

Malta

(MT)



Achieving Comprehensive Coordination in Organ Donation



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FINAL DISSEMINATION MEETING MADRID 2ND.

JUNE 15

Mr. Paul Calleja



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Malta & Gozo

THE MEDITERRANEAN ISLANDS

OSLO STOCKHOLM

GLASGOW

COPENHAGEN

DUBLIN

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BIRMINGHAM

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MONASTIR

GOZO

MALTA

LARNAÇA

DAMASCUS

BEIRUT

TEL AVIV

CAIRO

LISBON

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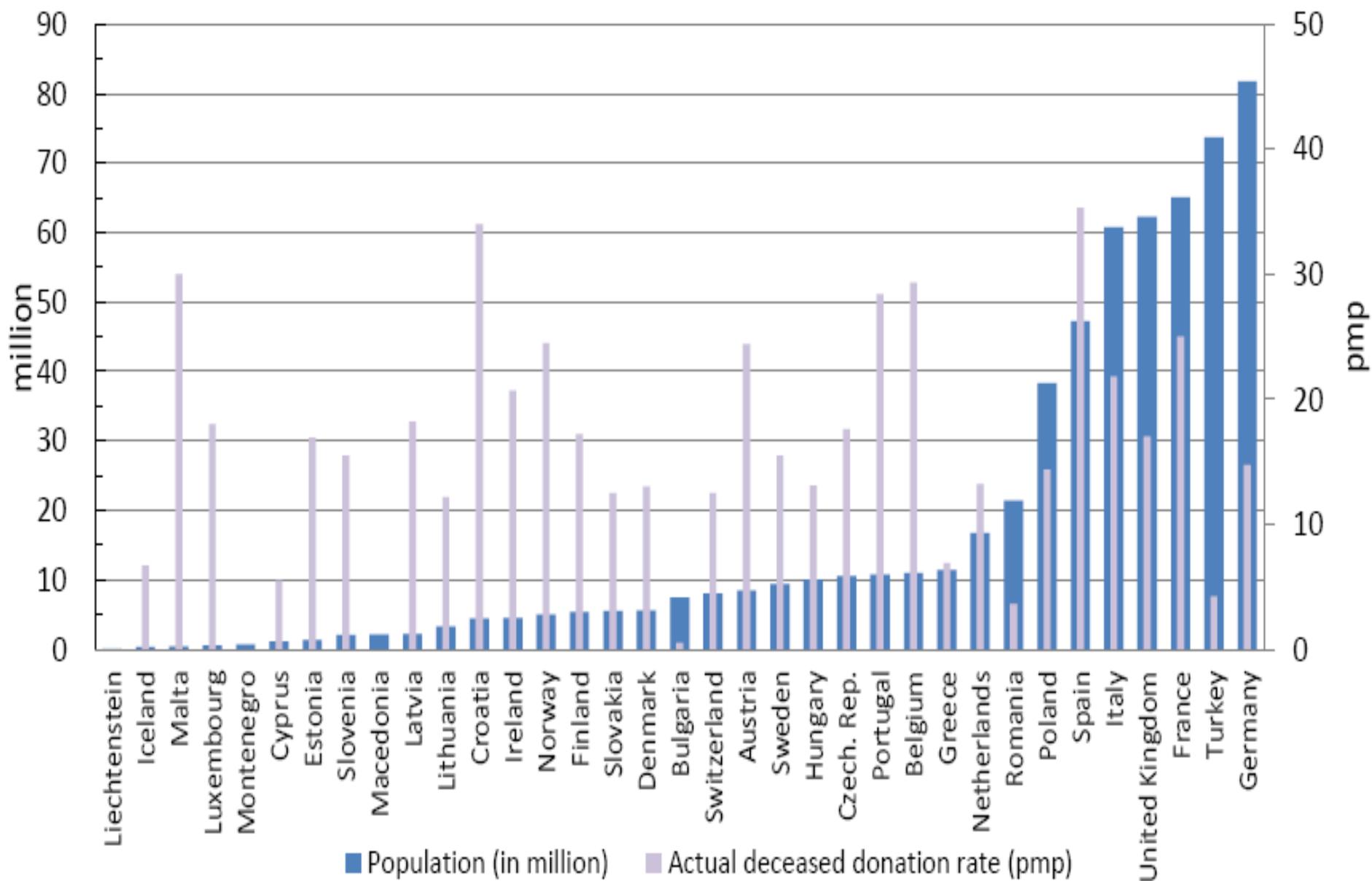


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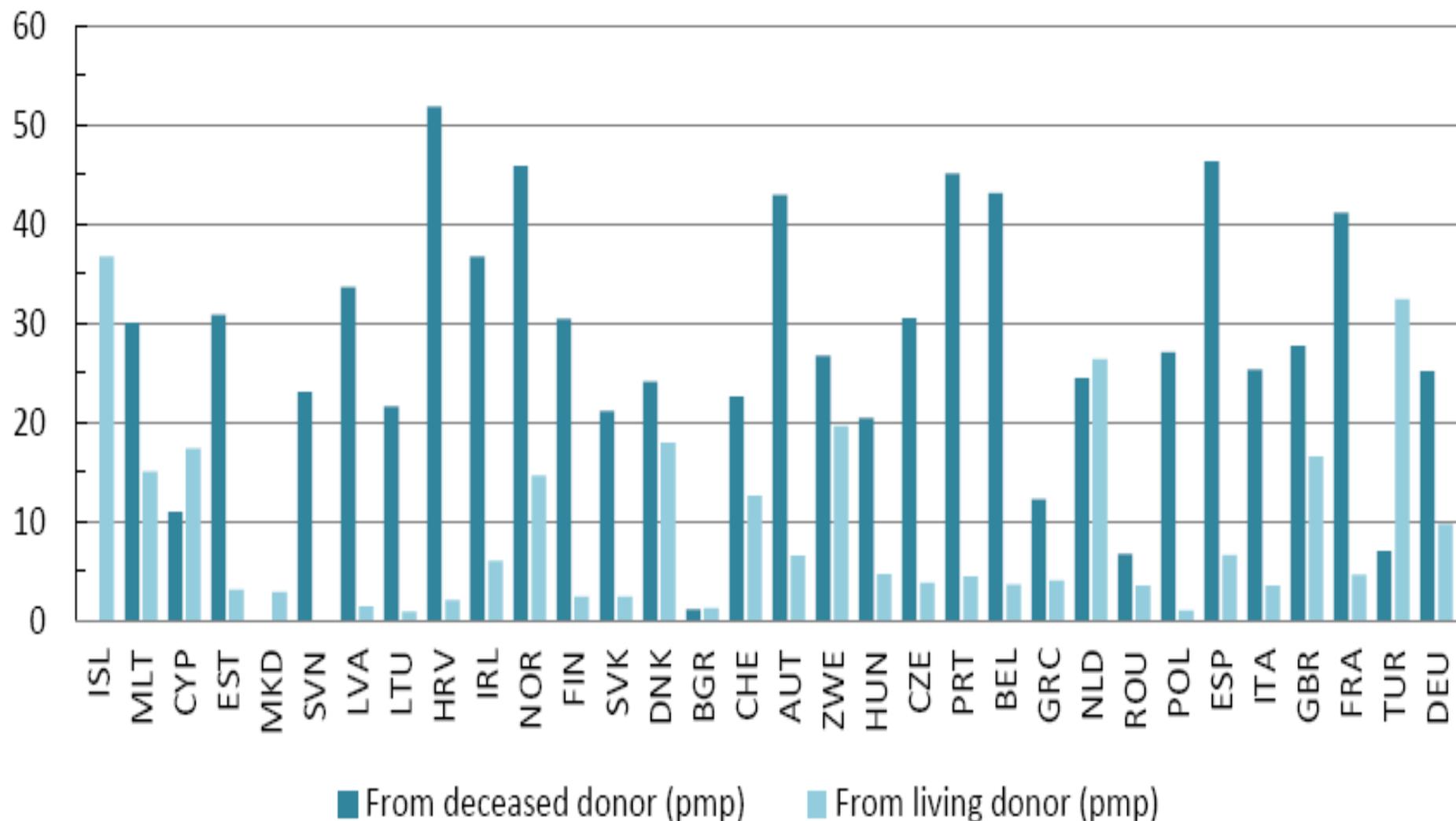
Transplantation in Malta

- Transplantation of Kidneys and Heart
- 1 donor hospital with a population of 0.4 m.
- ICU and Neuro. Surgical ward with 20 beds each
- 85 patients waiting for a kidney graft (WT 4-5yrs)
- Directed and undirected living donation programs
- No HLA lab with no sensitisation programme
- 4 patients waiting for a heart graft
- Bilateral collaboration with CRT and UK Tx
- Liver programme with UK
- Lung programme with Sicily
- Pancreas programme with Italy

Population/Actual deceased donation rate (pmp) 2011



Kidney transplant procedures in 2011: from deceased and living donors





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Legal framework

- There are 4 legal notices
- Dir. 2010/53/EU has been transposed 2012
- Present SOPs are according to EU standards
- White paper which closed last May
- New law on organ donation to be in place by end of 2015



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Proposal for the new law

- To keep the current ***soft opt in***
- Donor card to have more legal strength
- National register for donors and non donors
- National register for ***living donors***
- Legal frame work for organ allocation
- To clamp down on human organ trade



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ACCORD participation

- WP6 Italy Cyprus, Czech Rep. Lithuania, Malta
- Setting up a Nat. Accreditation & Audit system for organ Tx facilities based on the Italian model
- Improve the quality and safety of organ donation and Tx
- Training courses for Experts / Inspectors
- Harmonisation of SOP customised to every MS
- Systematic training and education



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Accreditation and Auditing of Transplant Center in Malta

- Based on the Directive 2010/53 and its transposition into Maltese Law
- Competent Authority
 - (a) Superintendant of Public Health (SPH)
 - (b) Based on advise from Experts in the Main Hospital (MDH)



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Twinning with CN

- Two visits from CNT to Malta
 - 1) discuss the project, visit of local facilities and meetings with the key stakeholders
 - 2) Follow up meeting after the training of local experts to discuss other areas for collaboration between Malta and Italy:
 - HLA Typing
 - Problematic renal transplant recipients
- Training course in Rome (Feb/2014)
- Formulation of local procedures and documents by the SPH



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Training in Rome for 2 Local Experts

- This occurred in February 2014
- A Liver Transplant centre accreditation was simulated
- This was followed by development of local documents for Transplant Centre Accreditation
- Serious Adverse Reactions/Events process also created



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Health Care Standards Directorate

Superintendence of Public Health

Ministry for Health

Checklist For Licensing of Transplant Facilities

Name of Hospital :

Address of the Hospital

I. GENERAL INFORMATION

Owner :

Chief of Hospital/CEO/Medical Director

Ownership : Government

Private

Hospital License Held and Validity

II. ADMINISTRATION

Organization/Program Setup and Goals	Yes	No
An organizational chart and structure, showing the scope of authority, function and responsibilities of the various personnel and the lines of communication among them, is available	<input type="checkbox"/>	<input type="checkbox"/>
A Hospital Organ Donation Program is created to oversee organ donation activities and process in the hospital	<input type="checkbox"/>	<input type="checkbox"/>

III. QUALITY MANAGEMENT

Quality Management	Yes	No
The hospital has an established, documented and maintained quality management program on organ donation and transplantation that reflects continuous quality improvement principles.	<input type="checkbox"/>	<input type="checkbox"/>
Availability of Quality Manager	<input type="checkbox"/>	<input type="checkbox"/>
Availability of Written Policies and Procedures	<input type="checkbox"/>	<input type="checkbox"/>
The hospital has a Manual of Operations or Quality Manual on Organ Donation and Transplantation and includes, among others, the following: <ul style="list-style-type: none"> • Operating procedures for the verification of donor identity; • Operating procedures for the verification of the details of 	<input type="checkbox"/>	<input type="checkbox"/>



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Health Care Standards Directorate
Superintendence of Public Health

Ministry for Health

Serious Adverse event/reaction Report Form

Organ Transplantation

A serious adverse event is defined as any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

A serious adverse reaction is defined as 'an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs hospitalisation or morbidity'.

REPORTER DETAILS

Title:	Name:	Date:
Establishment/Organisation/Department:		
Address:		
E-mail:		Telephone number:

REPORT DETAILS

Report identification number:	Report type: SAE <input type="checkbox"/> SAR <input type="checkbox"/>
Involves: Donor <input type="checkbox"/> Recipient <input type="checkbox"/> Donor and recipient <input type="checkbox"/> N/A <input type="checkbox"/>	
Type of donor: Deceased <input type="checkbox"/> Living <input type="checkbox"/>	
Type of organ involved: Liver <input type="checkbox"/> Pancreas <input type="checkbox"/> Heart Lung <input type="checkbox"/> Kidney <input type="checkbox"/> Other <input type="checkbox"/> If other, please specify:	
Retrieval team (name of hospital):	



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Living Donor register

- Register will be set up once legislation is in place
- We believe that it is our moral obligation to keep monitoring LD
- Standardised follow up of donors
- Donors shall be accommodated with beneficial rights
- Audit data will be useful for regular auditing and during accreditation visits



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Waiting List Management and selection of recipients

- ACCORD stimulated internal discussions on how to improve outcome by using HLA in the matching of DBD kidneys along with WT and age
- HLA typing is being made available for selecting the best donor in LDTx
- Waiting list is now better managed and regularly updated
- Marginal donors are more utilised



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Donation and transplant data for 2014

- We had 12 offered DBD donors of which 10 were utilised
- 25 utilised donors pmp
- 15 kidneys from these 10 utilised donors were transplanted locally
- This is an improvement over previous years (the result of more awareness through the ACCORD visit meetings)



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Milestones

- Organ allocation based on HLA will compliment the present WT and age (collaboration with IT)
- Sensitised recipients program with IT and UK
- An ongoing NHBD program
- Creation of a 'Website'
- Develop a system for accreditation and audit
- Foreign accreditation of our TC
- Upgrading local SOPs



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Thank you