International Technical Consultation on Cell, Tissue and Organ Donation/Transplantation in the Western Pacific Region

20–21 February 2014
Seoul, Republic of Korea
International Technical Consultation on Cell, Tissue and Organ Transplantation
20-21 February 2014, Seoul, Republic of Korea
INTERNATIONAL TECHNICAL CONSULTATION ON CELL, TISSUE AND ORGAN DONATION/TRANSPLANTATION IN THE WESTERN PACIFIC REGION

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NOTE

The views expressed in this report are those of the participants of the International Consultation on Cell, Tissue and Organ Donation/Transplantation in the Western Pacific Region and do not necessarily reflect the policy of the World Health Organization.

The report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the International Technical Consultation on Cell, Tissue and Organ Donation/Transplantation in the Western Pacific Region, 20-21 February 2014, Seoul, Republic of Korea.
# CONTENTS

1. INTRODUCTION ............................................................................................................... 3  
   1.1 Background ................................................................................................................ 3  
   1.2 Objectives ................................................................................................................ 3  
   1.3 Participants .............................................................................................................. 4  
   1.4 Organization and content .............................................................................................. 4  
   1.5 Opening remarks ........................................................................................................... 4  
   1.6 Appointment of Chairperson and Rapporteurs ............................................................. 5  

2. PROCEEDINGS ...................................................................................................................... 5  
   2.1 Self-sufficiency and the WHO initiative for Medical Products of Human Origin  
      (Dr Luc Noel, WHO/HQ) ............................................................................................. 5  
   2.2 Update on WHO activities and priorities in cell, tissues and organ transplantation  
      (Dr Jose Ramon Nuñez) ................................................................................................ 6  
   2.3 Essential legal and organizational requirements for national cell, tissue and organ  
      transplantation services (Professor Jeremy Chapman) ................................................. 8  
   2.4 Matching Global Observatory on Donation and Transplantation data with country  
      reports on activities and practices (Ms Mar Carmona) ............................................... 10  
   2.5 Regional experience in the development of organ donation after death -  
      achievement in the Republic of Korea (Dr Cho Won-Hyun) ........................................ 15  
   2.6 Plans for increasing organ donation after death in Japan (Dr Naoshi Shinozaki) ..... 17  
   2.7 WHO role in encouraging organ donation after death (Dr Jose Nunez) ................. 18  
   2.8 Role of vigilance and surveillance, project NOTIFY (Dr Luc Noel) ............................ 19  
   2.9 Information standard for blood and transplant ISBT128 (Mr Paul Ashford) .......... 21  
   2.10 The Council of Europe European Committee on Organ Transplantation  
       (CD-P-TO) (Dr Marta Fraga) .................................................................................... 22  
   2.11 The Latin American Council (Dr Elizabeth Coll) ...................................................... 24  
   2.12 The Role of Professionals Societies in the Development of Transplantation  
       (Dr Phillip O’Connell) ............................................................................................... 25  
   2.13 Visit of Dr Shin Young-soo – WHO Regional Director ......................................... 26  
   2.14 General discussion, conclusions and Plan of Action ................................................. 26  

3. CONCLUSION AND PLAN OF ACTION ........................................................................... 29  

4. CLOSING ............................................................................................................................. 29
ANNEXES:

ANNEX 1  -  LIST OF TEMPORARY ADVISERS AND SECRETARIAT
ANNEX 2  -  TIMETABLE
ANNEX 3  -  SPEECH OF DR SHIN YOUNG-SOO, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC
ANNEX 4  -  PRESENTATIONS

Keywords:

Organ transplantation / Tissue and organ procurement / Transplantation – standards
1. INTRODUCTION

1.1 Background

Transplantation of cells, tissues and organs prolongs and improve quality of life. Transplantation activity has steadily increased worldwide in recent years. Globally, it is estimated that 78,000 kidney, 24,000 liver, 6,000 heart, 4,600 lung, 2,400 pancreas and 170 small bowel transplantations were performed in 2012 (GODT website).

Unfortunately, end stage organ failure is also increasing, leading to significant unmet need. It is estimated that the nearly 115,000 solid organ transplants performed in 2012 represents less than 10% of the global requirement for organs (GODT website).

Countries therefore develop policies and systems to increase organs available for transplantation from living and deceased donors. The WHO has promoted ethical transplantation practices globally, first through the production of the “Guiding Principles on Human Organ Transplantation” in 1991, which were revised through World Health Assembly Resolution 63.22 dated 21 May 2010 entitled Human organ and tissue transplantation.

To date, transplantation practice in the Western Pacific Region has developed unevenly. Some countries in the Region have highly-developed nationally coordinated living and deceased donation programmes within appropriate legal and regulatory oversight, and world leading outcomes. Others countries have limited or no transplantation, or small unregulated programmes within single hospitals with limited data available on outcomes. Some countries have had to confront unethical practices.

A regional meeting was arranged in Seoul, Republic of Korea, on 20 and 21 February 2014, to discuss progress in countries of the Western Pacific Region and to enable exchange of ideas for promoting increased transplantation within recommended frameworks.

1.2 Objectives

The objectives of the consultation were:

(1) to discuss how to improve data collection and information sharing on cell, tissue and organ donation/transplantation in the Western Pacific region to ensure transparency and accountability of national authorities;

(2) to review the needs for national legislative frameworks and regulatory oversight regarding tissue and organ donation after death and make recommendations on how to strengthen these; and

(3) to discuss options for forming a regional expert group to promote collaboration, information sharing between national health authorities responsible for cell, tissue and organ donation and transplantation.
1.3 Participants

Twenty-one temporary advisers from countries currently undertaking organ transplantation including, Australia, China, Japan, New Zealand, Malaysia, Mongolia, Philippines, Republic of Korea, Singapore and Viet Nam attended the meeting. Also represented were bodies working to promote transplantation and information exchange within transplantation practice including the International Council for Commonality in Blood Banking Automation, the Council of Europe, the Transplantation Society and the Spanish Ministry of Health National Organisation of Transplants. A WHO Secretariat team from headquarters and the Western Pacific Regional Office also attended (Annex 1).

1.4 Organization and content

The meeting was held over two days. On the first day, after a formal welcome and photograph, the first session provided background from the WHO secretariat and included updates on WHO initiative for Medical Products of Human Origin. The second session was about legal organizational requirements for ethical transplantation practice, after which participants reported on the situation in individual countries including legal and regulatory structures and donor and transplant numbers by organ and donor source. The third session covered regional experiences in the development of donation after death and included updates from Republic of Korea, China and Japan.

The second day commenced with a session on global governance tools for donation and transplantation. The second session was about regional and subregional fora for health authorities in transplantation and covered the Council of Europe projects in the Black Sea region, and the Latin American Council. The final session provided a chance to discuss the role of scientific and professional societies, to have some general discussion about the content of the meeting and to conclude the meeting with resolutions for action. The workshop agenda is Annex 2.

1.5 Opening remarks

On behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific, Dr Klara Tisocki, Team Leader, Essential Medicines and Health Technologies, WHO Western Pacific Regional Office welcomed participants. She thanked the Government of the Republic of Korea, Vitallink and the Transplantation Society for hosting and co-organizing the meeting. Dr Luc Noel, Special Advisor, WHO headquarters, delivered the opening remarks placing this meeting in the context of previous consultations in the Region, commencing with the WHO Consultation Meeting on Transplantation with Western Health Authorities in the Western Pacific Region in Manila in 2005. Dr Noel also recalled the key contribution to earlier meetings of Professor Carl Groth who passed away in February 2014. Professor Jeremy Chapman (Australia) was invited to make some comments and noted that Professor Groth had been one of the first to elucidate ideas about overcoming shortage of organs for transplantation globally.
1.6 **Appointment of Chairperson and Rapporteurs**

The meeting participants elected Dr Cho Won-Hyun (Republic of Korea) as Chairperson, while Dr Nicholas Cross (New Zealand) and Dr Hirman Ismail (Malaysia) were asked to act as Rapporteurs.

2. **PROCEEDINGS**

2.1 **Self-sufficiency and the WHO initiative for Medical Products of Human Origin**  
(Dr Luc Noel, WHO/HQ)

Dr Luc Noel outlined the process that WHO has been undertaking since 2004, when issues and challenges in transplantation were discussed at the World Health Assembly (WHA). The WHA urged Member States to implement effective national oversight of procurement, processing and transplantation of human cells, tissues and organs, including ensuring accountability for human material and its traceability. Subsequently, WHO has been engaging health authorities, scientific and professional societies, experts, donors and recipients, and members of societies with the goal of fostering a common global attitude to transplantation.

Dr Noel also outlined the discrepancies apparent globally in access to transplantation. High-activity countries perform more than 70 transplantations per million population (pmp), whereas some countries have no access to transplantation. Issues specific to Asia include the high prevalence of viral hepatitis, leading to high rates of end stage liver failure, and a very large burden of end stage kidney disease (one quarter of the world’s dialysis patients live in Japan and China).

Dr Noel defined the self-sufficiency paradigm in transplantation — meeting the needs of patients from a given population with an adequate provision of transplantation services and supply of organs from that population. Self-sufficiency relies on increasing supply of transplantable organs, and reducing demand by prevention of end stage organ failure. For most countries in the Western Pacific this may seem a distant goal, but Dr Noel noted that in 2011, a handful of countries internationally (including Croatia, Norway, Portugal and Australia) provided kidney transplants to more patients that were added to the waiting list in those countries in that year.

There are four key principles underpinning the self-sufficiency paradigm:

1. **Government responsibility** – national governments are responsible for achieving self-sufficiency in transplantation.

2. **Equity** – the burden of donation should be equitable across a population, not isolated to subsections. There should also be equity of access to organs for transplantation.

3. **Education** – populations should be educated about the need for transplantation and donation, and also around prevention of end stage organ failure. Education should be via school curricula, media and health professionals.
Dr Noel described the WHO worldwide initiative on medical products of human origin (MPHO). MPHO are materials derived from the human body for clinical therapeutic application. This broad definition includes blood and blood products, cells, tissues, organs, gametes and embryos, secretions (for example, breast milk), and advanced cellular therapies developed *ex vivo*.

A key concept underlying the use of MPHO is recognition of their inherent humanity. Use of MPHO should be grounded in respect for the human body and dignity of persons (donors and recipients) involved. WHO is working towards standards of practice for MPHO including:

1. Responsibility of government authorities for provision of MPHO;
2. Equity – burden of donation and in allocation;
3. Prohibition of financial gain – or where profit is not forbidden (for some MPHO), guarantee of transparency
4. Genuine consent – donors and recipients
5. Justified use of MPHO – backed by scientific evidence and in the absence of a comparable alternative
6. Duty to constantly optimize – safety, quality, efficiency of procurement, process and clinical application of MPHO. This includes global vigilance and surveillance for outcomes via registries including the NOTIFY project
7. Traceability and accountability – including broadening the use of ISBT128 labelling standard (initially developed for blood and blood product labelling) to include all MPHO
8. Transparency – openness to scrutiny, while maintaining confidentiality and anonymity of individuals

2.2 Update on WHO activities and priorities in cell, tissues and organ transplantation (Dr Jose Ramon Nuñez)

Dr Jose Nuñez (WHO/HQ) presented data from the Global Observatory on Organ Donation and Transplantation. In 2012, approximately 114,700 solid organs were transplanted, an increase of 1.81% in 2011.

<table>
<thead>
<tr>
<th></th>
<th>Kidney</th>
<th>Liver</th>
<th>Heart</th>
<th>Lung</th>
<th>Pancreas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Values</td>
<td>77818</td>
<td>23986</td>
<td>5935</td>
<td>4359</td>
<td>2423</td>
</tr>
</tbody>
</table>
There are approximately 1.9 million tissue grafts distributed from AATB accredited tissue banks each year, including more than 200,000 tissue grafts in Germany and 500 cornea transplants in Italy each year.

There are more than 50,000 haemopoietic stem cell transplants per year globally. There are 22 million donors registered.

Dr Nunez noted that Asia has typically low deceased donation rates, and low numbers of haemopoietic cell transplants performed per capita.

It was noted that countries need to learn from activities in different regions, while recognizing the different realities within each countries context.

The priorities for WHO in this area include:

1. Guidance on the determination of death. This has commenced with meetings in Switzerland in 2010 and Canada in 2012. The next steps include a systematic review of the scientific literature and regional consultations with experts.

2. Increasing the global visibility of the Global Observatory on Donation and Transplantation.

3. Vigilance and surveillance, using the Notify Library.

4. Strengthen collaboration within regions, including within the Western Pacific.

Discussion

Dr Vathsala (Singapore) noted that religious and societal differences in some countries within the Western Pacific make concepts of death different from other parts of the world, impacting deceased donation rates. She asked if religious consultation had been part of the work on determination of death. Dr Nunez responded that the WHO's goal is to clarify the technical and medical aspects of death to produce guidance which each country could use for development of local policies, rather than focusing on religious, bioethical or societal impacts on death.

Dr Vathsala also asked whether there had been any indication that governments within the Western Pacific Region were interested in collaboration on this issue. Dr Nunez responded that this was a work in progress and there had not been much as yet. Dr Noel noted that some countries had indicated keenness within the region to tackle issues in this area, including China’s progress at addressing deceased donation. Dr Noel noted that the WHO Regional Office for the Western Pacific could help facilitate change.

Dr Curie (Republic of Korea) noted that there was great geopolitical and social variability in the Western Pacific Region which might make cooperation difficult. Dr Nunez felt that it would be possible for countries with issues to learn from other countries within the region where challenges in organ donation and transplantation were being successfully overcome. Dr Tisocki agreed that the heterogeneous nature of the countries within the Western Pacific Region did cause challenges, and suggested that potentially small groups of similar countries or bilateral collaborations could also be helpful (including with countries who are not within the Western Pacific Region, if necessary).
Dr Cho (Republic of Korea) noted that the issues facing individual countries were in fact global ones – if developing countries did not address issues they had the potential to affect others.

2.3 Essential legal and organisational requirements for national cell, tissue and organ transplantation services (Professor Jeremy Chapman)

Professor Jeremy Chapman (Australia) presented the framework required for both deceased and living donor transplantation services. The framework is established by the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (ratified by the 62nd World Health Assembly on 21 May 2010), the Declaration of Istanbul and the Madrid Resolution.

Professor Chapman noted that there are legal and regulatory requirements, that health authorities and governments need to address (via appropriate legislation and regulation), and then there are process elements that need addressing from a medical perspective (via appropriate medical protocols).

He used kidney transplantation as an example, and illustrated the process for living donor transplantation first:

He noted that deceased donation services are more organizationally complex, as they require additional structures for identification and management of donors, and chronic dialysis programme pool of potential recipients, organ retrieval services and allocation protocols.
A good legal framework is the fundamental first step. There are multiple elements which may be contained in several laws including:

1) ownership and gift laws;
2) therapeutic goods laws/regulations;
3) private health care laws/regulations;
4) customs and excise laws/regulations;
5) consent frameworks; and
6) definitions of nationality

There are fundamental issues that need to be addressed in transplantation laws in each jurisdiction. These issues should be resolved with reference to the Guiding Principles and the Declaration of Istanbul, and include:

1) The extent of inclusion of all Medical Products of Human Origin
2) The basis of consent for deceased donation (presumed consent vs explicit consent; first person consent)
3) The definition of death
All elements of transplantation practice should be covered, including parts that are not intended to be provided, either initially or at all, to ensure there is protection for the population from the development of unethical or dangerous practices.

**Discussion**

Dr Cho (Republic of Korea) noted that questions in this area are complex and can only be addressed through discussions at national level within each country. Professor Philip O’Connell (Australia/TTS) agreed but noted that the complexity is universal and individual jurisdictions could learn from others particularly at a legal level for what needs to be covered.

Professor Chapman also noted that governments can collaborate with each other in this area and that the New South Wales (Australia) is an example of a local government that had provided assistance to other local governments. He also noted that the initial questions are political – individual governments have to decide what types of transplantation services they are willing and able to support. Once this is clear, the legal, regulatory and clinical pathways need to follow.

2.4 Matching Global Observatory on Donation and Transplantation data with country reports on activities and practices (Ms Mar Carmona)

Ms Mar Carmona (ONT, Spain) presented the initial data for this session and chaired the session as the temporary advisers reported on the situation in individual countries.

The World Health Assembly resolution WHA63.22 (May 2010) urged Member States to collaborate on collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology and ethics of donation and transplantation. The Organización Nacional de Trasplantes (ONT) has been designated as a WHO Collaborating Centre to accomplish this.

GODT covers the 194 WHO Member States and currently contains information on legislative and organizational aspects, and annual donation and transplantation activities. Data is sourced from national authorities, or official designated authorities.

Data is collected by questionnaires from national focal point individuals within countries. Ms Carmona noted that it was important that there was collaboration between national health authorities and professionals in providing this data.

Data is analyzed and graphics and official maps are produced. The analysis is published on the GODT website which is freely available, and via presentations and journal publications.

For this session, the questionnaire used was provided to a representative from each country for completion before the meeting, to enable comparison with the data the ONT have collected.

Individual country data was presented for the remainder of the session as well as subsequent session. This was collated and summarized by Ms Carmona and then fed back to participants. Reports were received from Australia, China, Japan, Malaysia, Mongolia, New Zealand, the Philippines, Republic of Korea, Singapore and Viet Nam. Ms Carmona also presented data on Fiji.
2.4.1. Functioning transplant programme

All participating countries that reported have functioning solid organ transplantation programmes with living and deceased donation, except for Mongolia which only has a living donor programme, and Fiji which has no transplant programme.

2.4.2. Donation and transplantation activity

Table 1: Transplantation activity by donor source, organ type, year and country

<table>
<thead>
<tr>
<th></th>
<th>AUS</th>
<th>CHN</th>
<th>JPN</th>
<th>MYS</th>
<th>MNG</th>
<th>NZL</th>
<th>PHL</th>
<th>KOR</th>
<th>SGP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All Deceased donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DBD</td>
<td>354</td>
<td>110</td>
<td>18</td>
<td>0</td>
<td>38</td>
<td>43</td>
<td>459</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>DCD</td>
<td>277</td>
<td>45</td>
<td>18</td>
<td>0</td>
<td>38</td>
<td>43</td>
<td>458</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>All DD Kidney</td>
<td>606</td>
<td>457</td>
<td>193</td>
<td>29</td>
<td>0</td>
<td>54</td>
<td>86</td>
<td>768</td>
<td>23</td>
</tr>
<tr>
<td>DBD Kidney</td>
<td>477</td>
<td>77</td>
<td>29</td>
<td>0</td>
<td>54</td>
<td>86</td>
<td>766</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>DCD Kidney</td>
<td>129</td>
<td>116</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All LD Kidney</td>
<td>237</td>
<td>963</td>
<td>141</td>
<td>22</td>
<td>12</td>
<td>54</td>
<td>299</td>
<td>1015</td>
<td>24</td>
</tr>
<tr>
<td>Unrelated</td>
<td>28</td>
<td>0</td>
<td>559</td>
<td>0</td>
<td>22</td>
<td>149</td>
<td>35</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Related</td>
<td>209</td>
<td>853</td>
<td>22</td>
<td>12</td>
<td>150</td>
<td>980</td>
<td>20</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All DD Liver</td>
<td>227</td>
<td>2082</td>
<td>41</td>
<td>7</td>
<td>0</td>
<td>32</td>
<td>363</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>DBD Liver</td>
<td>210</td>
<td>41</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>363</td>
<td>11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCD Liver</td>
<td>17</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All LD Liver</td>
<td>4</td>
<td>62</td>
<td>382</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td>897</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Heart</td>
<td>76</td>
<td>147</td>
<td>28</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>107</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Lung</td>
<td>148</td>
<td>33</td>
<td>44</td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>37</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Pancreas</td>
<td>38</td>
<td>27</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>34</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DBD = donation after brain death; DCD = donation after cardiac death; DD = deceased donor; LD = living donor
2.4.3 Legislation

All participating countries except Fiji reported that donation and/or transplantation is covered by legal requirements. Legal requirements vary:

Table 2: Aspects of donation/transplantation covered by legislation by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Deceased donation</th>
<th>Living donation</th>
<th>Allocation</th>
<th>Organ transplantation</th>
<th>Organ Trafficking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>China</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Japan</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Mongolia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Rep. of Korea</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Singapore</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Living unrelated donation is permitted in all participating countries except China.

It is a legal requirement to report all transplantation activities in all participating countries except Australia, Malaysia and Mongolia. China, Japan, Republic of Korea and Viet Nam require centres to report deceased donors.

All participating countries except New Zealand and Singapore report intent to adopt or revise legal requirements.

2.4.4 Financial incentives

Incentives to obtain consent for deceased donation are permitted in the Philippines and the Republic of Korea, but prohibited in other countries.

Financial incentives are permitted for living donors in the Philippines and the Republic Korea only. However, in the Republic of Korea, incentives are regulated by the government but not in the Philippines.
China reports that living donors are prioritized in organ allocation if they subsequently require a transplant.

2.4.5 Organ trafficking

Explicit legal prohibition of, and penalties for, organ trafficking and transplant tourism exists in all countries except Malaysia and Mongolia.

2.4.6 Organizational system

All participating countries have a government-recognized authority responsible for overseeing donation and/or transplantation, except Fiji (which has neither) and New Zealand, which has an authority responsible for overseeing donation but not transplantation. All countries have organizations, institutions or agencies responsible for performance of organ donation and/or transplantation, and all report to the respective Ministries of Health (except Fiji).

2.4.7 Coverage of costs

There is variability in how donation and transplantation activity is funded among countries, with most countries relying on a variety of sources. In most countries, recipients meet the costs of post transplant care and drugs, either entirely (China, Fiji, the Philippines) or in part (Australia, Japan, Republic of Korea, Singapore, Viet Nam).

Table 3: Coverage of Organ Procurement Costs by Country

<table>
<thead>
<tr>
<th>Country</th>
<th>State</th>
<th>Private Health Insurance</th>
<th>Recipients</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Fiji</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Overseas hospital offering service</td>
</tr>
<tr>
<td>Japan</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Government funding to Japan Organ Transplant Network (JOT)</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Mongolia</td>
<td>-</td>
<td>-</td>
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**Table 4: Coverage of Transplantation Costs by Country**

2.4.8 Transplantation provided abroad

Only Australia reported a formal framework for providing transplantation for Australian permanent residents in other countries (the national Medical Treatment Overseas Programme). This is used by Australians requiring transplants not provided in Australia, for example, complex small bowel transplantation.

For citizens undergoing transplantation abroad, or donating organs abroad, health care is assured on return to home nation in Australia, China, Malaysia, Mongolia, New Zealand, Philippines, and Viet Nam. In Fiji, Japan and Republic of Korea, a report follow-up is not assured on return.

Australia, Fiji, Mongolia, the Philippines and Viet Nam report that living donor-recipient pairs travel overseas to access transplantation in some circumstances.
Discussion

Dr Vathsala noted that the interpretation of ‘incentive’ varies between reporters and that reimbursement for medical care and funeral costs with respect to deceased donors should not be defined as an ‘incentive’. She asked for clarification from the WHO secretariat on this. Dr Noel responded that for those in financial need authorities should meet funeral costs and that a ‘common sense’ approach was needed to define incentives from reimbursement of costs.

Dr Cho noted that Australia had many more lung transplants per capita than other countries in the Western Pacific Region. Dr O’Connell responded that this was due to two factors – sophisticated pre-transplantation \textit{ex vivo} reconditioning work being undertaken at the Melbourne transplant unit (enabling use of lungs that may otherwise have been discarded) and the high prevalence of cystic fibrosis in European Australians.

Dr O’Connell asked if the Chinese donation allocation was performed centrally or locally. Dr Liu responded that China has a central allocation scheme (although this does not apply to organs from executed prisoners).

Dr Noel asked if there was increased training in China for transplant teams. Dr Liu confirmed this was being undertaken, with the assistance of the Chinese Red Cross.

Dr Tisocki asked Dr Vathsala to clarify if there had been any prosecutions in Singapore for violation of regulations around the use of living donors. Dr Vathsala is only aware of one prosecution, and also noted that the application of the regulation relies on the ethical standards of the professionals involved.

Dr Cho asked how many transplant surgeons are in Viet Nam and Dr Phuc responded that there are approximately 10.

2.5 Regional experience in the development of organ donation after death - achievement in the Republic of Korea (Dr Cho Won-Hyun)

Deceased donation rates in the Republic of Korea have remained very low (<3 donors pmp) since the 1970s. From the late 1990s, a series of legislative and structural changes took place to address this, including brain death legislation (1999), prohibition of organ trade within the Republic of Korea (2000), creation of a nationwide organ waiting list and allocation system (Korean Network for Organ Sharing (KONOS), 2000) and creation of hospital based organ procurement organizations (2003).

Structural change was insufficient to achieve increased transplantation initially. Medical changes were required including cooperation during procurement between medical centres, and revision of the allocation system. Social change was directed at increasing awareness and consensus within the population in favour of organ donation. There was an expanded campaign that focused on students, engagement with community agencies including the Police, Ministry of Health, Congress, and engagement of media. Organ donation campaigns were undertaken by cooperating nongovernmental organizations, including Vitallink, which joined together as the Korean Organ Donation Network (KoDoNet).

Improvements in the donation rate after death is the result of a sustained, broad effort.
**Discussion**

Professor O'Connell noted that the Republic of Korea and Australia are very different culturally, but that the progress made in both countries has been achieved with similar reform.

Professor Chapman noted the substantial (approximately 2/3) reduction in the deceased donor rate in 2000 immediately after the introduction of the KONOS legislation, and asked if this might be due to the introduction of a national allocation scheme reducing local clinical incentives to retrieve organs – previously, hospitals retrieving organs would gain the benefit of performing the transplants. Dr Cho agreed that this probably had an effect.

Dr Noel noted that it has been suggested that population education about donation and transplantation should include school-based programmes. He also noted that nongovernmental organizations were responsible for delivering education to the population. He asked if the Republic of Korea had considered school-based education in that context. Dr Cho responded that there was resistance to providing education around these topics to elementary and middle schools, and the approach had been to educate parents and students together.

Ms Yael Cass (Australia) noted that engagement of Emergency and Intensive Care physicians was key to increasing donation, and asked whether the respective professional societies were involved. Dr Ha Jong-Won (Republic of Korea) responded that at the individual level, doctors working in Emergency and Intensive Care departments were involved. But he also note that Korean Intensive Care units tend to be ‘open units’ where care is provided by a broad range of visiting specialists, rather than by Intensive Care doctors. Dr Cho also mentioned that there was government funding provided for education and advertising.
2.6 Plans for increasing organ donation after death in Japan (Dr Naoshi Shinozaki)

Japan is a country with 126 million people, and while solid organ transplantation has been undertaken since the 1960s, Japan is an outlier among developed countries with a very low transplantation rate. In 2012 there were only 110 deceased donors in Japan.

In Japan, it is felt to be system issues rather than a cultural resistance to deceased donation. The Ministry of Health, Labour and Welfare have appointed a council for the promotion of organ transplantation to discuss and make decisions about how to promote organ donation and transplantation in the country.

From 2012 to 2014, seminars aiming to increase donor identification within hospitals, to educate in-house donor coordinators and to improve systems within hospitals have been run in collaboration with the Japan Emergency Medicine Society, the Clinical Emergency Medicine Society of Japan, the Japan Neurological Medicine Society, the Emergency Nurse Society and the Japan Organ Transplant Network.

Dr Shinozaki presented data suggesting that health professionals working within coronary care units in Japan are less supportive of donation, less confident with discussions about donation, and are less likely to have received specific training in aspects of the donation process than counterparts from Europe, indicating a need for ongoing education for health care workers. He also presented data showing the highly variable consent rate between transplant coordinators, attributed to varying humanistic skill levels, reinforcing the notion that specialist training for coordinators to increase skills is required.

An additional issue identified is that driver’s licenses, which previously contained information about the individual’s decisions about organ donation, are not held by a substantial proportion of the population. Therefore from 2015, donor wishes will be added to the back of social health insurance cards instead.

Japan is currently undergoing the process of reorganizing the responsibility for oversight of donation and transplantation activities, and the promotion of them, into prefectures with oversight across several hospitals and institutions.

Discussion

Dr Nunez asked if there was funding available for donor coordinators within hospitals. Dr Shinozaki responded that there were a small number of transplant coordinators within the central Japanese Organ Transplant (JOT) network who were directly funded, but that individual hospital level coordinators were funded by individual hospitals. Dr Ha Jong-Won commented that individual hospitals may not decide therefore to hire coordinators as there would not be direct benefit to those hospitals.

Professor O’Connell noted that Intensivists need to be closely involved in the process to increase organ donation, and asked if there was engagement of the Intensive Care professional societies. Dr Shinozaki confirmed that there were ongoing efforts.
Discussion around payments made to families of organ donors

During this session there was a general discussion about the nature of payments made to families of organ donors, in light of Guiding Principles 5 of the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (WHA 63.22):

**Guiding Principle 5**

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

There was discussion as to how payments could be distinguished from reimbursement for reasonable expenses.

Dr Ha Jong-won reported that families of deceased donors (organs and tissues) may be provided with cash payments to defer expenses of up to $7000. He felt this did constitute an incentive under Principle 5.

Dr Rose Lique (Philippines) reported that families of donors may receive financial assistance to cover the cost of burial and/or funerals.

Dr Noel pointed out that there was a ‘frail difference’ between incentives and reimbursements, and that a key imperative was to monitor the equity of donation within a population. Where incentives to donate were operating, underprivileged subsections of populations would be overrepresented among donors. This should cause countries to revisit their policy.

Professor Chapman noted that removal of disincentives to donation were not precluded (i.e. covering costs that would be incurred by the process of donation, including any ongoing medical care for the donor during the assessment and donation process), but that all other payments were incentives.

Professor O’Connell mentioned that transparency was important and countries should openly acknowledge and report where there was money available to donors, to enable scrutiny. Countries were encouraged to report all reimbursements or payments that were made to donors or donor families in the GODT survey.

2.7 WHO role in encouraging organ donation after death (Dr Jose Nunez)

Internationally, it may be said that transplantation has become a victim of its own success – excellent outcomes for transplant recipients increase demand for transplantation, leading to ever expanding waiting lists. In 2012, the 114 000 organs transplanted represent only 10% of the estimated global need.

The shortage of deceased donors has led to the use of living donors as a source of kidneys and livers. However, increasing recognition of the potential harm to living donors and expansion
of deceased donor programmes has seen a reduction in the proportion of kidney transplants from living donors internationally in recent years, from 46.2% in 2008 to 42.5% in 2011. Living liver donors account for around 15% of all liver transplants performed.

In recognition of the need to expand deceased donation internationally, WHO developed the 4D programme (Developing Donations from Deceased Donors).

It was noted that the human development index (HDI) and deceased donor rate is poorly correlated, indicating that the availability of financial resources is not a key constraint to increasing deceased donation.

It is recognized that there is no single unique formula for increasing deceased donation, but there are well-proven, successful models to be taken as reference. Each country must then diagnose its situation and find the best ways to work towards self-sufficiency in transplantation.

2.8 Role of vigilance and surveillance, project NOTIFY (Dr Luc Noel)

Dr Noel outlined the WHO initiative to have three global governance tools for all medical products of human origin (MPHO) to address aspects of the Guiding Principles (WHA63.22):

1) Standards of practices common to MPHO, including the non-commercial nature of the human body and its parts to be used for therapeutic purposes;
2) Universal use of the Information Standards for Blood and Transplant (ISBT) labelling standard 128 within 10 years
3) Global vigilance and surveillance, via Project NOTIFY, towards using making best use of the global experience of adverse events and reactions related to use of MPHO

Project NOTIFY aims to be a repository for all serious adverse events and reactions in the context of the use of MPHO, including transplanted organs and tissues. The definitions of serious adverse events and reactions are common to the European Union and Project NOTIFY:

‘Serious Adverse Reaction (SAR)’ means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalization or morbidity.

‘Serious Adverse Event (SAE)’ means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

Dr Noel clarified that a SAR was an adverse response that has occurred in a living donor or recipient, related to transplantation, whereas a SAE was an adverse occurrence that could have led to harm (i.e. a SAR) in a living donor or recipient.

NOTIFY project commenced in 2010 and in its current form after the 2010 Bologna Initiative for Global Vigilance and Surveillance Meeting. Further meetings have been held annually.
There is recognition that global vigilance and reporting of adverse outcomes is important for building trust of communities in the process of transplantation. Community trust in turn is key to maintaining and increasing deceased donation.

The NOTIFY project consists of

- NOTIFY website (http://www.notifylibrary.org)
- NOTIFY Library of didactic cases of events and reactions
  - Donor selection and management
  - Recipient management
  - Quality system - risk based management
- NOTIFY Booklet
- NOTIFY Journal

The NOTIFY website is open access and allows searching for SAE/SAR by parameters including type (malignancy, infection etc.), recipient, MPHO type, and also text words.

Events and reactions are retrieved from ongoing structured, comprehensive literature reviews, and direct communications from competent national authorities and scientific professional societies. Reported events are reviewed by five expert editorial working groups (Infection, Malignancy, Handling Errors, Genetic, and Living Donor) and decisions taken to accept or reject the potential record documented. Ongoing analysis is undertaken, and ad hoc queries are answered. The proposed NOTIFY Journal will publish reports and synthesised data, and would enable reporting of anonymised reports where identification would prevent release of the information to the global community.

While the database is in English, portals in other languages are being developed to facilitate access to the data.

**Discussion**

Professor O’Connell noted that transmission of disease is a rare event, so when it happens, any individual unit will have very limited or no experience. Project NOTIFY provides an important function in sharing information about rare events.

Dr Noel added that Project NOTIFY is not a reporting database, rather it provides an extra layer to bring attention to issues. Individual countries still require mechanisms for surveillance, but Project NOTIFY may add an incentive to develop national surveillance systems, in order to contribute.

Ms Cass asked what the criteria are for deciding whether there should be a systematic response from the international community. Dr Noel noted that NOTIFY is only starting and not currently in a position to provide this function. This is difficult, and the frequency of issues is likely to change over time and by region. A functioning database needs lots of data, and this is really the start. But it does have an important function now, for example, knowing that rare things can happen (e.g. accidental discarding of a kidney for transplant) may enable units to critically appraise their processes now to avoid potential for events. Dr Noel also recognized that there has been a large amount of work by professionals and authorities to date to get the library started – at least 200 people have given time and energy to this from all WHO regions. This is a strong demonstration that professionals in this area are dedicated to improving outcomes.
Professor Chapman noted that Project NOTIFY is a library, rather than a system for providing rapid alerts to the transplantation community. He felt that there was a lot of difficult work that still needs to be done on how to appropriately merge the gray literature. He commended Dr Noel and the Italian team who have led this work to date.

Dr Shinozaki asked if alerts can be provided for severe adverse reactions as he felt this would be very beneficial for professionals and health authorities and would also provide incentives for health professionals and authorities to contribute. Dr Noel responded that this raises the issue of the need for clarity around who would be the correct person for each country to provide the data to NOTIFY. Currently, they use official reports from national surveillance programmes where they exist.

Dr Noel also commented that relying on the published literature is not good enough for detecting all events. Publishing is variable between countries. For example, some of the information about adverse reactions from the USA is not published due to the risk of litigation. But ultimately, when everyone understands the value of sharing this type of information, there will be harmonization of practice. The process is just beginning.

2.9 Information standard for blood and transplant ISBT128 (Mr Paul Ashford)

The International Council for Commonality in Blood Bank Automation (ICCBBA) aims to enhance patient safety by promoting and managing the Information Standard for Blood and Transplantation 128 standard.

ISBT128 developed after the first Gulf War after the US Department of Defence requested standardized labelling of blood for transfusion. The first version of the standard was published in 1994. ISBT128 was expanded to cover all cellular therapies in 2000, and current work is underway to extend it to cover all medical products of human origin, including organs, tissues, milk, tissue engineering and advanced therapy.

ISBT128 provides globally unique identification numbers and standardized terminology to ensure understanding across multiple languages. Standardized labelling is essential for traceability to enable recall, vigilance and surveillance, and long term follow up across jurisdictions and over long time periods. ISBT128 also provides the standard for electronic data transfer systems to ensure error free rapid transfer of critical information.

Standardized terminology is important at several levels, including:

1) Clinical application – detailed descriptions are required to distinguish clinically distinct variants
2) Activity data collection – data needs to be captured at a more generic level of description
3) Vigilance and surveillance – identify trends by collating data across many product types
Discussion

Dr Ismail Hirman (Malaysia) asked how ISBT128 was facilitated in low and middle income countries. Mr Ashford responded that there is a tiered approach based on the human development index (HDI).

Dr Ha asked at what level the development for solid organ tracking had reached. Mr Ashford responded that the description of organs is done, but there is still work to do to produce standardised descriptors of other key parameters.

Dr Tisocki asked how the uptake of ISBT128 in the Western Pacific Region could be encouraged. Mr Ashford responded that awareness of the standard by governments and regulators was the first step. Accreditation bodies can also be very helpful – sometimes individual facilities want to implement the standard but are unable to get funding until the accreditors insist that the standard is required. Meetings such as this are also very helpful for promoting the standard.

Professor Cho noted that self-sufficiency in transplantation is promoted by the WHO on the one hand, but then the ISBT128 enables international sharing of tissues on the other, which might be seen as a contradiction. Dr Noel responded that some sophisticated tissue products require a high level of processing that will inevitably mean they are produced in only a few locations in the world and will need to cross boundaries. A standardized coding system is also very important in this regard.

2.10 The Council of Europe European Committee on Organ Transplantation (CD-P-TO) (Dr Marta Fraga)

Dr Fraga from the European Directorate for the Quality of Medicines and Healthcare reported on the experience in the Black Sea Area Project (BSA) international collaboration around donation and transplantation.

Within Europe there is tremendous heterogeneity with respect to organ donation and transplantation. Many countries in Western Europe have in excess of 20 deceased donors per million population per year, and perform 50 or more transplants per million persons per year. However, most countries in the Black Sea region have very low or negligible rates of donation and transplantation.

The Council of Europe has been actively working in the area of organ donation and transplantation since 1987, and the European Committee on Organ Transplantation (CD-P-TO) has 71 representatives from 32 Member States and 20 observer states and organizations (including the WHO). International collaborative approaches have been used to address the organ shortage in different countries. The CD-P-TO aims to enhance the exchange of knowledge, expertise and good practices between member states, and to elaborate tailor made programmes adapted for the socioeconomic context of different member states.

The CD-P-TO assisted Moldova between 2006 and 2008, during which time a new transplant law was developed and a transplantation authority established. Based on the positive experiences gained, the CD-P-TO proposed a BSA regional project (including Romania, Moldova, Ukraine, Russia, Georgia, Turkey, and Bulgaria).
The project aimed to address legislative requirements, establish national authorities, provide public and professional education about donation and transplantation, identify areas where additional training was required and to enhance regional networking and cooperation.

The project participants consisted of national focal point contacts within governments of each participating country, the CD-P-TO steering committee, and partners and supporters from expert organisations and professional societies.

It became apparent that within the participating countries there were natural groupings of countries based on the current level of transplantation activity. While all countries worked on all aspects of the project, the level of development dictated which work stream required the most attention.

The Russian Federation, Turkey and Romania all had established infrastructures and significant transplant activity that focus on increasing transplantation from deceased donors. Ukraine, Moldova and Bulgaria had minimal activity and set about creating National Transplantation authorities to create an infrastructure for deceased donation. Armenia, Azerbaijan and Georgia had no transplantation activity, so focus was on political engagement and support to deliver legislation and financing.

There was no universal successful approach to transplantation development in the BSA. However, there were three key components:

1) Government support - governments have to be willing to invest to make it sustainable, rather than expect support from external sources
2) Technical support - the committee needed to work directly with technical staff in each country who were able to implement recommendations
3) International support - expertise is needed from well-developed countries to help develop individualized solutions for each nation.

Discussion

Dr Vathsala asked how the first step, getting government support, was achieved. Dr Fraga responded that governments are often amendable to financial arguments about the cost effectiveness of organ transplantation relative to other therapies for organ failure. In addition, patient associations were helpful, and powerful within some countries.

Professor O’Connell noted that the major costs of transplantation have reduced in recent years, especially drug costs, relative to the costs used in many formal cost-benefit analyses. Recalculating costs now would probably show transplantation to be even more cost-effective. Dr Fraga agreed with this and also noted that governments were able to make good deals to buy immunosuppressive drugs for developing countries’ transplant programmes.
2.11 The Latin American Council (Dr Elizabeth Coll)

Dr Coll (Spain) reported on the collaborative approach the Spanish Organización Nacional de Trasplantes (ONT) has led to assist countries in Latin America to improve organ donation and transplantation.

In Spain, donation activity is part of routine medical activity of the hospital. Professional activity of donor coordinators is recognized and reimbursed. Spain’s excellent record in increasing deceased donation and transplantation from the late 1980s meant Spain was perfectly positioned to help Latin American countries.

The collaboration started in 1994 when recipient doctors and surgeons from Latin America came to Spain asking for assistance. This led directly to the Siembra programme. Thirty physicians from Latin America went to Spain for training in donation management.

This initial group continued to meet on return to their own countries, and developed into a network of friends, that eventually developed into Punta Cana group.

At this point, it was recognized that formal Government support was needed in order to develop a fully functional official transplantation network. A series of declarations in the early 2000s sought enhanced collaboration including government level collaboration, media engagement, training programme coordination, implementation of a registry and the establishment of an official forum on donation and transplantation, in line with WHA57.18.

In 2004, the Spain-Pan American Health Organisation (PAHO) programme started, with the main objective of promotion and development of programmes of donation and kidney transplantation in Latin America. Joint meetings of ONT and PAHO were held in 2005, and resolved a number of priority actions:

1) global analysis of donation and transplantation in Latin America;
2) training programmes on donation and transplantation;
3) standard definitions and clinical practice guidelines;
4) definition of improvement areas and cooperation in management and organization;
5) communication and information policies;
6) improvement strategies on immunotherapy; and
7) economic analysis of donation and transplantation

At the Seventh Iberoamerican Conference of Health Ministers in September 2005, approval was given for the establishment of the Iberoamerican Council and Network of Donation and Transplantation. This commitment was reiterated in the Declaration of Salamanca of the 2005 Iberoamerican Summit of Heads of States and Governments. The Council met later that year for the first time.

The Iberoamerican Council/Network of Organ and Tissue Donation and Transplantation (RCIDT) consists of official delegates from Member States, representation from PAHO and representatives from Spain. RCIDT has met frequently and been very successful at ongoing facilitating of training for donation coordinators and physicians, who travel to Spain for a two-month training programme. RCIDT has also provided training for communication in critical situations for more than 5000 health professionals. The RCIDT, along with the Colombian Government have successfully eliminated transplant tourism in the country. The RCIDT has
developed guidelines for all aspects of donation and transplantation in Latin America, assisting countries to develop laws and regulations for transplantation practice. Between 2005 and 2012, donations increased by 50% in Latin America.

Discussion

Professor Chapman asked both Dr Fraga and Dr Coll whether, in the situations described, if language and religion commonality was critical to the successes of both programmes, and whether heterogeneity of either was a barrier to successful international collaboration. Dr Coll agreed that in the Latin American situation, common language and religion were facilitators, enabling countries to take the first steps in collaborating. Dr Fraga noted that there were issues around language in the Black Sea project. The common language in that region is Russian, and there were difficulties communicating with local doctors. The Moldovans, who had been involved in the earlier project, were crucial at providing a link and transmitting information to colleagues. There were also political/religious dissimilarities making it difficult for some geographically and developmentally close countries to collaborate directly. Ultimately, where there were common language and religious ideals this made collaboration easier.

On enhancing collaboration on donation and transplantation, Dr Vathsala noted that Asian countries had not always worked well together in this area, due to heterogeneity and even economic disparity. Strong political movements in Europe and Latin America can provide major starting points in developing cooperation between governments in Asia.

2.12 The Role of Professionals Societies in the Development of Transplantation
(Dr Phillip O'Connell)

Professor O'Connell, President-Elect of the Transplantation Society (TTS), described the role that TTS has in promoting the development of transplantation globally.

TTS is the only truly global society in the field of transplantation. TTS liaises closely with national and regional transplantation societies, such as the Asian Society of Transplantation (AST). It also has close relationships with governmental and non-governmental organisations, such as WHO. TTS seeks membership from all transplantation health professionals and scientists working in the field. TTS provides education, global leadership and promotion of ethical research and practice in donation and transplantation. TTS facilitates educational meetings globally, including in emerging transplanting countries. In association with other bodies, including ONT, WHO and the United Nations, TTS has been instrumental in producing important guidelines such as the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, and the Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Care of Kidney Transplant Recipients.

Professor O'Connell noted that transplantation will always be somewhat of a niche practice, even in countries with high transplantation rates. In many countries therefore, not all possible expertise exists, but with strong international links and networking, information can be shared, providing assistance to transplant professionals, leading to better outcomes for transplant recipients.
2.13 **Visit of Dr Shin Young-soo – Regional Director, WHO Western Pacific Region**

Dr Shin attended the consultation meetings on the second day and made some comments. Dr Shin noted the critical nature of organ transplantation, and the shortage of organs. The Region has advancement of clinical knowledge on one hand, but on the other, the shortage of organs is limiting application. With advancing life expectancy, more people are going to need this type of intervention.

Dr Shin commented that he is hopeful that there will be an improved networking from this consultation. Further work is needed to address organ trafficking. Dr Shin noted that WHO has many issues to address and cannot manage everything hence experts are needed. WHO will continue to support this area in the future.

2.14 **General discussion, conclusions and Plan of Action**

Participants engaged in general discussion about the consultation, led by the Chairman and Dr Noel.

Dr Liquete reflected that while her country already has a framework and policy on transplant, political issues mean that she has not seen any improvement in the past years. Transplant professionals often return from abroad with good ideas, but implementation is difficult. Dr Noel noted that there seems to be some impetus within the Philippines to develop deceased donation policies. Dr Liquete commented that the professionals will strive to achieve this but will need support from the government and the legislature.

Dr Tisocki noted translating good intentions for reform into reality is very challenging in many areas due to main barriers. Dr Liquete responded that resources were key, and felt that the Philippine Government will need help from nongovernmental organizations, and that the organ procurement authority does not train enough coordinators. Dr Noel commented that all countries need to find their own solutions, but sharing experiences will help.

Dr Buyanjargal Yadamsuren (Mongolia) noted that there are religions and ethnic barriers to development of transplantation in Mongolia. She reiterated the need for the key structures discussed during meeting to be implemented in Mongolia. Dr Noel commented that Mongolia is an example of a country which would benefit greatly from a collaborative approach by countries in the region. Dr Yadamsuren confirmed Mongolia lacks transplantation laws, policies and guidelines. Dr Cho suggested that transplantation experts within Mongolia should recommend that this is pursued, but that neurologist and neurosurgeons should be involved so a definition of brain death can be reached by local experts.

Dr Yadamsuren felt that Mongolia was “fresh green ground” as far as transplantation was concerned, and any regional collaboration would need support from the Ministry of health.

Dr Shinozaki explained the difficulties that he had personally experienced progressing transplantation law within Japan over 20 years, with repeated visits to many congress representatives required. When finally a vote was taken, it was only with the support of Professor Chapman and Dr Noel that the law was passed. It had been thought that the new law would lead to growth in transplantation, but nothing has changed. Dr Shinozaki feels that there is insufficient buy in from neurologists caring for potential donors. There are many other bottle necks,
including cultural and political issues. A regional collaboration for support and information sharing can be a good advantage.

Dr Noel commented that a regional collaborative group will only work if it includes government representatives as well as clinicians. Dr Noel also referred to the guidance on the determination of death project being undertaken by the WHO (http://www.who.int/patientsafety/determination_of_death/en/). A regional meeting is planned with local experts to reach a consensus on death determination.

Dr Liu noted that the China Government has made progress in recent years. In the last year, there has been a country-wide campaign focused on organ donation. However, there is still need for revision of the law. A current pressing issue from Dr Liu’s perspective is how to reimburse the donor family. China will still be criticised by international community. Dr Liu wanted to get advice from WHO and TTS about this issue, because in China, the tradition has been that donor families are very poor, meaning that reimbursement is essential.

Dr Noel commented that this represents a significant problem for China. A strong effort will be needed to avoid creating inequity between the donors and the recipients in China, if donors are poor and recipients are not poor. Dr Noel commented on the importance of discussing this further alongside China, in the spirit of support. Dr Liu commented that reimbursement was only offered after donation, but Dr Noel was clear in his view that if money is associated with donation, it will be considered a sale, and people who want to profit from this situation will do so. But if there is a situation where money needs to be exchanged, it needs to be transparent, and monitored and produce equitable results in terms of transplantation to avoid room for criticism. Dr Liu further stated that the government hospitals are worried that transplant rate may drop if reimbursement does not occur; however, a change in practice needs a consensus.

Professor O’Connell suggested that as a first step, a look at examples of countries who have high transplantation rates who do not offer reimbursements can be considered. Ultimately, high transplantation rate is not dependent on money but on trust. Spain is not the richest country in Europe, but because the population see the benefits of transplantation and have trust in the system, they become donors in large numbers. The system is fair, transparent and trusted. Developing a successful transplant programme is long and hard work, but shortcuts, including financial incentives, lead to problems.

Dr Noel supported this comment, saying that money becomes compensation for a missing part of the body, and does not make people who donate respected. What we need is innovative and a region-specific way to promote deceased donation in a way that makes families proud to be involved. He felt that this approach was feasible in Asia.

Ms Cass commented that within the Black sea project there were good examples for Australia on how they can take the next steps at encouraging other countries to develop their transplantation programmes. She felt that there was opportunity for regional and/or bilateral relationships between Australia and other countries in the Western Pacific. There may be examples where meeting regularly is valuable, and she would be willing to participate, but would also want to explore bilateral arrangements. Australia would be willing to host people to come and learn how progress could be made. Ms Cass mentioned that Australia hold annual forums of the Donate Life network, so clinical people meet. There is specific work that has been done in Australia with the death audit, and to monitor progress at hospital level - this methodology may be of interest as tool that can help.
Dr Hirman commented that the meeting had been a good experience. He felt that there could have more frequent sharing of information, via newsletters, emails, Facebook so that updated information could be shared on what individual countries are doing. With respect to transplant rates within Malaysia, it is a diverse society. Most are Muslims, and they have engaged with religious leaders, but this has not increased donation rates (although there was a slight increase in registrations). Malaysia has a central organization, but there is a lack of commitment from professional groups at this stage. Dr Noel felt that sharing information in this way might be valuable but that nothing replaces meeting face-to-face.

Dr Cross noted that the key determinants of successful development of donation and transplantation programmes in most countries were similar and well described during this meeting. New Zealand had already achieved a well-developed and functioning transplantation system but problems existed with access to transplantation for some groups, and with the deceased donation rate which was poor by international standards among high HDI countries. He would be interested in learning more particularly from the Australian experience to improve performance in New Zealand.

Dr Curie commented that the country has arranged meetings for young doctors working within donation and transplantation from Asian countries to meet together. She felt there is a need for reform in the governmental structure around transplantation. Dr Ha felt that perhaps the TTS/WHO could ask the neurology society to help with encouraging deceased donor identification within the country, which remains a major barrier. He further commented that when transplantation clinicians offer symposia, there is poor attendance, but perhaps a meeting of international stature would encourage more attendance. He also noted that donation after cardiac death was not yet developed in the country and assistance from other countries might be needed.

Dr Vathsala reflected on the inspiring stories from Latin America and Eastern Europe. She noted that passionate individuals are needed, but cannot be relied upon for sustained development of donation and transplantation within countries. There is a need for systems and processes; governments need to set transplantation and donation structures in place, with transplantation professionals as catalysts and not the maintaining force. Secondly, transplantation professionals are not the limiting factor – there is a need to bring the intensivists and ICU to the table to make progress.

Dr Phuc (Viet Nam) commented that it has been a productive consultation. He felt that the development of donation and transplantation would not be easy in Viet Nam but is possible and look forward to future collaboration in the area.
3. CONCLUSIONS AND PLAN OF ACTION

Dr Nunez (WHO/HQ) summarized the conclusions from the meeting which were agreed by the participants:

1. **Contribution of data to the Global Observatory on Organ Donation and Transplantation (GODT).** Participants agreed to collaborate with WHO and its collaborating centre (ONT) to collect reliable data about transplantation activities in countries in the Western Pacific Region. Health Authority designated focal points should be identified within each nation to facilitate.

2. **National Vigilance and Surveillance Schemes to contribute to Project NOTIFY.** Participants recognized the value of reliable information about adverse events and reactions following donation and transplantation. Such information may strengthen efficacy and safety of donation and transplantation. National authorities should ensure that national vigilance and surveillance schemes contribute to the NOTIFY Library.

3. **Increase organ donation after death within jurisdictions.** Participants recognized the need to pursue deceased donation to strive for self-sufficiency in transplantation for populations. Depending on the state of development of deceased donation within countries, participants agreed to:
   a. **Strengthen legal and organizational frameworks for deceased donation.**
   b. **Advocate for public education about deceased donation, including through school education networks.**
   c. **Collaborate with intensivists and other relevant specialist groups to improve identification of potential donors and integrate donation into end of life practice.**

4. **Seek creation of an annual Western Pacific regional forum of national experts in donation and transplantation.** Participants recognized the potential value of such a forum to share experiences and assist countries in improving their donation and transplantation performance. This could lead to the development of a regional transplantation and donation network, or bilateral collaborations between Member States.

5. **Pursue internationally standardized labelling of Medical Products of Human Origin (MPHO) using ISBT128.** Participants agreed that international traceability of all MPHO, including organs and tissues for transplantation, was important to improve ethics and safety of donation and transplantation, and supported the use of ISBT128 to this end.

4. CLOSING

Dr Noel and Dr Tisocki thanked Dr Cho Won-Hyun for his chairmanship and also for his and Vitallink’s support in organizing the meeting. Dr Tisocki also thanked the TTS for providing financial and technical support.

Dr Liquete, on behalf of the participants, expressed appreciation to the organizers of the meeting.
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# TENTATIVE TIMETABLE

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<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>08.00</td>
<td><strong>Registration</strong></td>
<td>08.30</td>
<td><strong>Global governance tools for cell, tissue and organ donation and transplantation</strong></td>
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<tr>
<td>08.30</td>
<td>1. Opening ceremony and group photo</td>
<td>09.00</td>
<td>13. Role of vigilance and surveillance, Project NOTIFY <em>(Dr Luc Noel)</em></td>
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<td>09.30</td>
<td>14. Information standard for Blood and Transplant ISBT128 <em>(Mr Paul Ashford)</em></td>
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<td>09.45</td>
<td>15. Standards for medical products and human origin <em>(Dr Jose Nuñez)</em></td>
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<td>09.15</td>
<td><strong>COFFEE BREAK</strong></td>
<td>10.15</td>
<td><strong>COFFEE BREAK</strong></td>
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<tr>
<td>09.45</td>
<td><strong>Setting the scene/background</strong></td>
<td>10.45</td>
<td><strong>Regional/sub-regional fora of health authorities for transplantation</strong></td>
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<tr>
<td>10.00</td>
<td>2. Introduction: Objectives of consultation, overview of agenda, adoption of agenda <em>(Dr Klara Tisocki)</em></td>
<td>11.15</td>
<td>16. The Council of Europe CD-P-TO <em>(Dr Marta Fraga)</em></td>
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<td>10.20</td>
<td>3. Self-sufficiency and the WHO initiative for Medical Products of Human Origin <em>(Dr Luc Noel)</em></td>
<td>11.45</td>
<td>17. The Latin American Council <em>(Dr Elizabeth Coll)</em></td>
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<td></td>
<td>4. Update on WHO activities and priorities in cell, tissue and organ transplantation <em>(Dr Jose Nuñez)</em></td>
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<td><strong>General discussion</strong></td>
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<td>10.40</td>
<td><strong>The WHO/ONT Global Observatory on Donation and Transplantation and the Regional Situation</strong></td>
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<td>11.00</td>
<td>5. Essential legal and organizational requirements for national cell, tissue and organ transplantation services <em>(Prof Jeremy Chapman)</em></td>
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<td>12.10</td>
<td>6. Matching GODT data with country reports on activities and practices <em>(temporary advisers and Ms Mar Carmona)</em></td>
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*General discussion*
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<td>12.30</td>
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<tr>
<td>13.30</td>
<td><strong>LUNCH BREAK</strong></td>
<td>13.30</td>
<td><strong>General discussion on:</strong></td>
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<td></td>
<td>Activities and practices in organ transplantation</td>
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<td>18a. Increasing transparency in donation and transplantation throughout the Region</td>
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<td>7. Matching GODT data with country reports on activities and practices (cont'd) (temporary advisers and Ms Mar Carmona)</td>
<td>14.00</td>
<td>18b. Regional initiative for the development of organ and tissue donations after death</td>
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<td>18c. Towards regional synergies and regular consultation of health authorities</td>
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<td>15.00</td>
<td>19. Roles of scientific and professional societies (Prof Philip O’Connell and Dr Shiro Takahara)</td>
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<td><strong>COFFEE BREAK</strong></td>
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<td><strong>Regional experience in the development of organ donation after death</strong></td>
<td>15.30</td>
<td>20. Conclusion and plan of action</td>
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<td>16.45</td>
<td>9. The Chinese programme: current achievements and plans (Mr Wang Haibo)</td>
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<td>17.15</td>
<td>10. Plans for increasing organ donation after death in Japan (Dr Naoshi Shinozaki)</td>
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<td>17.45</td>
<td>11. WHO role in encouraging organ donation after death (Dr Jose Nuñez)</td>
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<td>General discussion on priorities and opportunities</td>
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<td><strong>Cocktails/dinner</strong></td>
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SPEECH OF DR SHIN YOUNG-SOO, WHO REGIONAL DIRECTOR FOR THE WESTERN PACIFIC, DELIVERED BY DR KLARA TISOCKI, TEAM LEADER, ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES, AT THE OPENING CEREMONY OF THE INTERNATIONAL TECHNICAL CONSULTATION ON CELL, TISSUE AND ORGAN DONATION/TRANSPLANTATION IN THE WESTERN PACIFIC REGION

DISTINGUISHED PARTICIPANTS, LADIES AND GENTLEMEN:

Dr Shin Young-soo, WHO Regional Director for the Western Pacific, regrets being unable to join us due to a previous commitment. He has asked me to welcome you and deliver these remarks on his behalf.

Welcome to the International Technical Consultation on Cell, Tissue and Organ Donation/Transplantation in the Western Pacific Region.

Human cells, tissues and organs for transplantation can save lives or restore essential functions, but access to them is highly limited in most countries globally and in this Region.

Only 11% of the global organ transplantation activity takes place in the Western Pacific Region, even though the Region accommodates 28% of the global population.

Human cells and tissues for transplantation represent a special class of health products as medical products of human origin.

They may also be used as starting material for more complex biotechnology products in the future.

All transplanted materials of human origin carry the risk of disease transmission.

This risk must be controlled by the application of stringent regulations of donors and transplantation activities and implementation of a comprehensive quality systems to ensure safety.

In May 2010, the World Health Assembly endorsed the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation.
The WHO Guiding Principles clearly outlined an ethical framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes.

Amongst other ethical norms, they highlighted the need for:

The development of transparent and accountable systems for the voluntary non-remunerated donation of cells, tissues and organs.

Ethical allocation rules, that should be equitable, externally justified, and transparent and defined by appropriately constituted committees.

Optimizing the safety, efficacy and quality of human cells, tissues and organs for transplantation by implementation global traceability system and vigilance to monitor adverse events and reactions.

In recent years, several countries in the Western Pacific Region have made rapid progress in developing transparent, accountable and high quality systems for cell, tissue and organ donation and transplantation.

Increasing organ donation after death in these countries helped to reduce the gap in the availability of suitable organs.

Though in most countries in the Region, the need for cell, tissue and organ donation still remains great, as the number of patients with end-stage diseases is increasing, due to non-communicable diseases.

In order to close this gap, there is a need to have the opportunity to donate organs after death, as much as possible. This is the key challenge for moving towards self-sufficiency in cells, tissues and organ donations.
However, we must also remember that health promotion, prevention and high quality health services must remain the priority and the cornerstone of government’s action to slow the increasing need for cells, tissues and organ donation.

I hope this consultation, building on your varied expertise, will provide the opportunity to review recent development and current best practices in the Western Pacific Region.

The potential opportunities for more interaction and collaboration between responsible national authorities will also be considered and I look forward to your opinion on this.

I would like to thank our host, the Government of the Republic of Korea, and the co-organizer Vitallink for supporting this international expert consultation.

I look forward to hearing your recommendations and outcomes of this meeting and wish you all a pleasant stay in Seoul.

Thank you.