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**Secretary General:** Miyamura, Koichi

# October 27, 2006 (Friday)

## Symposium 1 ~Registration System of Transplantation~

13:10 ~ 16:30

- Chairpersons: Lu, Dao-Pei (China)  
Hamajima, Nobuyuki (Japan)
- Invited Speakers: S1-1 Gratwohl, Alois (Switzerland)  
"Registration of Transplants"  
S1-2 Horowitz, Marry (U.S.A.)  
"The Use of Registries to Facilitate Clinical Research in Blood and Marrow Transplantation: Examples from the Center for International Blood and Marrow Transplant Research (CIBMTR)"
- Speakers: S1-3 Lu, Dao-Pei (China)  
"Asia-Pacific BMTR – Its Necessity, Harmonization and Standardization"  
S1-4 Kim, Dong Wook (Korea)  
"Current Status of Korean Registry of Hematopoietic Stem Cell Transplantation"  
S1-5 Chan, Lee Lee (Malaysia)  
"Registration System of Transplantation"  
S1-6 Saikia, Tapan K (India)  
"Asian Blood & Marrow Stem Cell Transplantation Registry"  
S1-7 Ghavamzadeh, Ardeshir (Iran)  
"The Hematology - Oncology and Bone Marrow Transplantation Research Center Report from 1991 Till Now"  
S1-8 Chang, Chao-Sung (Taiwan)  
"Development of Taiwan's Stem Cell Transplantation Registry"  
S1-9 Atsuta, Yoshiko (Japan)  
"Hematopoietic Stem Cell Transplantation in Japan -from Nationwide Survey 2005 Conducted by the Japan Society for Hematopoietic Cell Transplantation-"  
S1-10 Suzuki, Ritsuro (Japan)  
Toward the Registration System of Hematopoietic Stem Cell Transplantation in Asia Pacific Bone Marrow Transplantation (APBMT) Group

## **REGISTRATION OF TRANSPLANTS**

### **A. Gratwohl, Hematology & Stem Cell Transplant Unit, University Hospital Basel/Switzerland For the Activity Survey of the European Group for Blood and Marrow Transplantation EBMT**

Modern hematopoietic stem cell transplantation (HSCT) has a long history and dates back to the first successful HLA-identical sibling transplants in 1968. Today, it is an accepted therapy for many severe congenital or acquired disorders of the hematopoietic system and for radio-, chemo- or immuno-sensitive malignancies. Stem cells from peripheral blood, bone marrow or cord blood are used for autologous or allogeneic transplants. An estimated number of near 100'000 transplants are performed annually world-wide. Current status would not be possible without intensive scientific collaboration on local, national and global level. Exchange of experience and results of individual patient datas of retrospective or prospective cohorts and more recently of prospective controlled studies has contributed to progress. International organisations, such as CIBMTR and EBMT have been instrumental in this field. Initially, data collection and analysis has been regarded as a scientific tool for scientists and apart from the clinical hospital activity. This has changed as concept. In a recent WHO consensus conference on ethical issues in cell and tissue transplantation, data collection and data analysis were considered as integral part of the therapy. Outcome analysis is no longer a desired luxury but has become a must. In this setting, the transplantation community faces the challenge for standardised international collaboration in outcome research. Data collection of transplant results can be split into two categories. One concerns primarily outcome of individual transplants and is based on specific patient (and donor) data. Harmonisation of minimal essential data on a global level is here of primary importance. The second topic deals with transplant activity as challenge for the health care providers. HSCT requires complex infrastructure and planning is essential. The EBMT activity survey serves as such an example. Since 1990, EBMT collects on an annual basis the number of patients transplanted in Europe by indication, donor type, and stem cell source. This very limited information is supplemented by team information, e.g. location, size of the team, years of activity and by country information, such as Gross National Income, health care expenditures and population size. Based on >200'000 HSCT from more than 600 teams in 38 countries over a 15 years period, changes in technology can be documented and clear trends be established. Economic factors remain the key element for transplant decisions. This information is invaluable for health care providers, treating physicians and patients as well in their decision making as in providing the infrastructure.

**The Use of Registries to Facilitate Clinical Research in Blood and Marrow Transplantation: Examples from the Center for International Blood and Marrow Transplant Research (CIBMTR).**

Mary M. Horowitz, M.D., M.S., CIBMTR, Medical College of Wisconsin, Milwaukee, USA. Transplant outcomes are influenced by many patient- and disease-related factors such as age, disease stage and prior treatment, as well as transplant-related factors such as stem cell source and transplant regimen. Ideally, most transplant strategies would be evaluated by large randomized clinical trials. However, various factors limit application of randomized trials in this setting. Many diseases treated with transplantation are uncommon; single centers may treat few patients with a given disorder. This makes randomized trials difficult and limits the ability to perform non-randomized trials with sufficient power to detect meaningful effects. Some important transplant issues are not amenable to randomization, such as impact of donor type. Most clinical trials focus on short- and intermediate-term outcomes (one to five years). However, there is a need for long-term follow-up of transplant recipients, since some important problems, such as therapy-related cancers, may not occur until many years after treatment.

The CIBMTR was formed in 2004 through an affiliation of the International Bone Marrow Transplant Registry (established in 1972) and the research arm of the National Marrow Donor Program (established in 1987). The CIBMTR maintains a large database of clinical information on outcome of blood and marrow transplants performed in 450 transplant centers in 47 countries. The database includes information on more than 200,000 transplant recipients and registers about 12,000 new transplants yearly. Data quality and consecutive registration are ensured through extensive computer checks and on-site audits. Transplant centers are asked to provide yearly follow-up on survivors. The database includes information on 9000 survivors followed for 10 or more years. Additionally, pretransplant aired samples of cells and/or DNA are available for about 20,000 unrelated donor-recipient pairs. Both data and biologic specimens are available to investigators for research.

Observational databases like that maintained by the CIBMTR may facilitate understanding of transplant outcomes by addressing questions difficult to address in randomized trials. These include descriptions of transplant results in specific patient groups, analysis of prognostic factors, evaluation of new transplant regimens, comparison of transplant with non-transplant therapy, defining inter-center variability in practice and outcome, and developing innovative analytic approaches. Linking clinical data with immunologic and genetics information can provide important insights into transplant biology. Clinical databases may also aid development of optimal designs for randomized studies. Registry data can focus clinical trial efforts on areas most likely to be productive by providing preliminary estimates of use and efficacy of developing therapeutic strategies. They allow trial planners to make more precise estimates of outcomes and accrual patterns which can aid sample size calculations and implementation plans. Identification of appropriate centers for specific trials can increase efficiency. Information about most commonly used supportive care measures can be used to adapt protocols to standard practices and thus increase their acceptability in the transplant community. Failure to accrue can be systematically addressed by studying characteristics (and alternative treatment) of patients potentially eligible but not enrolled. Comparison of clinical trials outcomes with observational outcomes can give insight about generalizability and patient selection practices. Use of the CIBMTR database is an integral part of the trial planning process of the U.S. Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The BMT CTN is a cooperative trial network established in 2001 by the U.S. National Heart Lung and Blood Institute and the National Cancer Institute to perform multicenter clinical trials addressing important issues in blood and marrow transplantation. It currently has nine open protocols to which it has accrued about 1500 patients. Examples of the interrelationship between the CIBMTR observational research program and the design and implementation of prospective trials by the BMT CTN will be presented.

## S1-3

### **Asia-Pacific BMTR — its necessity, harmonization and standardization**

Dao-Pei Lu

While we are performing more and more stem cell transplantation in Asia-Pacific region, it becomes very imperative to form an Asia-Pacific BMTR for the aim of making knowledge out of the data from Asia-Pacific region. Moreover, through conducting and improving the outcome of the scientific studies, benefits will be brought to patients. An organization chart of APBMTR and its committees, such as executive committee, advisory board, statistical center, special subject working committee, clinical trial related programs and more are proposed. Each subcommittee's responsibilities are discussed. Standardization of laboratory practice and harmonization of clinical trials are emphasized.

## **Current Status of Korean Registry of Hematopoietic Stem Cell Transplantation**

**Dong-Wook Kim, MD, PhD**

Professor, Division of Hematology, St. Mary's Hospital, The Catholic University of Korea  
Chair, the Committee of Korean Blood and Marrow Transplantation Registry  
On Behalf of the Korean Society of Hematopoietic Stem Cell Transplantation

Since the successful opening of the first Korean hematopoietic stem cell transplantation in 1983, more than 1000 transplants have been annually conducted and 8031 transplants had been accomplished by December 2005.

To establish Korean registry, we organized the committee of Korean Blood and Marrow Transplantation Registry (KBMTR) within the Korean Society of Hematopoietic Stem Cell Transplantation (KSHSCT) in 2003. We developed registration software based on internet access (KOSTIA; Korean Stem cell Transplantation Internet Access), and started registration after an education of data managers in the 2004 Winter Congress. So far data managers from 33 transplantation centers have been educated and accredited for official registration.

During the past 2 years, 22 of 33 trained transplantation centers have participated and a total of 1097 patients' data have been registered. The registered data contain data on 423 acute leukemia, 171 CML, 130 solid tumors, 111 lymphomas, 82 aplastic anemia, 82 multiple myeloma, 50 MDS, and 48 other diseases. Among these data, 515 and 195 are the transplant data performed in 2005 and 2006 respectively.

KBMTR has some important official policies for registration process and data use. First of all, whole registration process is conducted only through internet access. Secondly, submission of patient consent form is a mandatory process for finalization of registration. Finally KSHSCT does not conduct any kind of clinical studies using data from individual transplantation center but can coordinate off-line analytical studies on behalf of each transplant center.

At present, KBMTR is trying to increase the number of registered patient through a continued education program and a simplified registration process. Additionally the Korean society is striving for the establishment of global standard registration forms via international collaboration.

## S1-5

### REGISTRATION SYSTEM OF TRANSPLANTATION

LL Chan, Department of Paediatrics, University Malaya Medical Centre, Kuala Lumpur, Malaysia.

Most transplant registries collect data on donors & recipients for reasons ranging from simple epidemiology to evaluation & planning of services in a community. Data collection is often a combination of retrospective & prospective analysis of transplantations.

Is there a need for an Asian Transplant Registry? There are numerous transplant units (TU) scattered across Asia serving vast populations but we have little data. Many of these TU have no links to either IBMTR/ ABMTR or EBMTR. Neither do they report to a national registry. Hence the practice and scope of blood and marrow transplant activities in Asia remain largely unknown.

The establishment of an Asian Transplant Registry would help answer questions pertaining to this most populous area of the world. Common to most registries, it could

- i) determine the frequency and distribution of transplantation activities
- ii) determine the outcome of transplantations
- iii) determine factors which influence outcome
- iv) evaluate availability and scope of transplant services
- v) stimulate and facilitate research on transplantation
- vi) establish links between Asian countries and the rest of the world

At present countries like Japan, South Korea and Malaysia have individual national bone marrow transplant registries but these differ in their modes of data entry and fields of study. The Malaysian Blood and Marrow Transplant Registry operates under the umbrella of the Malaysian Transplant Registries. All Malaysian TU submit data voluntarily with no monetary reimbursements. Data is submitted to a centralized clinical research centre via the internet. Funding remains one of our biggest burdens.

It would be logical for the well established registries in Asian countries to provide leadership in the creation of an Asian Transplant Registry. On the other hand we could look towards the well established CIBMTR which is upgrading its data management all the time. Should we adopt their well tested format to prevent duplication of data entry especially for those TU which are already reporting to CIBMTR? What is needed is a system which is easy to access and implement without adding great burden to the current individual data collection systems. It would be prudent to learn from experience of CIBMTR when making decisions on an Asian Transplant Registry.

Issues pertaining to sponsorship, governance, advisory committees, management committees and personnel would have to be considered. Basic concerns on the mode of data collection and its management, confidentiality, access to information and manpower would have to be addressed. For a region as diverse as Asia the cooperation of all parties would have to be secured if the registry is to have any chance of success. The task is great & perhaps workers are few. This is the challenge presently confronting us.

## S1-6

### ASIAN BLOOD & MARROW STEM CELL TRANSPLANTATION REGISTRY

Tapan K Saikia, M.D.

Department of Medical Oncology, Prince Aly Khan Hospital & Jaslok Hospital,  
Mumbai, INDIA

Since more than 15 years the APBMT Group has been struggling to form a functional BMT Registry. Despite tremendous enthusiasm amongst the transplant physicians in the region, a registry has not materialized till date. There have been some attempts by senior physicians in recent years. Led by Prof Y.Kodera, Asian BMT/HSCT Registry is being set up at Nagoya, Japan and looks a feasible project. There is very little doubt that need for such a registry has always been felt by the global community of transplanters. The compelling reasons are, 1. ethnic uniqueness of the region; this might impact transplant outcome significantly, 2. reported incidence of low acute and chronic GVHD in certain countries like Japan, 3. better long-term survival with any type of stem cell source, 4. the epidemiology of certain diseases like thalassemia, aplastic anemia and T cell NHLs appear to be different from the rest of the world, 5. rapid economic development across the region.

We need to look at the impeding factors that might have been responsible for non-development of the registry, 1. absence of a dedicated organization in the line of CIBMTR or EBMT and development of human resources, 2. funding, 3. development of an efficient network, 4. a simplified registry form for data collection, and 5. language barrier. There are efficiently run registries in countries like Japan, South Korea and similar efforts are on in some other countries. We are hopeful that in very near future all these factors will be looked into by a core group and prospective registration process will begin.



**THE HEMATOLOGY- ONCOLOGY AND BONE MARROW TRANSPLANTATION RESEARCH CENTER REPORT FROM 1991 TILL NOW**

A. Ghavamzadeh, K. A. Moghaddam, A. Mousavi, F. Khatami, N. Babhadiashar, M. Jalili, R. Taghipour, N. Mahdavi, A. Ashouri, B. Bahar, M. Jahani.

Hematology-Oncology and BMT Research Center, Tehran University of Medical Sciences, Dr. Shariati Hospital, Tehran, Iran.

Hematology- Oncology and Bone Marrow Transplantation (BMT) Research Center related to Tehran University of Medical Sciences located in Shariati Hospital. Our center activities have started in 1991 in order to help needful patients and augment new data to reach new aspects of therapeutic trials. Also it is one of the greatest bone marrow transplantation centers in world and is the second center in the world based on the transplanted Thalassemia patients. Also this center is doing scientific activities, so that it has presented over 250 assays in international congresses and also more than 150 Thesis has been performed under observation of our professors. Since the year 1991-when bone marrow transplantation was performed for the first time on three patients with Acute Myelogenous Leukemia(AML), Acute Lymphoblastic Leukemia (ALL) and Ewing's Sarcoma- 1520 blood and marrow transplantation have been performed in patients with different diseases .There are 1082 cases that have received allogeneic transplantation and 438 cases that have received autologous transplantation. The first peripheral blood stem cell transplantation was performed in 1997 and since then, there are 1180 patients were transplanted with this source. The first cord blood stem cell transplantation was performed in 1998 and since then there are 13 other Thalassemia patients received transplantation from cord blood. Recently, new methods have been used like low intensity conditioning regimen (non myeloablative) and Donor Lymphocyte Infusion (DLI).This center is member of the International Blood and Marrow Transplantation Registry (IBMTR) and European group of Blood and Marrow Transplantation Registry (EBMTR) and in accompanys with these associations, is gathering the patient's databases who have been undergone transplantation. We cooperate with these centers in scientific and research fields. So that gives help to researchers for a better understanding of transplantation and invent new therapeutic methods. Our center is the member of Asian Pacific Cancer Conference (APCC) and also we are collaborating with Hematology and Cancer Societies such as International Society of Hematology (ISH), American Society of Hematology (ASH), American Society of Clinical Oncology (ASCO), European School of Medical Oncology (ESMO), European Hematology Association (EHA) and other centers. The plans and aims include protraction of cytogenetic and molecular biological diagnostic tests, invention of a cord blood bank and develop the research activities in these fields.

Development of Taiwan's Stem Cell Transplantation Registry

Chao-Sung Chang M.D.

Kaohisung Medical University, Pingtung Christian Hospital, Taiwan

Taiwan Society of Blood and Marrow Transplantation

Since the first case of marrow transplantation was done at National Taiwan University Hospital in 1983, Taiwan has made a big progress in bone marrow and blood stem cells transplantation during the past two decades. There are sixteen bone marrow and blood stem cells transplantation centers established around this island since then. Although with the advancement of stem cell transplantation, there is still lacking of formal registry for stem cell transplantation in Taiwan. Therefore, to develop Taiwan Stem Cell Transplantation Registry (TSCTR) is an important issue in both the clinical hematology and the field of management. Taiwan Society of Blood and Marrow Transplantation has started the project to develop TSCTR by cooperating with the Department of Information Management, National Sun Yat-sen University, Taiwan, for two years. To reach a consensus for reporting and registering, a Delphi method was used to collect the experts' opinion in Taiwan's Stem Cell transplantation centers and finalize the report form. We report our experience in developing process and current situation. Although the initial implementation of TSCTR has been applied on line, it needs further input of stem cells transplantation data from individual center.

**HEMATOPOIETIC STEM CELL TRANSPLANTATION IN JAPAN  
-FROM NATIONWIDE SURVEY 2005 CONDUCTED BY THE JAPAN SOCIETY FOR  
HEMATOPOIETIC CELL TRANSPLANTATION-**

Y. Atsuta<sup>1</sup>, R. Suzuki<sup>1</sup>, A. Yoshimi<sup>1</sup>, N. Hamajima<sup>2</sup>, and Y. Kodera<sup>3</sup>

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<sup>2</sup>Department of Preventive Medicine /Biostatistics and Medical Decision Making, Nagoya University Graduate School of Medicine; <sup>3</sup>BMT Center, Japanese Red Cross Nagoya First Hospital

The Japan Society for Pediatric Hematology (JSPH) launched the nationwide survey on stem cell transplants (SCT) in 1983 for pediatric patients. Since 1993, the Japan Society for Hematopoietic Cell Transplantation (JSHCT) conducted nationwide surveys including adult patients. Collaboration with Japan Marrow Donor Program (JMDP) on nationwide survey has been established from 1999.

A total of 30,678 transplants in 377 transplant teams are reported by December 2005.

Among 2,895 transplants performed in 2004, there were 850 autologous transplants, 350 bone marrow transplants (BMT) from related donors, 434 peripheral stem cell transplants (PBSCT) from related donors, 758 BMT from unrelated donors, and 414 cord blood transplants (CBT). When limited to 2,440 first transplants performed in 2004, the main indications were leukemias (1,224 allogeneic transplants (allo), 21 autologous transplants (auto)), lymphomas (231 allo, 378 auto), multiple myeloma (18 allo, 220 auto), solid tumors (13 allo, 97 auto), aplastic anemia (80 allo), and other diseases (65 allo, 16 auto). The number of total transplants per million population performed in 2004 was 222.6; 66.5 per million for autologous transplants; 153.1 per million for allogeneic transplants. The approximate incidence of reporting rate are as follows; 75-80% for BMT and PBSCT from related donors, 99% for BMT from unrelated donors, 69% for CBT, and not known for autologous transplant.

From 2006, JSHCT started a new electronic registry system, through an affiliation of the JSHCT, JSPH, JMDP and Japan Cord Blood Bank Network, to decrease the burden of dual reporting in transplant centers, and to improve the quality of the registry data and incidence of report. With this new registry, we have strong expectation for ascertaining demographic data of SCT expeditiously, and for promoting research with dependable outcome.

## S1-10

### **TOWARD THE REGISTRATION SYSTEM OF HEMATOPOIETIC STEM CELL TRANSPLANTATION IN ASIA PACIFIC BONE MARROW TRANSPLANTATION (APBMT) GROUP.**

R. Suzuki<sup>1</sup>, Y. Atsuta<sup>1</sup>, A. Yoshimi<sup>1</sup> and Y. Kodera<sup>2</sup>

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There exist two major international registries of hematopoietic stem cell transplantation (HSCT) in the world; those supported by the Center for International Blood and Marrow Transplant Research (CIBMTR) and the European Group for Blood and Marrow Transplantation (EBMT). Although several Asian institutes have been participating for these registries, the Asian Registry has long been desired. Meeting for the Asian Registry have been held since APBMT 2000 (Bangkok). In Japan, the domestic registry of HSCT has been conducted by the Japan Society for Hematopoietic Cell Transplantation (JSHCT) from 1993, and now a total of 30,000 transplants are registered. From this year (2006) the JSHCT Registry has been revised to an electronic system for the purpose of unification of 4 registries (JSHCT, the Japanese Society of Pediatric Hematology, Japan Marrow Donor Program and Japanese Cord Blood Bank Network), as well as for registration convenience, analysis efficacy and research promotion. Based on our experience we here propose the Asian Registry of HSCT. This system is planned to use computer program that automatically anonymize patient personal information and encrypt data. Therefore, it is useful for each institute as well as for each registry in the countries. By combining these data together, we believe that we can make Asian BMT Registry which will much help the clinical and research facilities in the field of HSCT of Asian countries.

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