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## **Challenges of Setting up the First Stem Cell Transplant Centre in a Developing Country (Nigeria)**

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### **Author's contribution**

*This article was designed and written by the author GNB. Author GNB read and approved the final manuscript.*

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### **ABSTRACT**

Hematopoietic Stem cell Transplantation (HSCT) is an approved therapy by the World Health Organization (WHO) for non-malignant and malignant disorder. This is readily assessable and available in developed countries. In 2006 a total of 50,417 first HSCT was recorded worldwide and majority was done in Europe (48%) and the America's (36%). While only 2% in East Mediterranean and Africa. In a global perspective study the first factor for the low HSCT in poor resource country was Government health care expenditure representing 77.33% of the variance. Second factor was team density and the third Gross National Income (GNI) per capital which added another 4.41% explanation.

The first HSCT in Nigeria was done in September 2011 with several challenges in setting up a functioning unit. The challenges range from inadequate manpower compounded by brain drain of health workers. Only a Hematologist, two Nurses, two Laboratory scientists and a Hematopathologist trained for HSCT was available in Hospital. With respect to the challenges of infrastructure and equipment, a four bed isolation unit was constructed with HEPA-filtration and High-pressure machine, an Aphaeresis and platelet storage machine. Most of the supportive, diagnostic unit in the laboratory and Radio-imaging technique are below international substandard. There is need for improved laboratory culture especially

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for fungal and viral infections.

In selecting patients we started with a seven years old child who had severe Sickle Cell disease from a 14 years sibling donor. Also supportive care with parenteral nutrition, blood support (irradiate products), and procurement of rare drugs was a huge challenge. The cost of the first patient transplant patient was paid for by the hospital and is beyond the reach of most Nigerians. The health insurance policy of the nation is still ineffective. Challenges in setting up the first HSCT unit in Nigeria are enormous but with a good political will from government and improved health insurance policy. HSCT could be made available, assessable and affordable to Nigerians who will require this form of therapy.

*Keywords: Challenges; hematopoietic stem cell transplantation; developing country.*

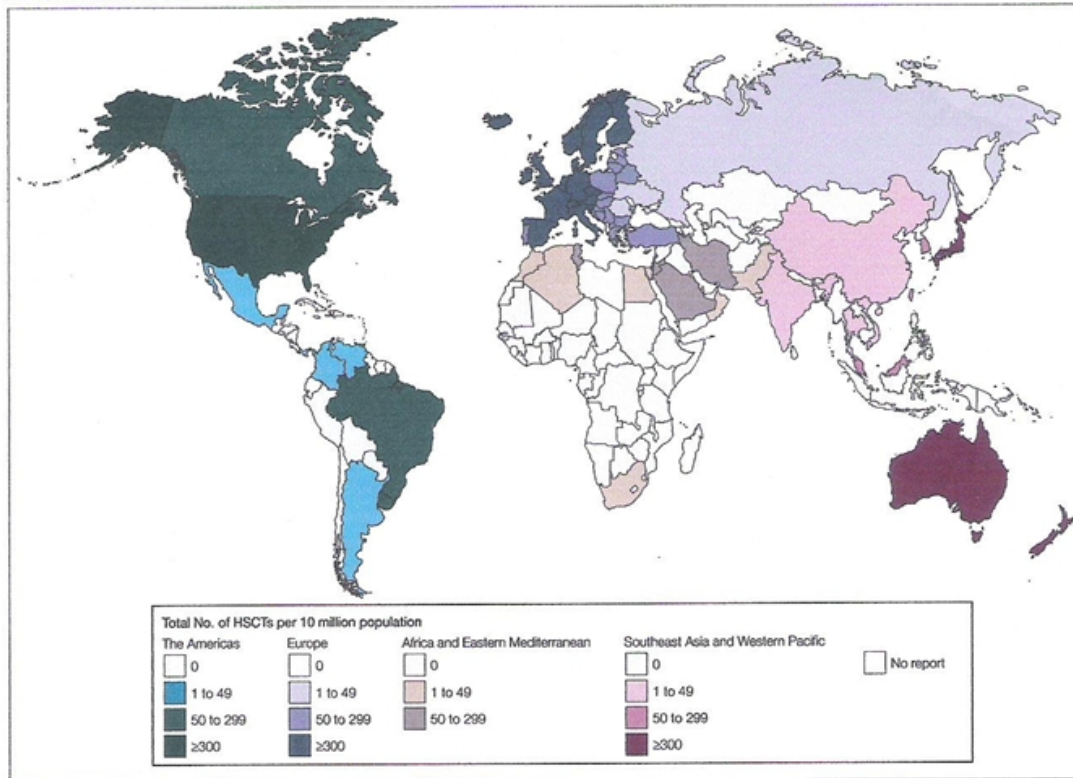
## **1. INTRODUCTION**

Since the pioneering work by Thomas ED in the 1950's in the field of Stem Cell Transplantation [1]. HSCT has become an approved therapy for both non-malignant (Sickle Cell disease, Aplastic Anemia etc) [2,3,4] and malignant disorder (Leukemia, Lymphoma, multiple myeloma, Ewing Sarcoma etc) [5,6]. In addition to the routine HSCT, novel therapy with Hematopoietic Stem Cells for Non-Hematopoietic organ and tissue repair are under investigation (Mensenchymal Stem Cell research, Stem Cell Cardiomyocyte for heart disease etc) [7,8]. The exploitation of this form of new therapy have become an international challenge and made Stem Cell transplant tourism a topic of concern and discuss [9].

A global perspective report in 2006 (figure 1) revealed that a total of 50,417 first HSCT was carried out worldwide from 1327 centre in 71 countries. Majority of these HSCT took place in either Europe (48%) or the America's (36%) while only 2% was in the Eastern Mediterranean and Africa [10]. The reason for low HSCT in some region of the world as enumerated by Gratwohl et al. in the global perspective report include government health care expenditure [10]. Representing 77.33% (most developing countries like Nigeria budget less than what are recommendation for Health by WHO). The second factor is team density and the third factor gross national income (GNI) per capital which added another 4.41% explanation. The close Link between HSCT rates with gross national income per capital was long observed that no HSCTs were performed in countries with less than US \$680 GNI per capital [11,12].

Nigeria with a population of over 150 million people, a high prevalence (3%) of Hemoglobinopathy (Sickle Cell disease) [13]. Several authors have documented enormous challenges in setting up a Stem Cell Transplant centre in Nigeria. These challenges range from manpower shortage, ineffective health insurance policies, inadequate infrastructure, substandard equipment etc. [14,15,16,17]. In pursuance of meeting these challenges the WHO and World Bone Marrow Transplant group organized a workshop for 16 countries including Nigeria with limited resources to guide and create awareness among policy makers to highlight the values of HSCT.

In establishing the first HSCT at the University of Benin Teaching Hospital Edo state Nigeria on the 28<sup>th</sup> of September, 2011 there were several challenges. These challenges included those documented by several authors and new ones encountered with respect to the peculiarity of Nigeria. These challenges and the ways we tried to overcome them will serve as a guide to proposed new developing centres with poor resources.



**Fig. 1. Global Distribution of Hematopoietic Stem Cell Transplantations (HSCT) in 2006**

Regions are colored by World Health Organization regional office code (see text) (<http://www.who.int/about/regions/en/>). Transplant rates indicate the number of first HSCTs per 10 million inhabitants in 2006 and are allogeneic and autologous by continental region. 1620 JAMA, April 28, 2010—Vol 303, No. 16 (Reprinted) ©2010 American Medical Association. All rights reserved.

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## 2. INADEQUATE MANPOWER

Most Specialists in the medical field in Nigeria have migrated to Europe and other parts of the world as part of brain drain. Also HSCT is a new method of therapy hitherto not available in Nigeria with very scarce trained personnel. In 2009 the management of UBTH sent a Hemato-oncologist, two laboratory scientist and two Nurses (Adult and Pediatric) to understudy HSCT in Basel Hospital Switzerland. On return in July 2010, there was a six (6) month in-training of Physicians, Laboratory Scientist, Nurses, Dieticians, Cleaners and other supporting staffs.

As noted by the 2006 global report, low trained personnel to population (team density) is the second most important factor responsible for low HSCT [10]. To improve this low team density there was a Memorandum of Understanding (MOU) for two Hematologist, two Nurses and two laboratory Scientist to be trained each year in Basel Hospital Switzerland.

Also experts from Basel hospital Switzerland will visit UBTH yearly to coordinate HSCT for the first five years.

### **3. INADEQUATE INFRASTRUCTURE**

HSCT requires structures that will enable the use of HEPA-filtration and High pressure machines. The management of UBTH built a four bed isolation room unit with a kitchen to ensure special meals and avoid contamination of food from the general kitchen.

Also an attached Laundry, a changing room, an Aphaeresis room with basic blood bank machine, two consulting rooms to avoid exposing post transplant patient to the general infected patients, a pharmacy with Bio-safety Lamina flow Cabinet where intravenous fluids and stem cells are manipulated. A thirty bed Hemato-oncology ward was built where patients will be admitted pre and post transplant to reduce the pressure of patients admitted to the transplant centre.

This temporal infrastructure will not be sufficient to cope with the population of patients that will require HSCT. The Federal Government will have to build a Stem Cell Transplant complex of international standard to cope with the demand of HSCT in Nigeria.

### **4. SUBSTANDARD AND INADEQUATE EQUIPMENT**

Equipment used for HSCT was hitherto not available in Nigeria. We purchased an Aphaeresis machine for single platelet collecting, Peripheral Stem Cell harvest and plasma Aphaeresis. A platelet storage agitator, a tube sealant, a Hyper-filtration and High pressure machine. Equipment purchased were single units and the centre will require pairs (back-up) for an effective/safe HSCT program as recommended by international standards.

### **5. POOR SUPPORTIVE DIAGNOSTIC UNITS**

For an effective HSCT the diagnostic unit of the hospital especially laboratory and Radio-imaging technique must be standard. In most poor resource countries like Nigeria these units lack modern equipment and those available have no quality control. The hospital purchased another CT scan machine, a Linear accelerator (for radiotherapy), a research laboratory with basic laboratory facility and immune diagnostic machine dedicated to the HSCT to avoid sending samples to the general laboratory.

However viral, fungal, and cytogenetic studies with HLA typing were not available. Samples for HLA typing was sent to Switzerland under a free package cover for the next five years during which period the centre will perfect and improve HLA typing. To avoid fungal and viral infection, patient had to be placed on prophylaxis antifungal and antiviral drugs.

### **6. SELECTION OF PATIENTS/DONOR**

HSCT is a new phenomenon in Nigeria with very little awareness. In selecting the first patient for HSCT in Nigeria we had to consider the infrastructure, equipment and most especially the need of the people to get political and Government support.

Although some authors have recommended that new centers should start with Autologous HSCT and then Allogeneic. Sickle Cell disease with a prevalence of 3% [13] is one of the

greatest challenges of the country. We had to start with Allogeneic for SCD, a genetic disorder that has been shown not to benefit from autologous HSCT. Also we do not currently have facilities for Cryopreservation needed for autologous Transplantation. Most importantly HSCT for sickle cell disease patients will provide the needed financial and political support from the Nigerian Government.

Getting donors was a huge challenge and even relatives were skeptical about donating stem cells for their siblings. This was expected as HSCT was strange in the country and willingness to donate hematopoietic stem cells will not be totally accepted [18]. Sibling donors were considered as the first option since we do not have a donor registry for unrelated donors. After series of education and counseling samples of patients with severe SCD from eleven families were sent to Basel Switzerland for HLA matching with their HbAA sibling donors. However only a seven year old boy with a previous history of Cerebrovascular Accident (CVA) was matched with his 14 years old brother.

This is unlike in most developed centres where donors are now mainly unrelated. The highest number of bone marrow donor registry is that of the USA with 6.4 million donors and the highest per capita was that from Cyprus (10.6% of the population) [19].

## **7. NON AVAILABILITY OF HSCT DRUGS**

Drugs used for induction, condition, immune-suppression and supportive care in HSCT are rare/expensive to procure in developing countries like Nigeria. The process of importation and clearing of drugs by immigration is another hurdle in Nigeria.

We employed the services of a pharmaceutical agent with a license in importing some of these rare drugs but despite this we had difficulties in getting some required rare drugs. This challenge could be improved if the Federal government gives license to the hospital for direct importation of these rare drugs.

## **8. HARVESTING OF STEM CELLS**

There are several approved sources of Hematopoietic Stem Cell which include Bone Marrow, Peripheral blood, Cord blood and Adipose tissue. The current trend in the world is increasing unrelated and peripheral stem cells than bone marrow stem cells. In 2009, world marrow donor association reported increase in unrelated donor transplantation worldwide from 9588 in 2006 to 15,399 (3,445 bone marrow donations, 8162 peripheral blood stem cells donation and 3792 cord blood units) [20].

Bone Marrow Stem Cell has been reported by authors as a better source for HSCT with reduced incidence of GVHD when compared to peripheral stem cells [21]. The transplant unit had no theater but the most modern and sterile theater of the hospital was used for harvesting the Bone Marrow cells. A total of 800mls was harvested from the bone marrow representing a calculated  $9.1 \times 10^8$ /Kg nucleated cells. (There was no CD34 counting machine).

Transfusing a 7 year old child with a total of 900mls of fluid (800mls bone marrow extract and 100mls anticoagulant) over 3 hours was very challenging. We struggled with complications of circulating overload, transient hypertension and risk of Cerebrovascular bleeding. There is need for the hospital to procure the machine for separating Bone Marrow

harvest into CD34 Stem Cells, Plasma and Red Cells. This will reduce the complication associated with transfusing large volume of harvested marrow and anticoagulant.

## **9. POOR SUPPORTIVE CARE AND POWER SUPPLY**

In the management of HSCT especially during the phase of Aphaeresis and other complications, an effective supportive care is necessary, for survival. Effective management of the central venous lines, parenteral nutrition, administration of high dose chemotherapy, mucositis, modified oral feeding, and management of GHVD is a modern challenge. Only two nurses were trained in the management of patients for HSCT and they had to cover the nursing shifts during the first 30days post transplant while training others. We hope to train two nurses yearly for the next five years at Basel hospital to complement the two trained nurses.

A very important indicator of a developing country like Nigeria is the inadequate power supply. For an effective use of a HEPA- filtration and High pressure machine in the isolation rooms, there must be a continuous uninterrupted power supply. The hospital had to provide a diesel generating plant and an inverter battery to provide an alternative power supply for the period of admission for the first HSCT patient. During the phase of changing from public power supply to generator the machines had to be connected to the inverter battery to reduce the interval of no power supply. The federal government should upgrade the public power supply to be regular and efficient but in the interim provide an alternative automatic switch generating plant to provide regular alternative power supply.

Blood products support in most hospitals in Nigeria is insufficient and not readily available. Most donors are still commercial and there are wastages of available blood dispensed as whole blood [22]. We had to set up a blood donor club made up of mainly medical students, nursing students, laboratory and medical workers. Blood products for HSCT patients had to be irradiated with at least 25G. The linear accelerator procured by the hospital had no license to operate and we had to take our blood products to the nearest Hospital (300km from Benin) for irradiation. The blood products were transported by an Ambulance vehicle with its air conditioner on to get a temperature of 25°C for platelets concentrate loaded in an agitator. Also the packed red cell was put in a small Refrigerator and both machines powered by an inverter battery loaded in the Ambulance.

## **10. POVERTY AND INEFFECTIVE HEALTH INSURANCE SYSTEM**

The income of an average Nigerian low (GNI per capita of \$2500 per annum in 2010) [23]. The Health Insurance policy is only for those working with the government but does not cover for malignancies or Stem Cell Transplantation. The estimated cost for the first transplanted patient was about five (N5) million Naira which was paid for by the Hospital. This bill is beyond the reach of most Nigerians and will require the assistance of NGO's and Government to subsidize the cost for HSCT. On the long run an efficient health insurance system that will cover HSCT will be the best option. These challenges are not different from the global perspective analysis that showed that increased Government health care expenditure and NGI per capital is a very important factor for setting up HSCT centres.

## **11. CONCLUSIONS**

HSCT is curative for some malignant and non-malignant diseases; however in setting up the first stem cell transplant centre in a developing poor resource country has several challenges. However we ensured that the basic needs for a successful HSCT which include HLA typing (typed in Switzerland), sterile isolation rooms with generator power backup, sterile harvesting of bone marrow stem cells in theater, standard protocol for induction chemotherapy/immunosuppression, irradiation of blood products were available. With improved power supply, continuous manpower training, improved supportive care and efficient health care system, HSCT in Nigeria could be improved to international standards and made affordable and assessable to Nigerians who need HSCT.

## **CONSENT**

Not applicable.

## **ETHICAL APPROVAL**

Not applicable.

## **COMPETING INTERESTS**

Author has declared that no competing interests exist.

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