

HACIA UN CONSENSO GLOBAL EN TRASPLANTES: DISPONIBILIDAD, TRANSPARENCIA Y REGISTRO

09-10/NOV/2023
Reunión de Alto Nivel



PRESIDENCIA
ESPAÑOLA
CONSEJO DE LA
UNIÓN EUROPEA

9 DE NOVIEMBRE DE 2023

8:30 – 9:00 **REGISTRO**

9:00 – 9:15 **APERTURA INSTITUCIONAL**

9:15 – 9:35

La donación y el trasplante en el mundo: objetivos de la reunión, metodología y resultados esperados

Beatriz Domínguez-Gil, España

9:35 – 9:45

Transformando el trasplante: el papel de los pacientes

Daniel Gallego, Federación Europea de Pacientes Renales (EKPF)
y Alianza Europa por la Salud Renal (EKHA)

9:45 - 12:00

Moderadores:

Elmi Muller,
Luciano Potena

MESA REDONDA 1: Por qué los trasplantes deben ser una prioridad sanitaria y cómo pueden contribuir a alcanzar los Objetivos de Desarrollo Sostenible de Naciones Unidas

- **Caso 1: Hacer del trasplante una prioridad sanitaria** (15 min)
Joel de Andrade, Brasil

- **Impacto del trasplante en salud (enfermedades no transmisibles y acceso universal a la atención sanitaria)** (20 min)
Efstratios Chatzixiros, OMS
Luciano Potena, Italia

- **Impacto del trasplante en otros Objetivos de Desarrollo Sostenible de Naciones Unidas** (20 min)
Vivekanand Jha, India
Marina Berenguer, España

- **El trasplante como parte de un sistema sanitario más resiliente** (20 min)
Derek Manas, Reino Unido

- **Cuándo y cómo iniciar un programa de trasplante en países de bajos y medianos ingresos** (20 min)
Elmi Muller, Sudáfrica
Curie Ahn, Corea del Sur

- **DEBATE**

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12:00 - 13:00 PAUSA COMIDA

13:00 - 15:15

Moderadores:

Matthew Cooper,
Francis L.
Delmonico,
Dale Gardiner,
Sanjay Nagral

MESA REDONDA 2: Donación y trasplante: retos y soluciones

- **Caso 2 : Transformar la donación de fallecido con la donación en asistolia controlada (15 min)**
Eduardo Miñambres, España
- **Cómo promover el concepto único de muerte (20 min)**
Francesco Procaccio, Italia
- **Cómo reducir las disparidades en la donación de personas fallecidas y aumentar la utilización de órganos (20 min)**
Helen Opdam, Australia
- **Cómo reducir las disparidades en la donación de vivo (20 min)**
Krista Lentine y Amy Waterman, Estados Unidos
- **Cómo reforzar la supervisión: registros de actividad y resultados tras la donación y el trasplante (20 min)**
Michel Spiro, Reino Unido
Dimitri A. Ratis, Arabia Saudí
- **DEBATE**

15:15 - 15:45 PAUSA CAFÉ

15:45- 18:15

Moderadores:

Nancy Ascher,
Natividad Cuende,
Stefan Tullius

MESA REDONDA 3: Innovación en la donación y aplicación clínica de sustancias de origen humano (SoHO): células y tejidos

- **Caso 3: Terapia celular para la inducción de tolerancia inmunológica (15 min)**
Rafael Correa, España
- **Cuando las SoHO se convierten en medicamentos y productos sanitarios: límites e implicaciones regulatorias (20 min)**
Ander Izeta, España
- **Cómo abordar la eficacia y seguridad antes de que la innovación llegue a la clínica (20 min)**
Verena Plattner, Austria

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- **Cómo hacer la innovación sostenible para los sistemas sanitarios** (20 min)

Martin Börgel, Alemania

- **Alianzas público-privadas para hacer la innovación accesible a los pacientes** (20 min)

Rachele Ciccocioppo, Italia

- **DEBATE**

19:30 - 20:30 **EVENTO SOCIAL**

20:30 - 22:30 **CENA**

10 DE NOVIEMBRE DE 2023

8:30 - 9:10

Moderadores:

Nancy Ascher,
Natividad Cuende,
Stefan Tullius

MESA REDONDA 3: Innovación en la donación y aplicación clínica de sustancias de origen humano (SoHO): órganos

- **Cómo abordar la innovación en la donación y el trasplante de órganos** (20 min)

Gabriel Oniscu, Suecia

- **DEBATE**

9:10 - 11:40

Moderadores:

John Forsythe,
Marta López-Fraga,
Dominique Martin

MESA REDONDA 4: Problemas éticos y hoja de ruta para impulsar los Principios Rectores del Trasplante de la Organización Mundial de la Salud

- **Caso 4 : Crisis y trasplante** (15 min)

Dominique Martin, Australia

- **Cómo garantizar la equidad en el acceso a las terapias basadas en SoHO** (20 min)

Esteve Trias, España

- **Cómo abordar el acceso al trasplante cuando los pacientes cruzan fronteras** (20 min)

Thomas Mueller, Suiza

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- **Cómo hacer realidad el principio de neutralidad económica en la donación** (20 min)

Benita Padilla, Filipinas

- **Cómo prevenir el tráfico de órganos y otras sustancias de origen humano (SoHO)** (20 min)

Riadh Fadhil, Qatar

- **DEBATE**

11:40 - 12:10

SESIÓN FINAL: Mirando al futuro

Moderadores:

Efstratios Chatzixiros,
Beatriz Domínguez-Gil

- **La Declaración de Santander**

Alicia Pérez Blanco, España

Kristof Van Assche, Bélgica

12:10 - 12:30 PAUSA CAFÉ

12:30 - 13:45

MESA REDONDA *El trasplante: una visión a 10 años*

- **Gabriel Oniscu**

Presidente, European Society for Organ Transplantation

- **Elmi Muller**

Presidenta, The Transplantation Society

- **Stefaan Van der Spiegel**

Jefe del área de sustancias de origen humano, Comisión Europea

- **Nicolás González Casares**

Diputado español, Parlamento Europeo

- **Petra Doerr**

Directora EDQM, Consejo de Europa

- **Yukiko Nakatami**

Directora general adjunta, Organización Mundial de la Salud

CIERRE INSTITUCIONAL

- **Marija Bubas**

Secretaria de Estado de Sanidad, Croacia

- **Carla Vizzotti**

Ministra de Salud, Argentina

- **José Miñones**

Ministro de Sanidad, España

13:45

COMIDA

TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

09-10/NOV/2023
High Level Meeting



PRESIDENCIA
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NOVEMBER 9TH 2023

8:30 – 9:00 **REGISTRATION**

9:00 – 9:15 **INSTITUTIONAL OPENING**

9:15 – 9:35 *Overview of donation and transplantation in the world: aims of the meeting, methodology and expected outcomes*
Beatriz Domínguez-Gil, Spain

9:35 – 9:45 *Patient-driven transformations in transplantation*
Daniel Gallego, European Kidney Patients Federation and European Kidney Health Alliance

9:45 - 12:00

Chairs:

Elmi Muller,
Luciano Potena

ROUND TABLE 1: Why transplantation should be a priority in the health-care agenda and how can transplantation contribute to attaining the United Nations Sustainable Development Goals

- **Case study 1: Making transplantation a health-care priority (15 min)**
Joel de Andrade, Brazil
- **The impact of transplantation upon health (non-communicable diseases & universal access to health) (20 min)**
Efstratios Chatzixiros, WHO
Luciano Potena, Italy
- **The impact of transplantation upon other United Nations Sustainable Development Goals(20 min)**
Vivekanand Jha, India
Marina Berenguer, Spain
- **Transplantation as part of more resilient health-care systems (20 min)**
Derek Manas, UK
- **When and how to start a transplantation program in a low resource environment (20 min)**
Elmi Muller, South Africa
Curie Ahn, South Korea

• **DISCUSSION**

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12:00 - 13:00 LUNCH BREAK

13:00 - 15:15

Chairs:

Matthew Cooper,
Francis L.
Delmonico,
Dale Gardiner,
Sanjay Nagral

ROUND TABLE 2: *Donation and transplantation: challenges and way forward*

- **Case study 2: Transforming deceased donation through donation after the circulatory determination of death** (15 min)
Eduardo Miñambres, Spain
- **Promoting the unified concept of death** (20 min)
Francesco Procaccio, Italy
- **Reducing disparities in deceased donation and increasing organ utilization** (20 min)
Helen Opdam, Australia
- **Reducing disparities in living donation** (20 min)
Krista Lentine & Amy Waterman, United States
- **Reinforcing oversight: activity monitoring and registries of post-donation and post-transplant outcomes** (20 min)
Michel Spiro, UK
Dimitri A. Ratis, Saudi Arabia

• **DISCUSSION**

15:15 - 15:45 COFFEE BREAK

15:45- 18:15

Chairs:

Nancy Ascher,
Natividad Cuende,
Stefan Tullius

ROUND TABLE 3: *Innovation in the donation and clinical application of substances of human origin (SoHO): cells & tissues*

- **Case Study 3: Cell therapy to induce tolerance** (15 min)
Rafael Correa, Spain
- **When SoHO become medicines and medical devices: regulatory borderlines and implications** (20 min)
Ander Izeta, Spain
- **Addressing clinical efficacy and safety before innovation reaches the bedside** (20 min)
Verena Plattner, Austria

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- **Making innovation sustainable for health-care systems** (20 min)
Martin Börgel, Germany
 - **Public-private partnerships to make innovation accessible to patients**
(20 min)
Rachele Ciccocioppo, Italy
 - **DISCUSSION**

19:30 - 20:30 SOCIAL EVENT

20:30 - 22:30 DINNER

NOVEMBER 10TH 2023

8:30 - 9:10

Chairs:

Nancy Ascher,
Natividad Cuende,
Stefan Tullius

ROUND TABLE 3: Innovation in the donation and clinical application of substances of human origin (SoHO): organs

- **Addressing innovation in organ donation and transplantation** (20 min)
Gabriel Oniscu, Sweden
- **DISCUSSION**

9:10 - 11:40

Chairs:

John Forsythe,
Marta López-Fraga,
Dominique Martin

ROUND TABLE 4: Ethical challenges and the way forward to implement the WHO Guiding Principles

- **Case Study 4: Crisis and transplantation** (15 min)
Dominique Martin, Australia
- **Promoting equity in access to SoHO-based therapies** (20 min)
Esteve Trias, Spain
- **Promoting fairness in access to transplantation when people cross borders** (20 min)
Thomas Mueller, Switzerland

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- **Making financial neutrality in donation a reality** (20 min)
Benita Padilla, Philippines

- **Preventing trafficking in organs and other SoHO** (20 min)
Riadh Fadhil, Qatar

- **DISCUSSION**

11:40 - 12:10

FINAL SESSION

Chairs:

Efstratios Chatzixiros,
Beatriz Domínguez-Gil

- **The Santander Statement**
Alicia Pérez Blanco, Spain
Kristof Van Assche, Belgium

12:10 - 12:30 COFFEE BREAK

12:30 - 13:45

ROUND TABLE: A vision of transplantation 10 years ahead

- **Gabriel Oniscu**
President, European Society for Organ Transplantation
- **Elmi Muller**
President, The Transplantation Society
- **Stefaan Van der Spiegel**
Head of Sector, Substances of Human Origin (SoHO), European Commission
- **Nicolás González Casares**
Member, European Parliament
- **Petra Doerr**
EDQM Director, Council of Europe
- **Yukiko Nakatami**
Assistant Director-General, World Health Organization

INSTITUTIONAL CLOSING

- **Marija Bubas**
State Health Secretary, Croatia
- **Carla Vizzotti**
Health Minister, Argentina
- **José Miñones**
Health Minister, Spain

13:45

LUNCH

TOWARDS GLOBAL CONVERGENCE IN TRANSPLANTATION: SUFFICIENCY, TRANSPARENCY & OVERSIGHT

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CHAIRS & SPEAKERS

(in alphabetical order)

Curie Ahn

Nephrologist, National Medical Center
Seoul, Korea

Nancy L. Ascher

Past President, The Transplantation Society
Isis Distinguished Professor of Transplantation
Professor of Surgery, University of California
San Francisco, California, US

Marina Berenguer Haym

Hepatology and Liver Transplant Unit,
Hospital Universitari i Politècnic La Fe,
Ciberehd, Instituto de Investigación Sanitaria,
University of Valencia,
Valencia, Spain

Martin Börgel

CEO, German Society for Tissue Transplantation
President elect, European Association of Tissue and Cell Banks
Secretary General, World Union of Tissue Banking Associations
Hannover, Germany

Efstratios (Stratos) Chatzixiros

Adviser, Transplantation Human Organs-Tissues-Cells
Blood and Other Products of Human Origin team
Health Product Policy and Standards department
WHO Headquarters
Geneva, Switzerland

Rachele Ciccocioppo

Associate Professor in Gastroenterology
Gastroenterology Unit, Department of Medicine
A.O.U.I. Policlinico G.B. Rossi & University of Verona
Verona, Italy

Matthew Cooper

Mark B. Adams Chair in Transplant Surgery
Chief, Division of Transplant Surgery
Director, Solid Organ Transplant Service Line
Froedtert Memorial Lutheran Hospital
Director, Solid Organ Transplantation
Children's Wisconsin
Tenured Professor of Surgery
Medical College of Wisconsin
Milwaukee, Wisconsin, US

Natividad Cuende Melero

Deputy Director of the Andalusian Transplant Coordination
Andalusian Health Service
Seville, Spain

Rafael Correa Rocha

Founder Chief of the Laboratory of Immune-regulation
Instituto de Investigación Sanitaria Gregorio Marañón
Founder Director, THYTECH SL
Madrid, Spain

Joel de Andrade

State Transplant Coordinator
Santa Catarina Health Authority
Florianopolis, Brazil

Francis L. Delmonico

Professor of Surgery, Harvard Medical School
Massachusetts General Hospital, Transplantation Center
Chief Medical Officer, New England Donor Services
World Health Organization
Advisor Organ Transplantation
Pontifical Academy of Sciences
Boston, Massachusetts, US

Beatriz Domínguez-Gil González

General Director
Organización Nacional de Trasplantes (ONT)
Ministry of Health
Spain

Riadh A. S. Fadhil

Professor of Urology & Transplant Surgery
Director of Qatar Organ Donation Center
Hamad Medical Corporation/ Weill Cornell College of Medicine-Q
Doha, Qatar

John Forsythe

Chair of the Ethics Committee and Council Member, The Transplantation
Society
United Kingdom

Daniel Gallego Zurro

President European Kidney Patients Federation
Board of Direction member European Kidney Health Alliance
Spain

Dale Gardiner

Associate Medical Director
Deceased Organ Donation
NHS Blood and Transplant
United Kingdom

Ander Izeta Permisán

Advanced Therapies Unit
Donostia University Hospital
Donostia-San Sebastián, Spain

Vivekanand Jha

George Institute for Global Health, India
School of Public Health, Imperial College
London, United Kingdom

Krista Lentine

SSM Health-Saint Louis University Transplant Center
St. Louis, Missouri, US

Marta López Fraga

Scientific Programme Manager
Organ Transplantation
Department of Biological Standardisation, OMCL Network & HealthCare.
EDQM, Council of Europe
Strasbourg, France

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CHAIRS & SPEAKERS

(in alphabetical order)

Derek M Manas

Medical Director Organ & Tissue Donation & Transplantation
NHS Blood and Transplant
United Kingdom

Dominique Martin

Professor in Health Ethics and Professionalism
School of Medicine, Faculty of Health
Deakin University Australia
Australia

Eduardo Miñambres García

Intensivist and Head of the Transplant Coordination Unit
Marqués de Valdecilla University Hospital
Associate Professor in Surgery at University of Cantabria
Santander, Spain

Thomas F Mueller

Professor of Medicine
Director a.i., Clinic of Nephrology
Medical Lead of the Renal Transplant Program
Co-chair, Declaration of Istanbul Custodian Group
University Spital of Zurich
Zurich, Switzerland

Elmi Muller

President, The Transplantation Society
Dean at University of Stellenbosch, Faculty of Medicine and Health
Sciences
City of Cape Town, Western Cape, South Africa

Sanjay Nagral

Director Department of Surgical Gastroenterology
Jaslok Hospital & Research Center
Co-Chair, Declaration of Istanbul Custodian Group
Mumbai, India

Gabriel C Oniscu

President, European Society for Organ Transplantation
Chair of Transplantation Surgery
Head of Transplant Division
Department of Clinical Science, Intervention and Technology
Karolinska Institutet
Stockholm, Sweden

Helen Opdam

Intensive Care Specialist, Austin Hospital
Director of Intensive Care, Warringal Private Hospital
National Medical Director, Australian Organ and Tissue Authority
President, International Society for Organ Donation and Procurement
Australia

Benita Padilla

National Kidney and Transplant Institute
Philippines

Alicia Pérez Blanco

Intensivist. Medical Officer
Organización Nacional de Trasplantes (ONT)
Ministry of Health
Spain

Verena Plattner

Austrian Federal Office for Safety in Healthcare (BASG/AGES MEA)
Head of Department Blood, Tissue & Vigilance
Austria

Luciano Potena

Past President, European Society for Organ Transplantation
Director Heart Failure and Transplant Unit
IRCCS Azienda Ospedaliero-Universitaria di Bologna
Bologna, Italy

Francesco Procaccio

Advisor, National Transplant Centre Roma
National DCD Project, ANED Milan
Former Director, Neuro ICU Dpt.
University City Hospital of Verona
Verona, Italy

Dimitri Aristotle Raptis

Consultant HPB and Liver Transplant Surgeon
Lead of the Analytics Data Unit, Organ Transplant Center of Excellence
King Faisal Specialist Hospital and Research Center
Riyadh, Saudi Arabia

Michael Spiro

Consultant in Anaesthesia and Liver Intensive Care Medicine
The Royal Free NHS Foundation Trust
Associate Professor. The Division of Surgery
University College London
London, United Kingdom

Esteve Trias

Technical Director
Advanced Therapies Unit, Hospital Clinic of Barcelona
Executive Medical Director, Leitat Technological Center
Barcelona, Spain

Stefan G. Tullius

Joseph E. Murray, MD Distinguished Chair in Transplant Surgery
Chief, Division of Transplant Surgery
Professor of Surgery, Harvard Medical School
Brigham and Women's Hospital
Boston, Massachusetts, US

Kristof Van Assche

Research Professor in Health Law
University of Antwerp
Antwerp, Belgium

Stefaan Van der Spiegel

Head of Sector. Substances of Human Origin (SoHO)
European Commission
DG SANTE (Health and Food Safety)
Unit B4 – Medical Products: quality, safety, innovation

Amy D. Waterman

Director, Patient Engagement, Diversity, and Education
Professor of Outcomes Research
Houston Methodist Department of Surgery and J.C. Walter Jr.
Transplant Center
Houston, Texas, US