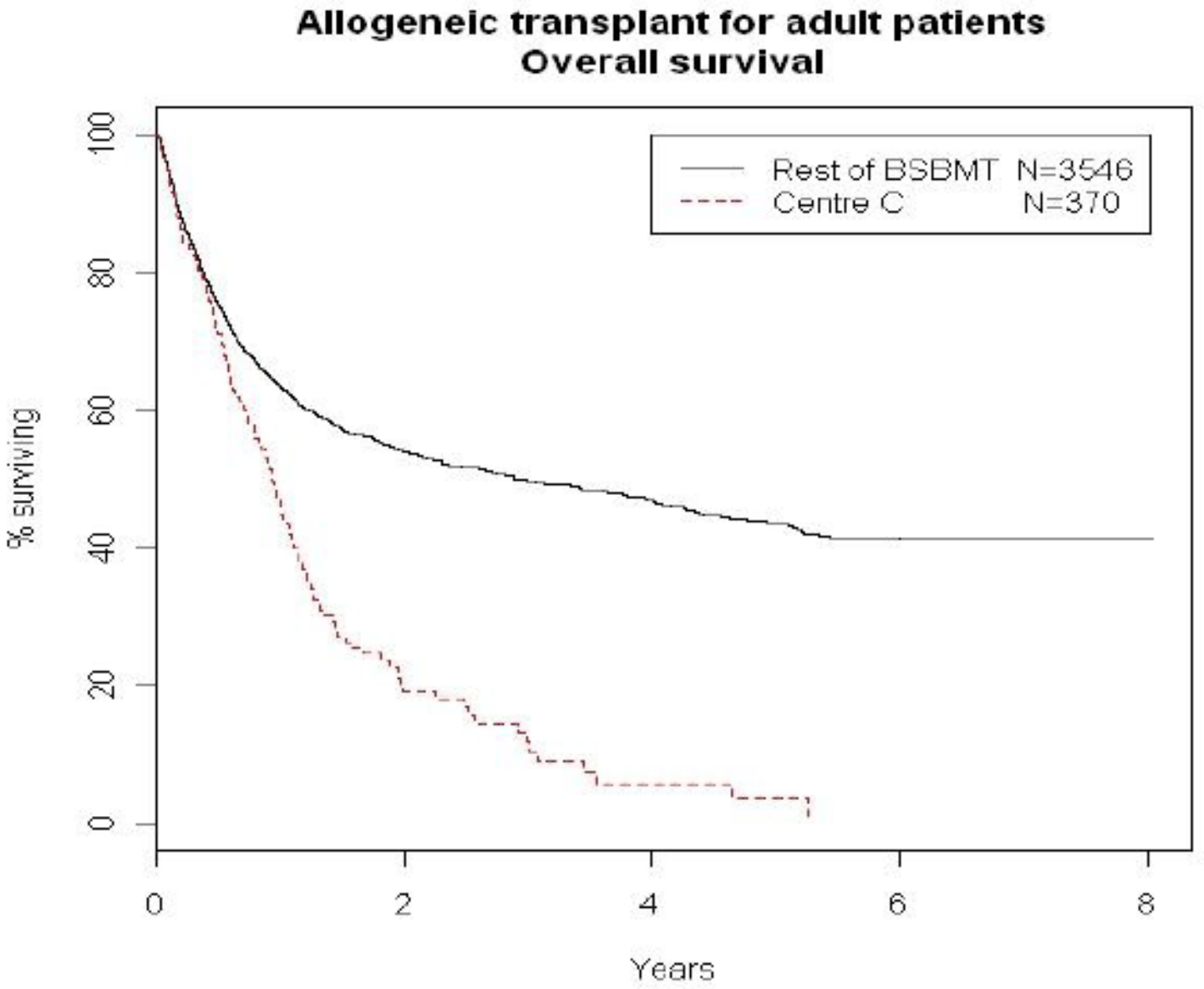
DATA DOESN'T JUST HAPPEN

- Providing the data needed to do good clinical research, quality improvement is demanding
- But quality is essential if data are to be useful

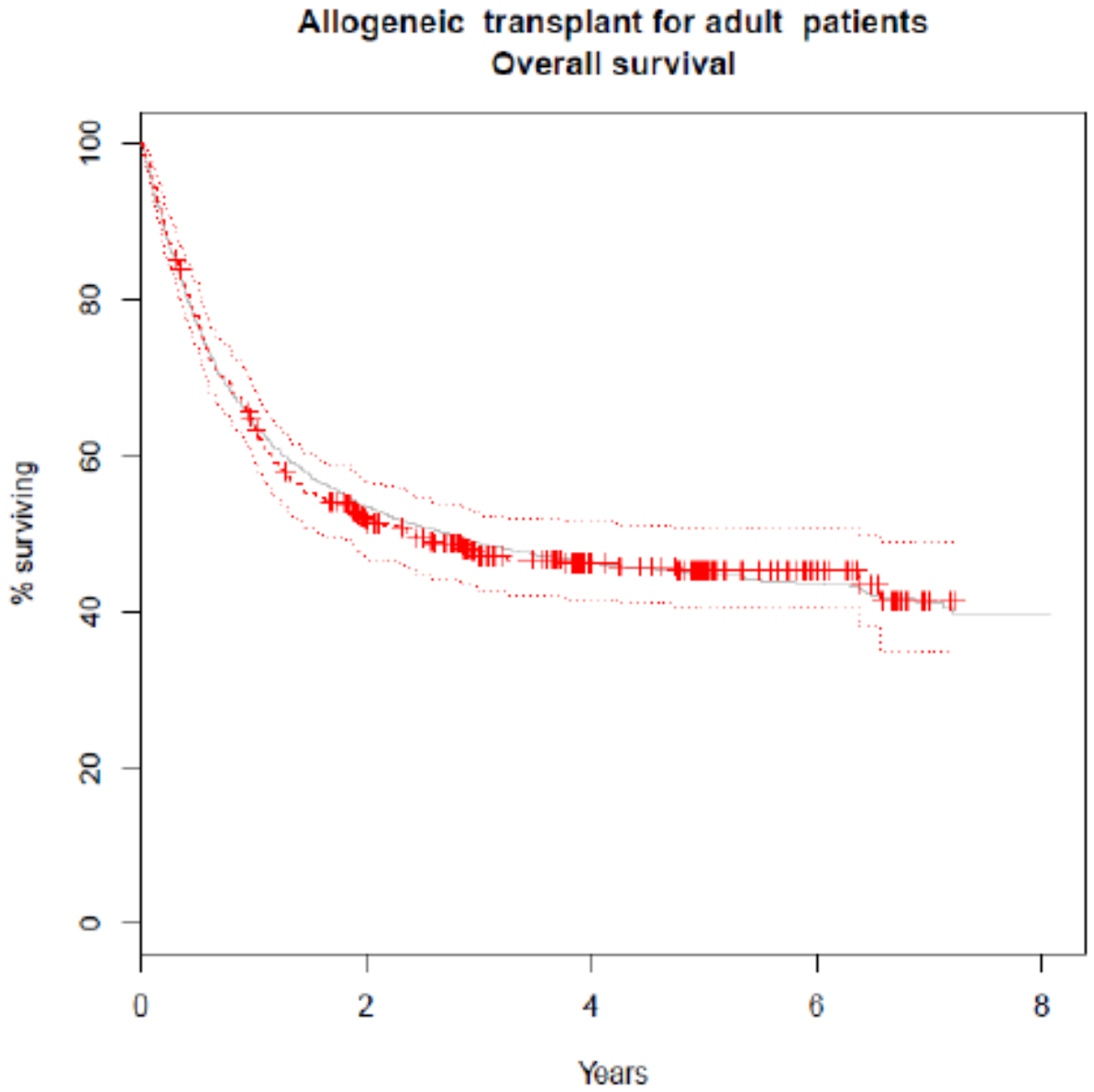


Outcome Registries : Challenges



British Society of Blood and Marrow Transplant Annual Report 2012

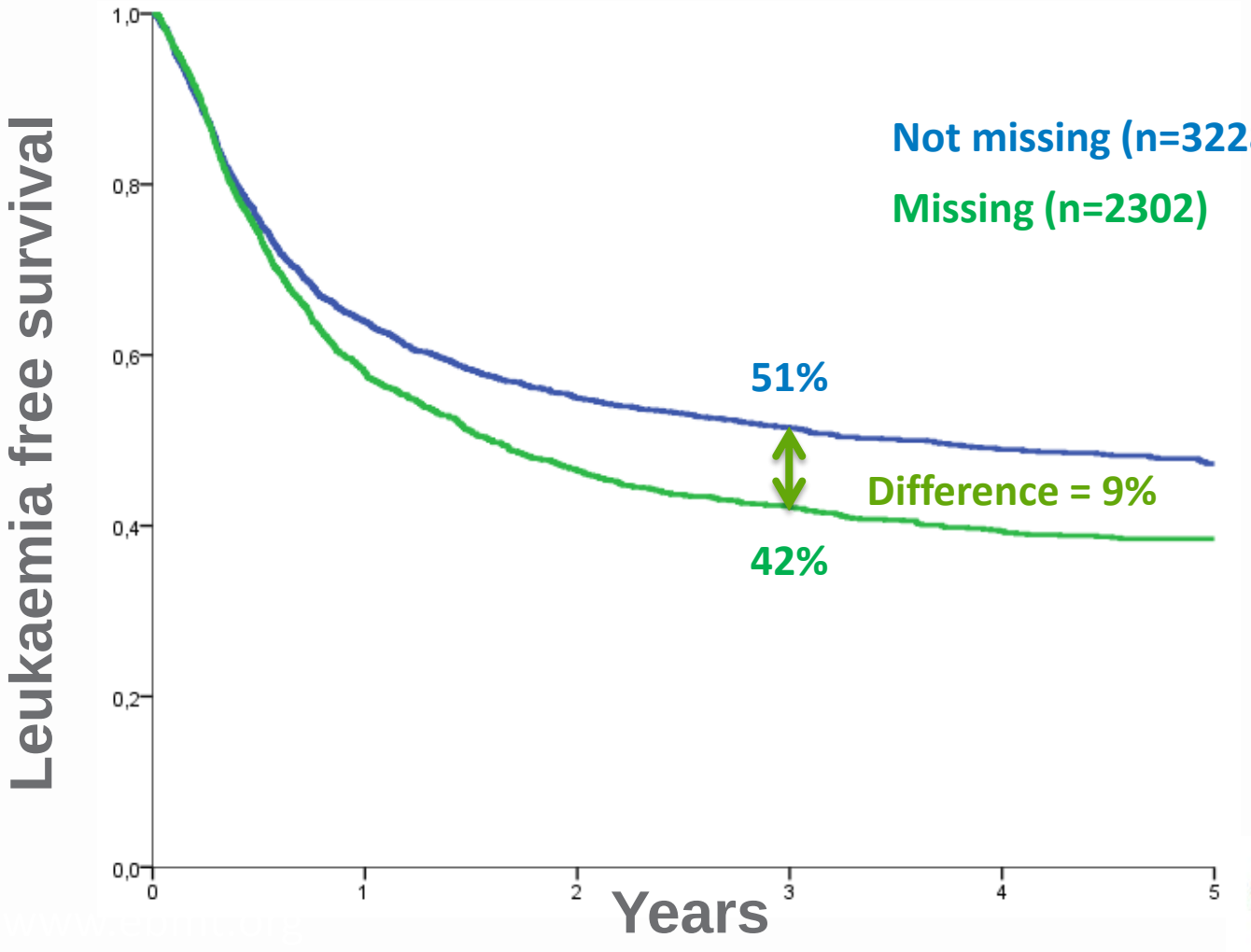
Outcome Registries : Challenges



British Society of Blood and Marrow Transplant Annual Report 2012

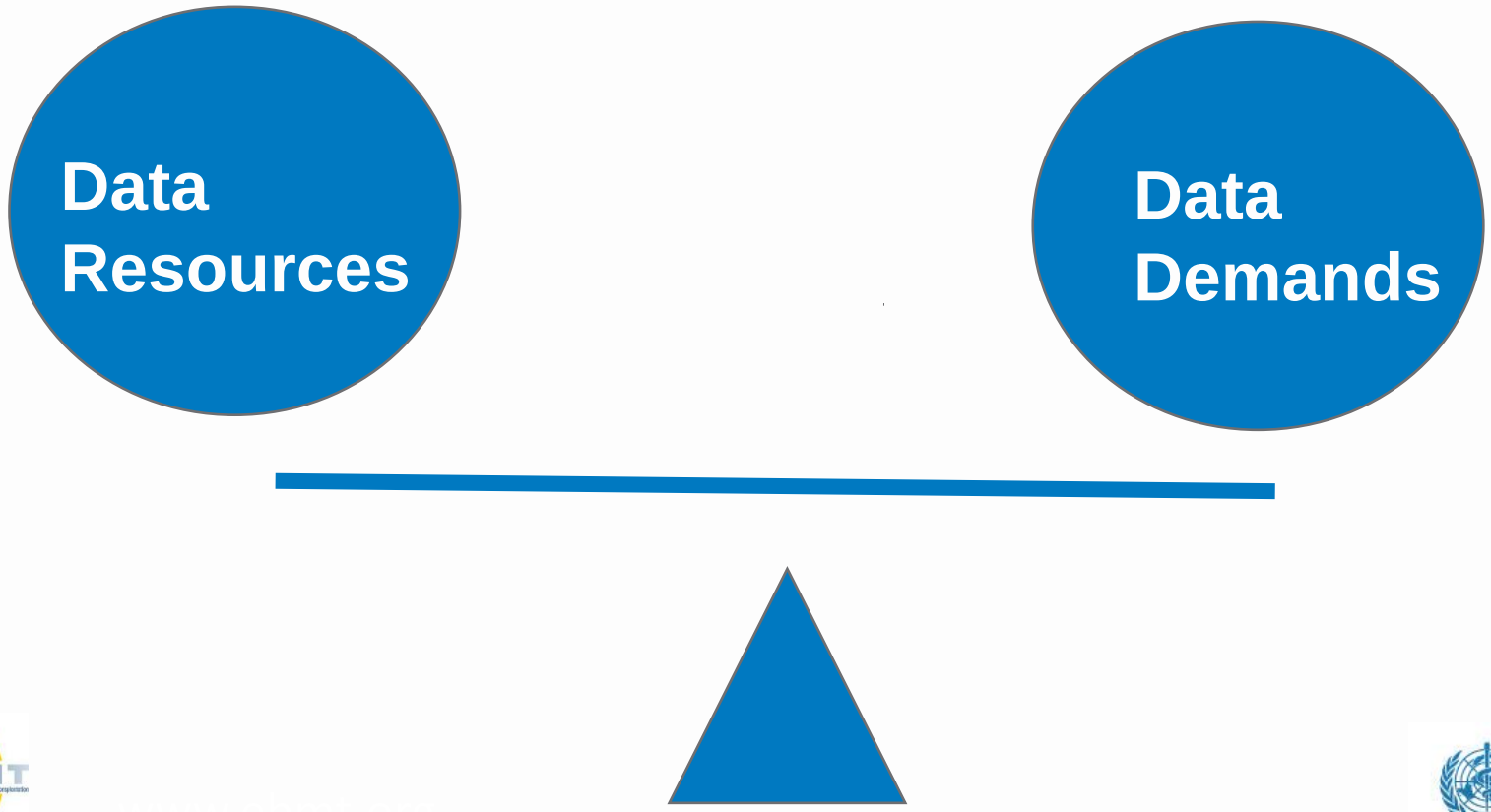
Outcome Registries : Challenges

Outcome of myeloablative transplant for AML 2000-2010: influence of cytogenetics

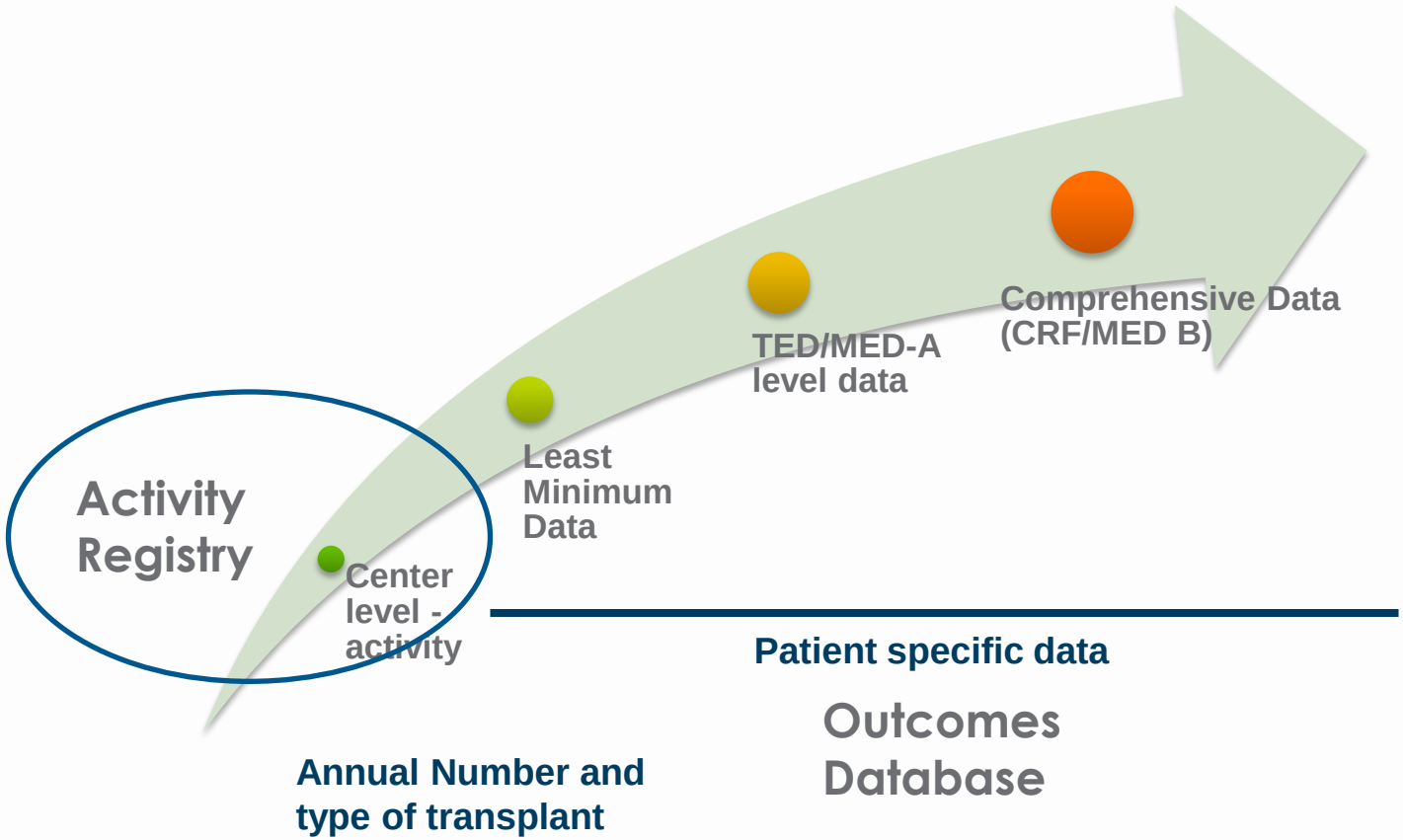


Outcome Registries: Meeting the Challenge

We have to ensure that we balance resources and demands – by *both* increasing resources and making sure that demands are reasonable.



Levels of Data to Share



Various Levels of Data Collection

Data Collection Set	Number of Data Fields
Activity Survey	Aggregate data
APBMT Least Minimum Data Set	~100/patient
CIBMTR/EBMT Consensus Data Set (TED/MED-A)*	~275/patient
TRUMP (Japanese Registry)	~750/patient
Comprehensive Data (CIBMTR CRF/EBMTR MED-B)	>1000
*FACT/JACIE minimum data set	

Discussion: Developing the AFBMT

Panelists	Country
Yoshiko Atsuka	Japan
Eliane Gluckman	France
Nosa Bazuaye	Nigeria
Faisal Hussain	Saudi Arabia
Nicolas Novitsky	South Africa
Marcelo Pasquini	USA
Wael Saber	USA
Adriana Seber	Brazil

Moderator:
Mary Horowitz

An African BMT Registry: Benefits and Challenges

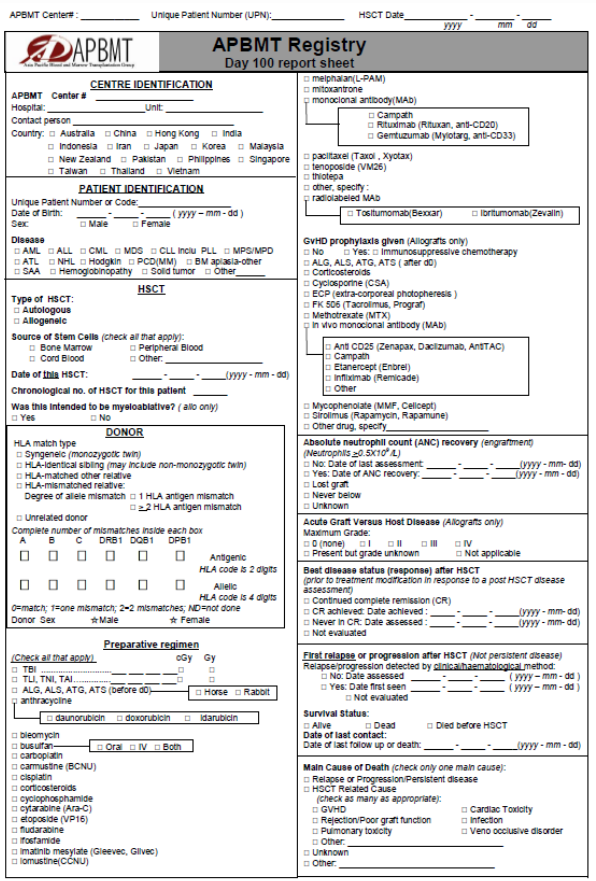
- What are the most important benefits of developing an African BMT registry?
- What are the biggest obstacles/challenges? How can they be overcome?
- What kind of training is necessary to collect and submit data?
- What are potential strategies to minimize cost?
- What should be the next steps?

An African Outcomes Registry: Meeting the Challenge

If you want to go fast, go alone; if you want to go far, go with others.

APBMT Least Minimum Data Items	
Characteristics	**Fields**
Identification	Center and patient numbers
Patient	age, gender
Disease	disease status and subtype
Transplant	Date, graft type, conditioning regimen (intensity, agents, irradiation),GVHD prophylaxis
Donor type	Donor type, multiple donors, HLA match, donor gender and relation
Outcome	
Engraftment	Date, graft failure
GVHD	Acute, date of maximum grade, date of chronic
Disease status post transplant	Response, relapse and date
Survival	Status at last f/u, cause of death
Follow up	
Data collection calendar	100 days, 6 months, 1 year and yearly thereafter.

Least Minimum Dataset of APBMT



APBMT Center# : _____ Unique Patient Number (UPN):_____ HSCT Date_____ - _____ - _____ (yyyy mm dd)

APBMT Registry
Day 100 report sheet

CENTRE IDENTIFICATION
APBMT Center # _____
Hospital: _____ Unit: _____
Contact person _____
Country: □ Australia □ China □ Hong Kong □ India □ Indonesia □ Iran □ Japan □ Korea □ Malaysia □ New Zealand □ Pakistan □ Philippines □ Singapore □ Taiwan □ Thailand □ Vietnam

PATIENT IDENTIFICATION
Unique Patient Number or Code:_____
Date of Birth: _____ - _____ - _____ (yyyy – mm - dd)
Sex: □ Male □ Female
Disease
□ AML □ ALL □ CML □ MDS □ CLL Inclu PLL □ MPS/MPD
□ ATL □ NHL □ Hodgkin □ PCD(MM) □ BM aplasia-other
□ SAA □ Hemoglobinopathy □ Solid tumor □ Other_____

HSCT
Type of HSCT:
□ Autologous
□ Allogeneic
Source of Stem Cells *(check all that apply)*:
□ Bone Marrow □ Peripheral Blood
□ Cord Blood □ Other: _____
Date of this HSCT: _____ - _____ - _____(yyyy - mm - dd)
Chronological no. of HSCT for this patient _____
Was this intended to be myeloablative? *(allo only)*
□ Yes □ No

DONOR
HLA match type
□ Syngeneic *(monozygotic twin)*
□ HLA-identical sibling *(may include non-monozygotic twin)*
□ HLA-matched other relative
□ HLA-mismatched relative:
Degree of allele mismatch □ 1 HLA antigen mismatch □ ≥ 2 HLA antigen mismatch
□ Unrelated donor
Complete number of mismatches inside each box

	A	B	C	DRB1	DQB1	DPB1	
□	□	□	□	□	□	□	Antigenic
							HLA code is 2 digits
□	□	□	□	□	□	□	Allelic
							HLA code is 4 digits

0=match; 1=one mismatch; 2=2 mismatches; ND=not done
Donor Sex ☆Male ☆ Female

Preparative regimen
(Check all that apply) cGy Gy
□ TBI ..... □ □
□ TLI, TNI, TAI ..... □ □
□ ALG, ALS, ATG, ATS (before dd)——— □ Horse □ Rabbit
□ anthracycline
□ daunorubicin □ doxorubicin □ idarubicin
□ bleomycin
□ busulfan——— □ Oral □ IV □ Both
□ carboplatin
□ carmustine (BCNU)
□ cisplatin
□ corticosteroids
□ cyclophosphamide
□ cytarabine (Ara-C)
□ etoposide (VP16)
□ fludarabine
□ ifosfamide
□ imatinib mesylate (Gleevec, Glivec)
□ lomustine(CCNU)
□ melphalan(L-PAM)
□ mitoxantrone
□ monoclonal antibody(MAb)
□ Campath
□ Rituximab (Rituxan, anti-CD20)
□ Gemtuzumab (Mylotarg, anti-CD33)
□ paclitaxel (Taxol , Xyotax)
□ tenoposide (VM26)
□ thiotepa
□ other, specify :
□ radiolabeled MAb
□ Tositumomab(Bexxar) □ Ibritumomab(Zevalin)

GvHD prophylaxis given (Allografts only)
□ No □ Yes: □ Immunosuppressive chemotherapy
□ ALG, ALS, ATG, ATS (after dd)
□ Corticosteroids
□ Cyclosporine (CSA)
□ ECP (extra-corporeal photopheresis)
□ FK 506 (Tacrolimus, Prograf)
□ Methotrexate (MTX)
□ In vivo monoclonal antibody (MAb)
□ Anti CD25 (Zenapax, Daclizumab, AntiTAC)
□ Campath
□ Etanercept (Enbrel)
□ Infliximab (Remicade)
□ Other
□ Mycophenolate (MMF, Cellcept)
□ Sirolimus (Rapamycin, Rapamune)
□ Other drug, specify_____

Absolute neutrophil count (ANC) recovery *(engraftment)*
(Neutrophils ≥0.5X10⁹ /L)
□ No: Date of last assessment: _____ - _____ - _____(yyyy - mm- dd)
□ Yes: Date of ANC recovery: _____ - _____ - _____(yyyy - mm - dd)
□ Lost graft
□ Never below
□ Unknown

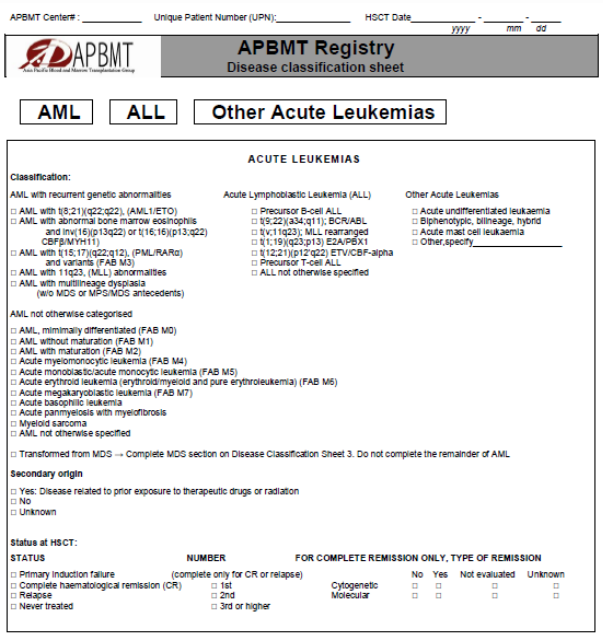
Acute Graft Versus Host Disease *(Allografts only)*
Maximum Grade:
□ 0 (none) □ I □ II □ III □ IV
□ Present but grade unknown □ Not applicable

Best disease status (response) after HSCT
(prior to treatment modification in response to a post HSCT disease assessment)
□ Continued complete remission (CR)
□ CR achieved: Date achieved : _____ - _____ - _____(yyyy - mm- dd)
□ Never in CR: Date assessed : _____ - _____ - _____(yyyy - mm- dd)
□ Not evaluated

First relapse or progression after HSCT *(Not persistent disease)*
Relapse/progression detected by clinical/haematological method:
□ No: Date assessed _____ - _____ - _____ (yyyy – mm - dd)
□ Yes: Date first seen _____ - _____ - _____ (yyyy – mm - dd)
□ Not evaluated

Survival Status:
□ Alive □ Dead □ Died before HSCT
Date of last contact:
Date of last follow up or death: _____ - _____ - _____(yyyy - mm - dd)

Main Cause of Death *(check only one main cause)*:
□ Relapse or Progression/Persistent disease
□ HSCT Related Cause
(check as many as appropriate):
□ GVHD □ Cardiac Toxicity
□ Rejection/Poor graft function □ Infection
□ Pulmonary toxicity □ Veno occlusive disorder
□ Other: _____
□ Unknown
□ Other: _____



APBMT Center# : _____ Unique Patient Number (UPN):_____ HSCT Date_____ - _____ - _____ (yyyy mm dd)

APBMT Registry
Disease classification sheet

AML **ALL** **Other Acute Leukemias**

ACUTE LEUKEMIAS

Classification:

AML with recurrent genetic abnormalities
□ AML with t(8;21)(q22;q22), (AML1/ETO)
□ AML with abnormal bone marrow eosinophils and inv(16)(p13q22) or t(16;16)(p13;q22) CBFβ/MYH11)
□ AML with t(15;17)(q22;q12), (PML/RARα) and variants (FAB M3)
□ AML with 11q23, (MLL) abnormalities
□ AML with multilineage dysplasia (w/o MDS or MPS/MDS antecedents)

Acute Lymphoblastic Leukemia (ALL)
□ Precursor B-cell ALL
□ t(9;22)(a34;q11); BCR/ABL
□ t(v;11q23); MLL rearranged
□ t(1;19)(q23;p13) E2A/PBX1
□ t(12;21)(p12;q22) ETV/CBF-alpha
□ Precursor T-cell ALL
□ ALL not otherwise specified

Other Acute Leukemias
□ Acute undifferentiated leukaemia
□ Biphenotypic, bilineage, hybrid
□ Acute mast cell leukaemia
□ Other,specify_____

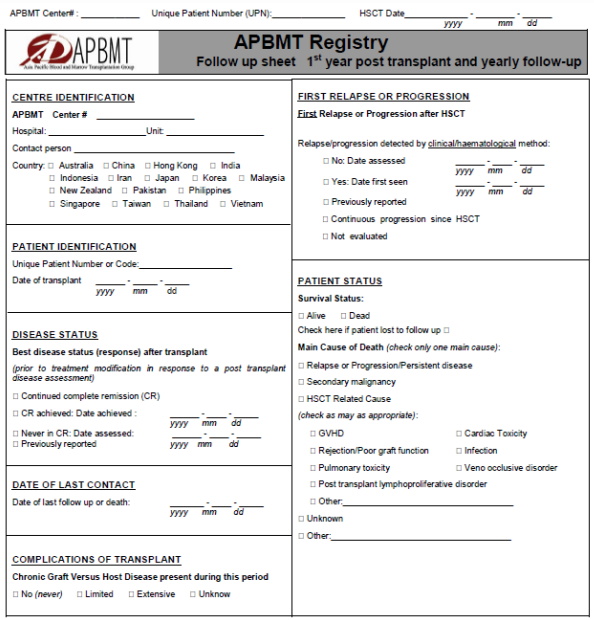
AML not otherwise categorised
□ AML, minimally differentiated (FAB M0)
□ AML without maturation (FAB M1)
□ AML with maturation (FAB M2)
□ Acute myelomonocytic leukemia (FAB M4)
□ Acute monoblastic/acute monocytic leukemia (FAB M5)
□ Acute erythroid leukemia (erythroid/myeloid and pure erythroleukemia) (FAB M6)
□ Acute megakaryoblastic leukemia (FAB M7)
□ Acute basophilic leukemia
□ Acute panmyelosis with myelofibrosis
□ Myeloid sarcoma
□ AML not otherwise specified

□ Transformed from MDS → Complete MDS section on Disease Classification Sheet 3. Do not complete the remainder of AML

Secondary origin
□ Yes: Disease related to prior exposure to therapeutic drugs or radiation
□ No
□ Unknown

Status at HSCT:

STATUS	NUMBER (complete only for CR or relapse)		FOR COMPLETE REMISSION ONLY, TYPE OF REMISSION	No	Yes	Not evaluated	Unknown
□ Primary induction failure							
□ Complete haematological remission (CR)	□ 1st		Cytogenetic	□	□	□	□
□ Relapse	□ 2nd		Molecular	□	□	□	□
□ Never treated	□ 3rd or higher						



APBMT Center# : _____ Unique Patient Number (UPN):_____ HSCT Date_____ - _____ - _____ (yyyy mm dd)

APBMT Registry
Follow up sheet 1st year post transplant and yearly follow-up

CENTRE IDENTIFICATION
APBMT Center # _____
Hospital: _____ Unit: _____
Contact person _____
Country: □ Australia □ China □ Hong Kong □ India □ Indonesia □ Iran □ Japan □ Korea □ Malaysia □ New Zealand □ Pakistan □ Philippines □ Singapore □ Taiwan □ Thailand □ Vietnam

PATIENT IDENTIFICATION
Unique Patient Number or Code:_____
Date of transplant _____ - _____ - _____ yyyy mm dd

DISEASE STATUS
Best disease status (response) after transplant
(prior to treatment modification in response to a post transplant disease assessment)
□ Continued complete remission (CR)
□ CR achieved: Date achieved : _____ - _____ - _____ yyyy mm dd
□ Never in CR: Date assessed: _____ - _____ - _____
□ Previously reported yyyy mm dd

DATE OF LAST CONTACT
Date of last follow up or death: _____ - _____ - _____ yyyy mm dd

COMPLICATIONS OF TRANSPLANT
Chronic Graft Versus Host Disease present during this period
□ No *(never)* □ Limited □ Extensive □ Unknow

FIRST RELAPSE OR PROGRESSION
First Relapse or Progression after HSCT
Relapse/progression detected by clinical/haematological method:
□ No: Date assessed _____ - _____ - _____ yyyy mm dd
□ Yes: Date first seen _____ - _____ - _____ yyyy mm dd
□ Previously reported
□ Continuous progression since HSCT
□ Not evaluated

PATIENT STATUS
Survival Status:
□ Alive □ Dead
Check here if patient lost to follow up □
Main Cause of Death *(check only one main cause)*:
□ Relapse or Progression/Persistent disease
□ Secondary malignancy
□ HSCT Related Cause
(check as may as appropriate):
□ GVHD □ Cardiac Toxicity
□ Rejection/Poor graft function □ Infection
□ Pulmonary toxicity □ Veno occlusive disorder
□ Post transplant lymphoproliferative disorder
□ Other:_____
□ Unknown
□ Other:_____

One page for day 100 report

One page for disease items

One page for follow-up

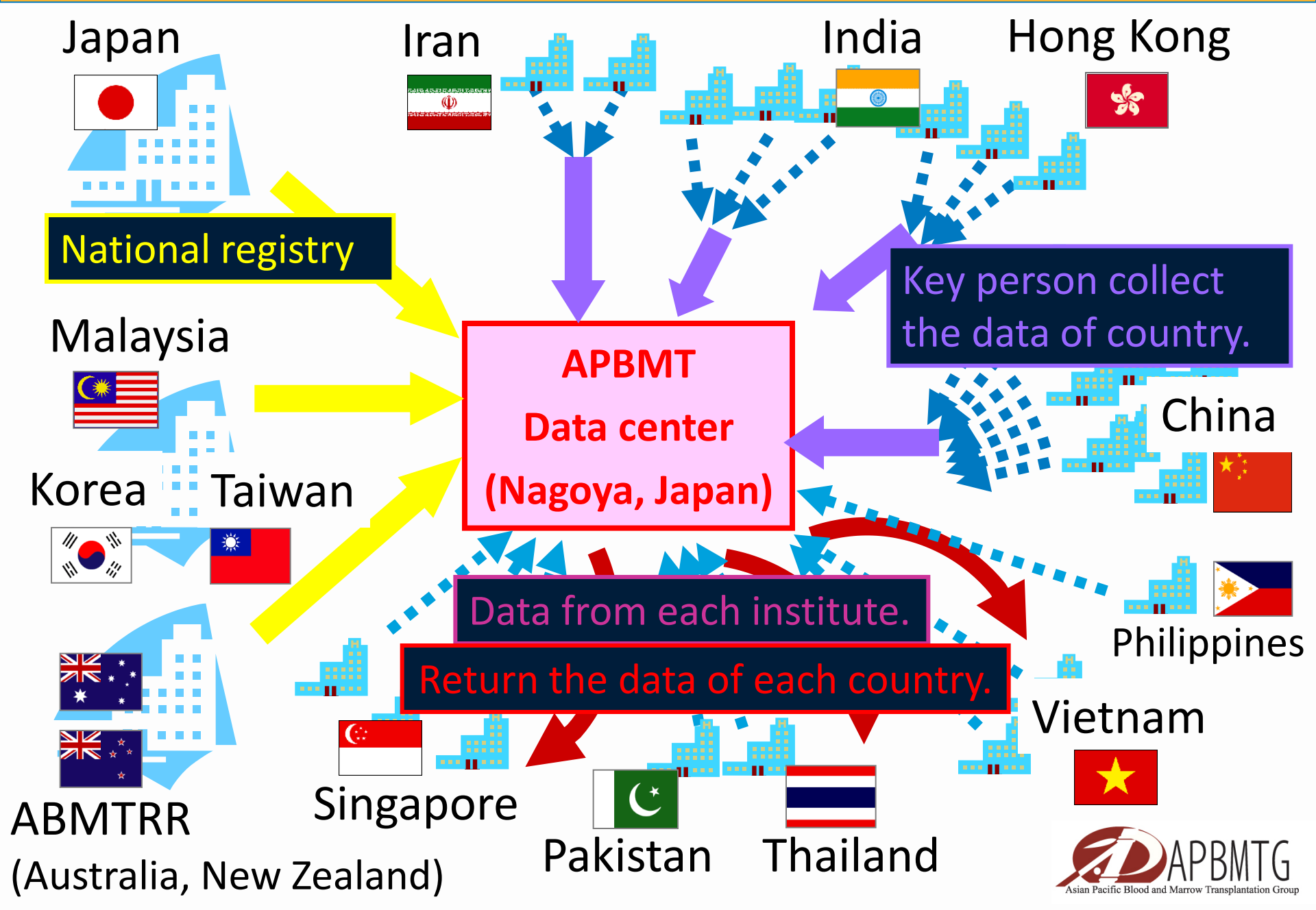
Other Items of Potential Local Interest

- Length of hospital stay
- Costs
- Prior therapy
- Depends on most important issues to be addressed

IMPORTANT PRINCIPLE – Think about what you want to use the data for before deciding what to collect.

Making Use of Existing Resources May Make Data Sharing More Feasible Logistically and Financially

APBMT Data Collection



APBMTG
Asian Pacific Blood and Marrow Transplantation Group

Agreement Form

Data Transmission Agreement

This Data Transmission Agreement, effective September 16, 2010, is entered into by and between the Asia-Pacific Blood and Marrow Transplantation ("APBMT"), an international organization whose office and data center in Aichi Medical University School of Medicine and Nagoya University Graduate School of Medicine, and Singapore General Hospital ("Transplant Center").

The APBMT is an international organization to share information and promote

This form can be applied to the agreement between CIBMTR and societies other than APBMT.

The purpose of this Agreement is to set forth terms by which the APBMT will facilitate Transplant Center's participation in data submission for research activities of the APBMT.

Section 1. Data Collection and Records

(a)Types of Data

i. APBMT Outcome Registry Data. Transplant Center shall participate as a APBMT Outcome Registry Registration Center, and shall submit the initial baseline and follow-up APBMT Outcome Registry Data forms for all allogeneic and /or autologous transplant recipients.

ii. Transplant Essential Data (TED). If Transplant Center is a Center for International Blood and Marrow Transplant Research (CIBMTR) Registration Center, Transplant Center may submit TED data equivalent to APBMT Outcome Registry Data directly to CIBMTR. CIBMTR may provide such TED data to the APBMT. Similarly, centers submitting data to APBMT agree to allow APBMT to share these with CIBMTR.

Some Best Practices for Designing a Registry

- Identify the People Who Are Key to the Effort – develop shared commitment
- Define the objectives together
  - What you collect is determined by what you want to do with the data
  - Long-term enthusiasm will depend on producing a database that is useful
  - May differ for local, national and international efforts
  - Address issues of ownership, access and governance

Some Best Practices for Designing a Registry

- Carefully assess existing resources to determine what can be leveraged
  - Data elements – use those already curated/defined
  - Leverage existing data collection infrastructures (including local hospital systems) where possible
- Start small but plan for expansion
  - Data elements can be categorized as “must-haves” versus “nice to haves”

Some Best Practices for Designing a Registry

- Consider how to recruit, train and support data entry personnel
  - On-line training tools exist through CIBMTR and EBMT
  - Integrate data collection into flow of clinical care (point of treatment collection)
  - Even doctors need some help

Role for WBMT: Advocacy

- **Recognition** that data collection and analysis are an essential part of our work – and critical to improving patient outcomes
- **Uniform data standards** so that data systems in different sectors /centers/countries can talk to each other
- Governmental and private **funding** for data collection
- **Sensible regulations** regarding research and privacy that protect patients and donors but do not preclude the research that will, in fact, help them in the long run.