



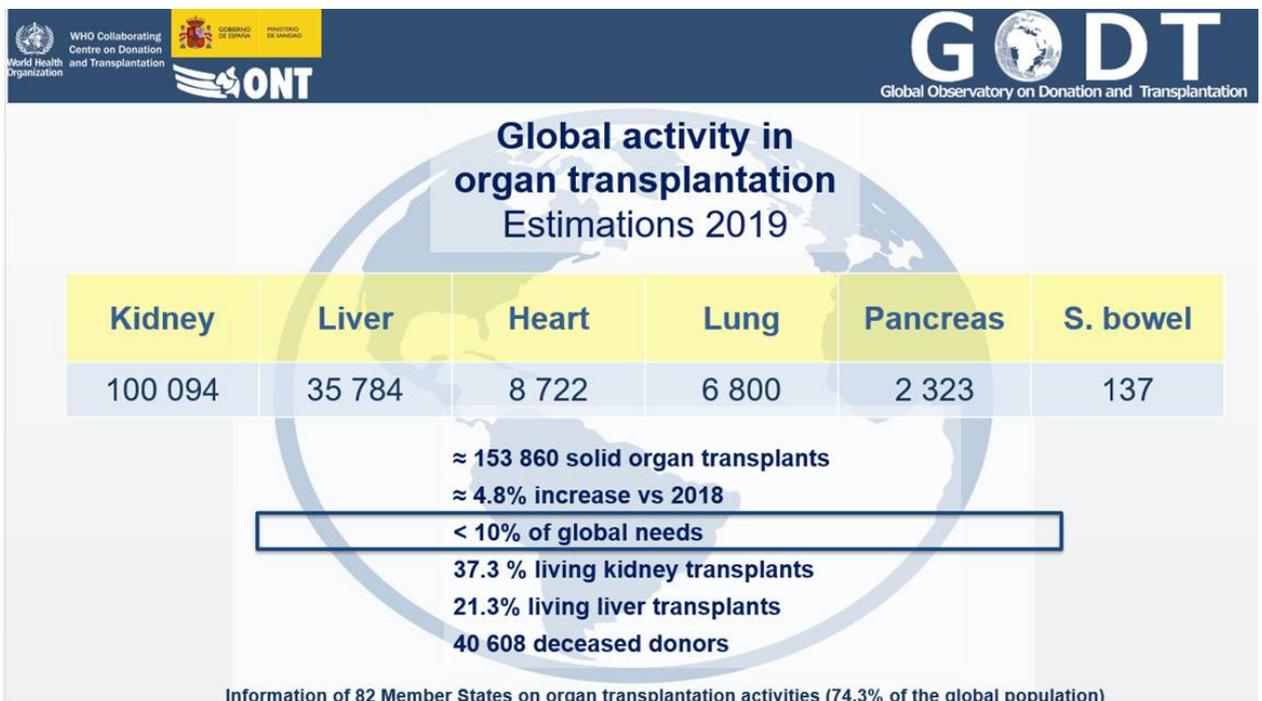
# THE ROLE OF SCIENCE

in the Development of International Standards of

# ORGAN DONATION AND TRANSPLANTATION

21-22 June 2021

Meeting organised by the Pontifical Academy of Sciences and co-sponsored by the World Health Organization





*The Pontifical Academy of Sciences, Casina Pio IV*

*“Faced with threats to life, which we unfortunately have to witness almost daily...  
society needs these concrete gestures of solidarity and generous love  
to make it clear that life is something sacred.”*

*Address of His Holiness Pope Francis  
to the Italian Association for the Donation of Organs, Tissues and Cells (AIDO), 13 April 2019*



## Concept Note

The Pontifical Academy of Sciences (PAS) is convening a Workshop promoting **THE ROLE OF SCIENCE in the Development of International Standards of ORGAN DONATION AND TRANSPLANTATION** in June, 2021.

This event is co-sponsored by the World Health Organization (WHO).

Organ failure, particularly kidney and liver failure, are conditions caused primarily by non-communicable diseases (NCD) that are increasing exponentially throughout the world. These global challenges are of a great concern to the PAS and the WHO that are striving to promote universal health care and improve the quality of life.

Following the direction of Pope Francis to combat organ trafficking as a form of human trafficking and a crime against humanity, the PAS has been actively seeking to alleviate the suffering experienced by those with inequitable access to organs needed for successful transplantation. The key objective of this Workshop is therefore, to address the responsibility of authorities in developing sustainable national transplant systems in light of the growing demand for organs.

The WHO's mission is to promote health, keep the world safe, and serve the vulnerable. WHO therefore, supports this initiative which contributes in the establishment and global diffusion of organ transplantation as a lifesaving treatment.

The Workshop will be conducted virtually and will address 4 topics over a 2 day period:

### **Day 1, Monday (21 June)**

Session 1: Evaluation of the burden of disease that results in organ failure and necessitating organ transplantation for treatment;

Session 2: A compelling case for prioritizing organ transplantation in the treatment of organ failure.

### **Day 2, Tuesday (22 June)**

Session 3: Technical considerations for developing and optimizing organ transplantation as a healthcare treatment option for patients with organ failure;

Session 4: Strengthening the regulatory capacity for oversight of practice.

The cause of organ failure is not being examined scientifically to implement preventive measures and utilize the most cost-effective measures of treatment. This Workshop is expected to provide knowledge and guidance to policy makers and health authorities in developing sustainable transplant services with the overall objective of achieving a national self-sufficiency in treatment of end stage organ disease and facilitating patient's access to optimal transplantation care.

A panel of renowned experts will be comprehensively addressing the role of science in designing a national system and the provision of data as part of a robust oversight consistent with WHO Guiding Principles and international standards.

## DAY 1 - Monday 21 June 2021

15:00 - 15:06 Welcome: Opening remarks  
*PAS: Marcelo Sánchez Sorondo*  
*WHO: Mariângela Simão, Assistant Director General,*  
*Access to Medicines and Health Products*

15:07 - 15:12 Setting of the agenda: introduction with data from GODT  
*Francis Delmonico & Efstratios Chatzixiros*

### **Session 1: To evaluate the burden of disease that results in organ failure and necessitating organ transplantation for treatment**

*Moderators: Nancy Ascher & Philip O'Connell*

15:14 - 15:24 The burden of disease as it relates to the need for transplantation in the WHO goal of universal health care  
*André Ilbawi, Department for Management of NCD, Disability, Violence and Injury Prevention, WHO*

15:25 - 15:40 Discussion / Q&A

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### **Session 2: To present the compelling case for prioritizing organ transplantation in the treatment of organ failure**

*Moderators: Elmi Muller & Curie Ahn*

15:42 - 15:52 Benefits of kidney transplantation: survival, quality of life and cost-effectiveness  
*David Harris, Past President of International Society of Nephrology*

15:53 - 16:03 Benefits of liver transplantation: survival, quality of life and cost-effectiveness  
*Marina Berenguer, President (Elect) of the International Society of Liver Transplantation*

16:04 - 16:14 Requirements for a transplant program (financing, workforce, infrastructure-equipment, medication) to progress towards self-sufficiency  
*Vivekanand Jha, Immediate Past President of the International Society of Nephrology*

16:15 - 16:25 Developing integrated kidney replacement therapy in low-resource settings  
*Elmi Muller, President Elect The Transplantation Society*

16:26 - 16:44 Discussion / Q&A

16:45 Closing of Day 1

## DAY 2 - Tuesday 22 June 2021

15:00 - 15:01 Welcome: Opening remarks  
*Francis Delmonico & Efstratios Chatzixiros*

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### **Session 3: Provide technical expertise to Member States to develop and optimize organ transplantation as a healthcare treatment option for patients with organ failure**

*Moderators: Beatriz Domínguez-Gil & Gabriel Gondolesi*

15:03 - 15:13 The legislative framework (KVA to address general aspects of legislation, MLF to address criminal activities)

*Marta López Fraga, Council of Europe & Kristof Van Assche, Belgium*

15:14 - 15:22 The role of professional societies to propose standards of suitability for transplantation

*Marcelo Cantarovich, President of The Transplantation Society*

15:23 - 15:31 Deceased donor transplantation

*Mirela Bušić, Croatia*

15:32 - 15:40 Living donor transplantation

*Hiroto Egawa, Japan*

15:41 - 15:59 Discussion / Q&A

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### **Session 4: The Regulatory Capacity for Oversight of Practice**

*Moderators: Benita Padilla & Riadh Fadhil*

16:01 - 16:09 Role of Ministerial Agency in oversight of practices

*Sergio Andrés Madera, INCUCAI Argentina*

16:10 - 16:18 Requirements for national registries (waiting lists, donors, recipients, follow-up) and mandatory reporting to the GODT

*Axel Rahmel, Germany*

16:19 - 16:27 Comprehensive data collections at center level to ensure the quality and safety of transplantation.

*Ryo Hirose, United States*

16:28 - 16:40 Discussion / Q&A

**Panel Discussion: Country Models**

*Moderators: Mehmet Haberal & Faissal Shaheen*

- 16:41 - 16:44 China  
*Haibo Wang*
- 16:44 - 16:47 Spain  
*Beatriz Domínguez-Gil*
- 16:47 - 16:50 Iran  
*Katy Najafidadeh*
- 16:50 - 16:53 Kenya  
*Ahmed Twahir*
- 16:53 - 16:56 Global situation  
*Efstratios Chatzixiros*
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- 16:56 - 17:00 Closing remarks  
*Francis Delmonico*

## Participants

**Curie Ahn**, MD, PhD. Professor of Division of Nephrology at National Medical Center, Secretary-General, Asian Society of Transplantation, Seoul, Korea

**Nancy L. Ascher**, MD. Professor and Past Chair: Department of Surgery, University of California, San Francisco. Past President, The Transplantation Society

**Marina Berenguer**, MD. Professor of Medicine, University of Valencia, Spain. Chief of the Hepatology and Liver Transplant Unit Research, CIBERehd and Instituto de Investigación Sanitaria, La Fe University Hospital, Spain

**Mirela Bušić**, MD. Specialist in epidemiology, National Transplant Coordinator, Ministry of Health of the Republic of Croatia

**Marcelo Cantarovich**, MD. Professor of Medicine, Associate Director Multi-Organ Transplant Program, McGill University Health Center, Montreal, Quebec, Canada. President, The Transplantation Society

**Efstratios (Stratos) Chatzixiros**, Adviser, Transplantation Human Organs-Tissues-Cells, Division of Access to Medicines and Health Products at WHO Headquarters, Geneva, Switzerland

**Francis L. Delmonico**, MD. Professor of Surgery, Harvard Medical School at the Massachusetts General Hospital. Chair, WHO Task Force Donation and Transplantation of Organs and Tissues. Chief Medical Officer, New England Donor Services

**Beatriz Domínguez-Gil**, MD. Director General, Organización Nacional de Trasplantes, Ministerio de Sanidad, Spain

**Hiroto Egawa MD**, PhD. Professor, Chairman, Department of Surgery, Tokyo Women's Medical University

**Riadh A. S. Fadhil**, MD. Professor of Urology and Transplant Surgery. Director of Qatar Organ Donation Center - Hamad Medical Corporation. Weill Cornell College of Medicine-Qatar

**Gabriel E. Gondolesi**, MD. General Surgery; Liver, Pancreas and Intestinal Transplant Chief. Professor of Surgery, Hospital Universitario Fundación Favaloro, Argentina

**Mehmet Haberal**, MD, FASA FACS FICS FRCS. Professor of Surgery and Founder President, Başkent University, Ankara, Turkey. Experimental and Clinical Transplantation Editor-in-Chief, Immediate Past-President, The Transplantation Society

**David Harris**, AM, MD, FRACP. Professor of Medicine, University of Sydney at Westmead Hospital, Australia. Past President, International Society of Nephrology

**Ryutaro Hirose**, MD. Professor, Vice Chair Clinical Operations, UCSF Department of Surgery, Surgical Director, Scientific Registry of Transplant Recipients

**André Ilbawi**, MD. Department for Management of NCD, Disability, Violence and Injury Prevention, WHO

**Vivekanand Jha**, MD DM FRCP FAMS. Executive Director of the George Institute for Global Health, India, Immediate Past President of the International Society of Nephrology

**Marta López Fraga**, PhD, Scientific Officer at the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe. Secretary to the European Committee on Organ Transplantation (CD-P-TO)

**Sergio Andrés Madera**, Coordinator of the International Relations Department at INCUCAI, Argentina

**Elmi Muller**, MD. Head: Transplant Services, University of Cape Town: South Africa. President-elect, The Transplantation Society

**Katayoun Najafizadeh**, MD, Pulmonologist and Associated Professor of Shaheed Beheshti University of Medical Sciences. CEO of Iranian Society of Organ Donation

**Clive Ondari**, Director of Health Products Policy and Standards, WHO

**Axel Rahmel**, MD. CEO, Medical Director DSO – Deutsche Stiftung Organtransplantation (German Organ Procurement Organisation), Germany

**Marcelo Sánchez Sorondo**, Bishop-Chancellor, Pontifical Academy of Sciences, Vatican City

**Faissal A.M. Shaheen**, MBBCH, FRCP, FACP. Head of Nephrology, King Fahad Hospital. Former Director-General, Saudi Center for Organ Transplantation. Co-Chairman WHO Task Force, Organ and Tissue Donation and Transplantation

**Mariângela Simão**, Assistant Director General, Access to Medicines and Health Products, WHO

**Ahmed Twahir**, MD. Consultant Physician/Nephrologist, AgaKhan University Hospital. Clinical Director, Parklands Kidney Centre, Nairobi, Kenya

**Kristof Van Assche**, Research Professor in Health law, University of Antwerp, Belgium

**Haibo Wang**, MBBS, MSc, MPH. Director, China Organ Transplant Response System

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