

OPENING ADDRESS BY
Y. BHG. TAN SRI DATO' SERI DR. HJ. MOHD ISMAIL MERICAN
DIRECTOR-GENERAL OF HEALTH MALAYSIA
ON THE OCCASION OF
MEETING ON WHO GUIDING PRINCIPLES ON HUMAN ORGAN
TRANSPLANTATION

@ Le Meridian, Kuala Lumpur on 8th June 2009

Thank you Mr/Ms Chairperson,

(Salutations)

Dr Han Tieru, WHO Representative in Malaysia, Brunei and Singapore

Prof Dr Jeremy Chapman, President of The Transplantation Society

Datuk Dr Harjit Singh, President of the Malaysian Society of Transplantation

Distinguished advisers and participants,

Ladies and Gentlemen,

Assalaamu'alaikum and a very good morning,

It is indeed a great pleasure for me to be here amongst such a distinguished audience on this significant day in the annals of the Ministry of Health Malaysia.

Today's occasion is the first ever **Regional Meeting on the WHO's Guiding Principles on Human Organ Transplantation** to be held in Malaysia. The meeting

is jointly organised by the WHO and the Malaysian Society of Transplantation, and ably supported by the Ministry of Health of Malaysia. I am especially delighted that the distinguished advisers at this meeting are “giants” in this very important field of Medicine. This Regional Meeting is very apt, in view of the increasing prominence of organ transplantation in the prolongation of life or maintenance of survival, as well as the improvement of quality of life for many patients who are unfortunate enough to suffer from end-stage failure of their various organ systems.

I am thus very pleased to be in the company of so many committed healthcare professionals and policy makers who have gathered here to participate in the commendable and time-honoured professional practice of “sharing in the pursuit of high quality caring”. We in the health care profession have traditionally used the sharing of information to build a healthier and better world. With this sharing, we hope to gain better insights into the intricacies and implications of the *Revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, a valuable resource indeed to many countries in the world, that have moulded their policies and practices based on the invaluable principles contained in these Guidelines. In the next three days, we will share and be oriented to the revised WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation;

identify gaps and draft follow-up action points for strengthening legislation, regulations and ethics in organ transplantation as well as update ourselves on tissue banking and xeno-transplantation

Ladies and gentlemen,

It is a well-known saying by Benjamin Franklin, the renowned American scientist that *“God Heals and the Doctor takes the fee”*. However, this is done in an ethical and responsible as well as transparent manner. Compare this with trade in organs where *“Organs fail and the profiteer takes the fee”*, which is a highly undesirable situation; one that is abhorred because it involves exchange of money for vital organs, leading to many undesirable ramifications such as *“Transplant Tourism”* and trafficking in human organs.

The dawn of the new millennium has heralded exciting times for the world, which has been moulded and shaped by the impressive advancements in science and technology. In fact, Freeman Dyson was quoted to have said that *“Technology is a gift of God. After the gift of life it is perhaps the greatest of God's gifts. It is the mother of civilizations, of arts and of sciences”*. We have, at our service, Transplantation Technology, which is a powerful tool to do good, and this is

further reinforced by Evan Bayh's statement that *"In recent years, we have seen technology advance at lightning speed, allowing us to accomplish life-saving feats never imagined before. It is our responsibility to ensure that these advances are used for positive medical breakthroughs..."* and may I add, the benefit of humankind in an ethical and responsible manner that is far above financial issues because the market has no morals. It is up to us to impose morals on the market to ensure that the medical world is not a jungle, where only the fittest survive and the unfortunate lose out in the scheme of things. This is highly applicable to the issues that are plaguing transplantation technology, which we are here to discuss and find solutions to.

Ladies and gentlemen,

The transplantation of human organs, tissues or cells is now regarded as the best and preferred treatment of choice for a wide range of diseases which have no realistically effective alternative, in particular end-stage organ failures such as end-stage renal failure and end-stage heart failure. Rapid advancements in medical technologies are resulting in better care, leading to enhanced survival prospects for transplant patients. In addition, life-style related chronic diseases of affluence have resulted in the explosion of diseases resulting in end-stage organ

failure in many countries in the world. This has led to astronomical levels of demand for organs globally, one that cannot be met any time soon. Countries are struggling to attain self-sufficiency in the availability of organs for transplantation. It is in this unfortunate situation that unethical market practices such as transplant tourism and human trafficking are rearing their ugly heads. It is our duty to decapitate these ugly heads and restore order, equity and accountability to the practice of organ transplantation. Which is why, the WHO, in its wisdom, has prepared and promulgated the revised Guiding Principles on Human Organ Transplantation.

Ladies and Gentlemen,

Ever since the establishment and general acceptance of organ transplantation as a viable treatment for the various end-stage organ failures, ethical and moral issues as well as concerns about human rights violations have consistently plagued this very important means of sustaining life for patients with end-stage organ failure. Ethical issues relate to organ donation and allocation, in particular those involving live donors. Issues relating to live donors have emerged in the context of non-maleficence of live donors who run the the risk of mortality as well as physical and psychological morbidity. Life, ladies and gentlemen, is about balancing risks with benefits. And so it is with organ transplantation. The risks to

the donor are normally minimal, with some studies reporting a mortality rate of about 0.03%, although if any concern exists that the potential donor may undergo more than the minimum risk, the surgery shall not be carried out.

In addition, moral issues also involve the allocation of organs to recipients, the shared problem of shortage of organs available for transplantation, commercialisation of organ donation and the emerging concerns regarding *transplant tourism*. Worldwide, there have been attempts to regulate the unbridled commercialisation with various strategies, proposals and mechanisms to “introduce morals into the market”. However, the ingenuity of regulated “*organ entrepreneurs*” knows no bounds and we have witnessed their many creative solutions” to the regulatory efforts of Government agencies to make organ transplantation a safe, ethical and transparent process. In addition, the notion of obtaining organs from non-human donors i.e. xeno-transplantation and human cloning for organ harvesting are already becoming exciting but contentious issues.

Ladies and Gentlemen,

Over the past few decades, we in Malaysia have witnessed rapid socio-economic development and this has led to changes in the health care needs and expectations of the public. The Ministry of Health Malaysia is the principal agency responsible for the Herculean task of developing, providing, monitoring and improving healthcare services. We have been cognisant of these changes and continue to endeavour to be responsive to the needs of the population. Previously we had dealt successfully with traditional public health concerns such as infections, but currently are facing the challenges of “new public health problems” such as the life-style related chronic diseases, which require tremendous coordinated effort to prevent and treat. We can be proud of the fact that we have a relatively balanced health care system that gives priority to health promotion and primary prevention as well as secondary and tertiary care. However, despite our intensified efforts, we cannot but acknowledge that more resources are now needed to address the sequelae of these diseases including organ failure. The management of the various types of end-stage organ failure requires costly technology-dependent interventions such as organ transplantation. Because we have a caring Government that gives priority to its people and performance (“People First, Performance Now”), such programmes are given full support by the Government despite consuming a disproportionate share of the health care budget. This is the Malaysian Government’s commitment

to the people of Malaysia, to ensure that we have a healthy nation and a productive workforce.

Ladies and Gentlemen,

Allow me take you on a trip down memory lane... In Malaysia, the transplantation services started in the 1970's with corneal transplantations. The first solid organ transplantation was performed in Kuala Lumpur Hospital in 1975 involving the kidney, 20 years after the world's first kidney transplantation in the United States. We in the MOH are keen to ensure that our transplantation services are at par with the best in the world and we are making every effort to ensure that this becomes a reality in the near future. In the last 3 decades, we have seen major improvements in graft and patient survival rates for kidney transplants, the publication of annual reports of the National Transplant Registry since 2004, the setting up of a well-equipped liver and kidney transplant centre in Selayang Hospital, as well as the country's first lung transplantation in 2005. In addition, the National Organ, Tissue and Cell Transplantation Policy was formulated in 2007 to support an official National Transplantation Programme, complete with its own dedicated budget. The policy provides guidance towards attaining the highest professional and ethical standards in the field of transplantation. Furthermore, it also addresses the needs for adequate resources, properly

trained and credentialed personnel and the organisational structure needed to operate a national programme effectively and efficiently.

The implementation of Malaysia's National Transplant Programme is based on five thrusts viz:

1. Strengthening the organizational structure;
2. Improving the organ and tissue donation rate;
3. Consolidating the existing transplantation services;
4. Consolidating the clinical support services;
5. Strengthening the legal and ethical framework.

I am confident that with the adoption of the policy together and with the execution of these five thrusts, the transplantation programme in Malaysia will go from strength to strength.

Ladies and Gentlemen,

These initiatives undertaken by Malaysia have come at an opportune moment as the WHO has been similarly taking steps to assist countries to improve their transplantation programme. WHO has entered into a solid partnership with The Transplantation Society. Its President, Prof Dr Jeremy Chapman, is here with us

today. Thus, the Global Alliance for Transplantation (GAT) has been conceived to promote organ and tissue transplantation worldwide. The goal of the GAT is to provide access to transplantation for all patients in need. We are proud that Malaysia is more than prepared to pool resources and provide its support towards achieving this worthy objective. We are fully supportive of all WHO's commendable efforts.

A few months ago, I wrote to Prof Chapman, in my capacity as DG of Health, to support the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, which is an important proclamation of the ethical principles and practices also adopted by this country. Malaysia also fully endorses the WHO's Guiding Principles on Human Organ and Tissue Transplantation and I am happy to note that we have complied with almost all of the 11 Guiding Principles through our various Acts and policies as well as practices. We have adopted the Guiding Principles in the formulation of our National Organ, Tissue and Cell Transplantation Policy. We have put in place efforts to foster public awareness and understanding of the benefits of a voluntary non-remunerated organ, tissue and cell donation, compared with the multi-faceted risks caused by organ trafficking and transplant tourism. We oppose the unfair seeking of financial gain or comparable advantage in any transactions involving human body parts. As

much as possible, we have practised equitable access to our transplantation services in accordance with our capacities. We constantly insist on international best practices to improve the safety and efficacy of donation and transplantation. Additionally, we have strengthened our national authorities to provide the necessary oversight, organisation and coordination of donation and transplantation activities. In addition, we are willing to collaborate in collecting data including adverse events and reactions on the practices, safety, quality, epidemiology and ethics of organ, tissue and cell donation and transplantation.

Ladies and Gentlemen,

Despite all our concerted efforts, the various issues associated with transplantation will continue to figure prominently in the years to come. The continued commercialisation of transplantation and the shortage of organs will pose major challenges to ethics and the way transplantation will develop in the future. Further advancements in this field, particularly the availability of new organs and tissues through genetic engineering or cloning for xeno-transplantation will pose concerns for the international community that is struggling to come to terms with the enormous issues that surround medical technologies such as organ transplantation. Therefore it is hoped that today's meeting will provide valuable insights on our we should address these issues.

Before I close, I would also like express my vote of appreciation and also congratulate Datuk Dr Harjit Singh, President of the Malaysian Society of Transplantation and the organizing committee for their diligence and efforts in ensuring that this meeting is a huge success. Our country is always supportive of the various activities carried out by the WHO, especially when it provides the country with an opportunity to collaborate with several of our neighbours here in the Western Pacific region. In the spirit of “Teamwork” which, I may add, is a core value of the Ministry of Health, I am confident that there is a lot more that we can strive together in terms of networking and cooperation to improve the overall health status, as well as formulate solutions for distinctive issues within the region.

It is my earnest hope that all of you achieve the objectives of this meeting. May I also invite you to visit our tourist spots and taste our multiethnic cuisine and discover for yourself why ‘Malaysia is truly Asia’. Do enjoy your stay here in Malaysia.

It is with great pleasure that I now declare this meeting officially open. Thank you.