



Stefaan Van der Spiegel



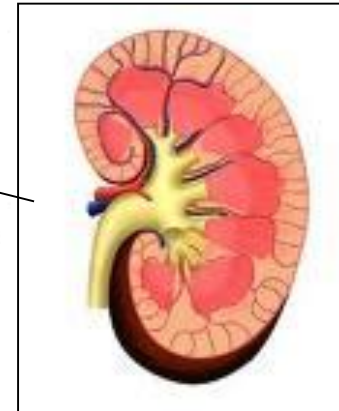
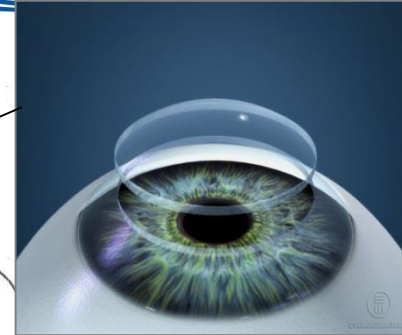
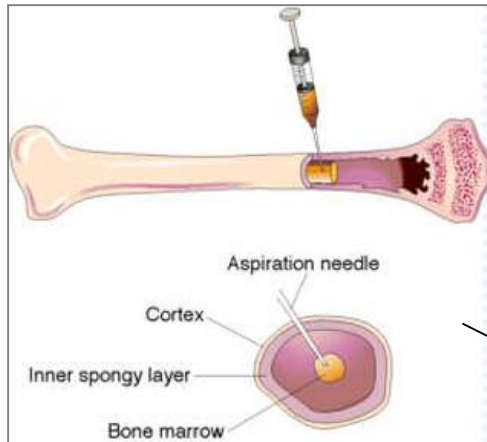
Organ Donation and Transplantation in the EU

Stefaan Van der Spiegel
Substances of Human Origin (SoHO)

European Commission
DG Health and Food Safety (SANTE)
Unit B4 / Medical products:
quality, safety and innovation

*EKHA Forum
European Parliament
26 April 2018*

Substances of Human Origin



The Treaty of the Functioning of the European Union Article 168



- Health is a competence of the Member States (MS)
- EU role: to complement national policies, foster cooperation between MS and third countries.

!BUT, Art 168 4(a) calls to set 'measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives;

these measures shall not prevent any Member State from maintaining and introducing more restrictive standards'



2002

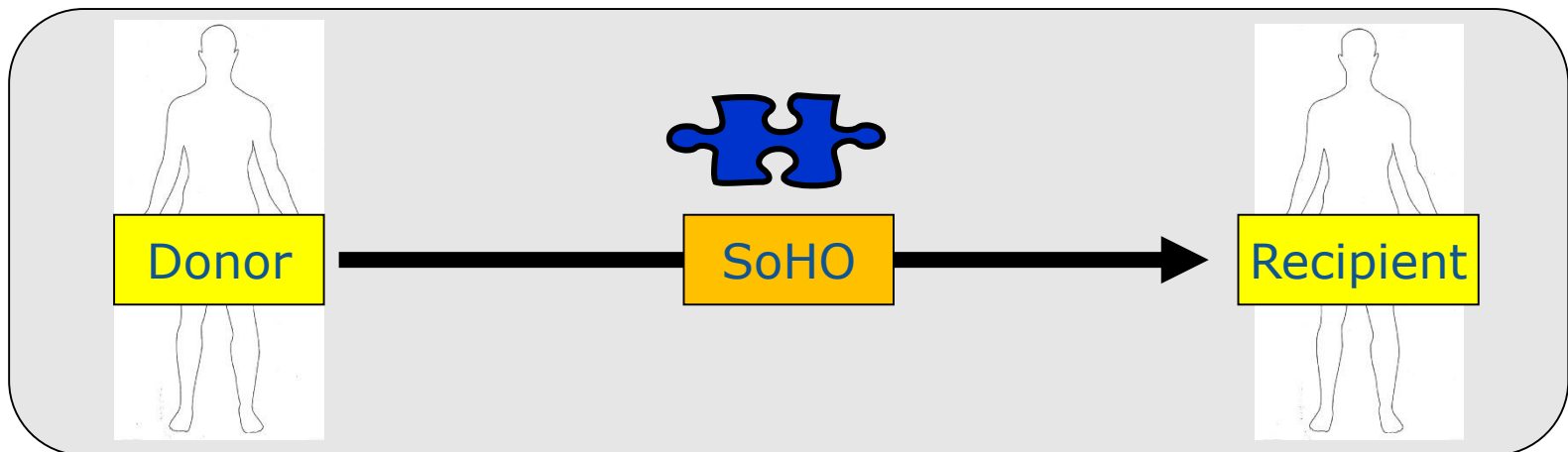


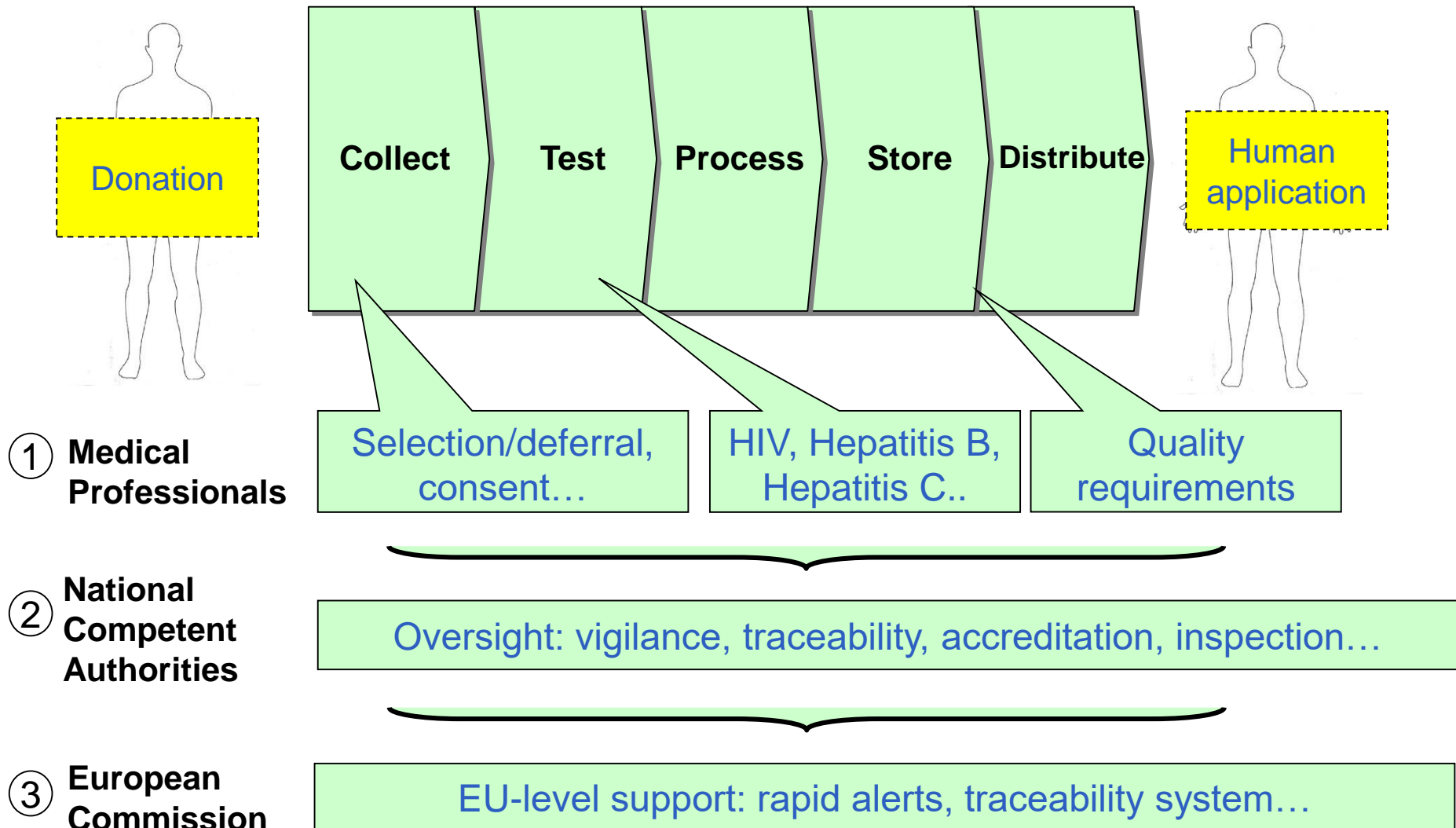
2004

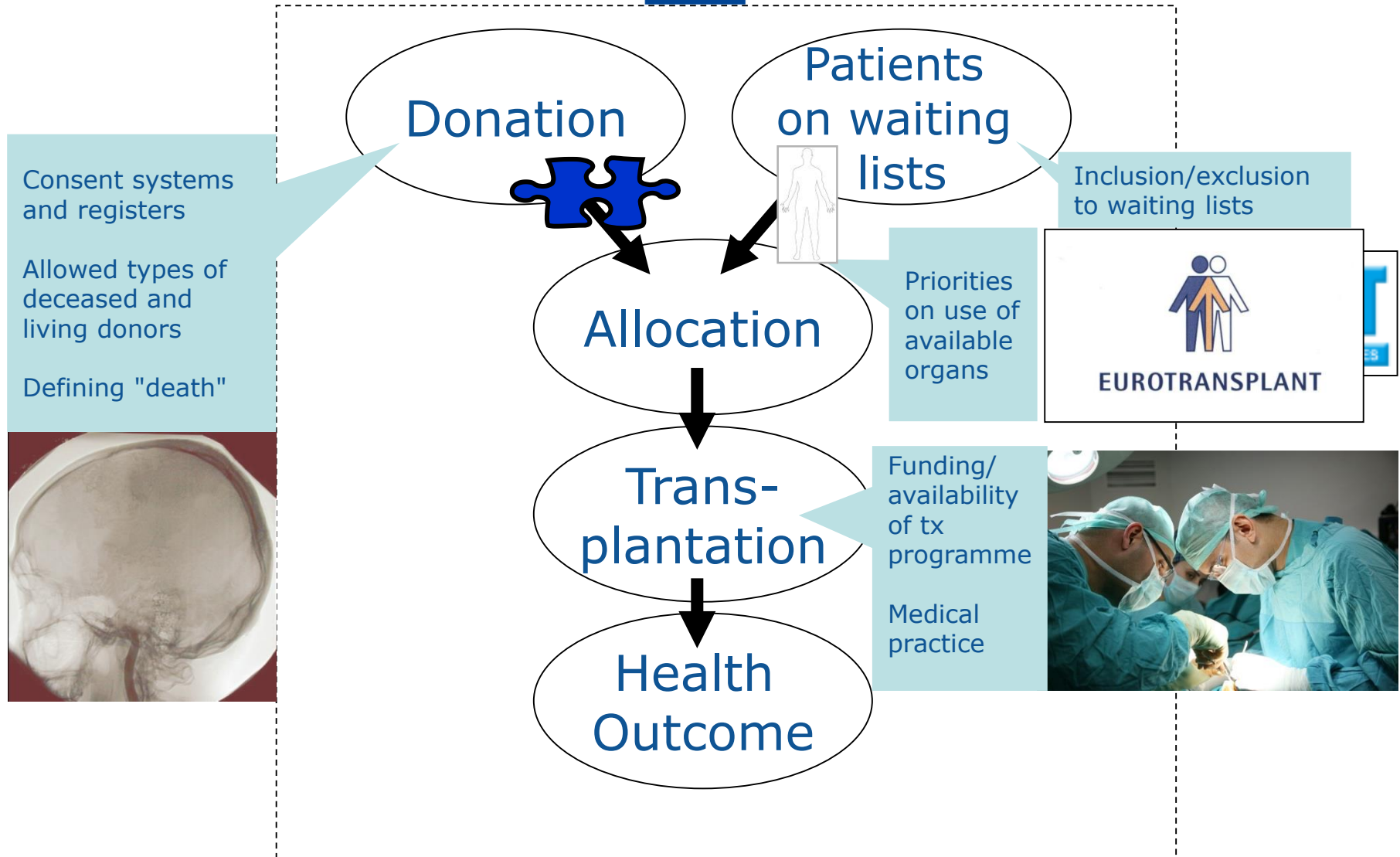


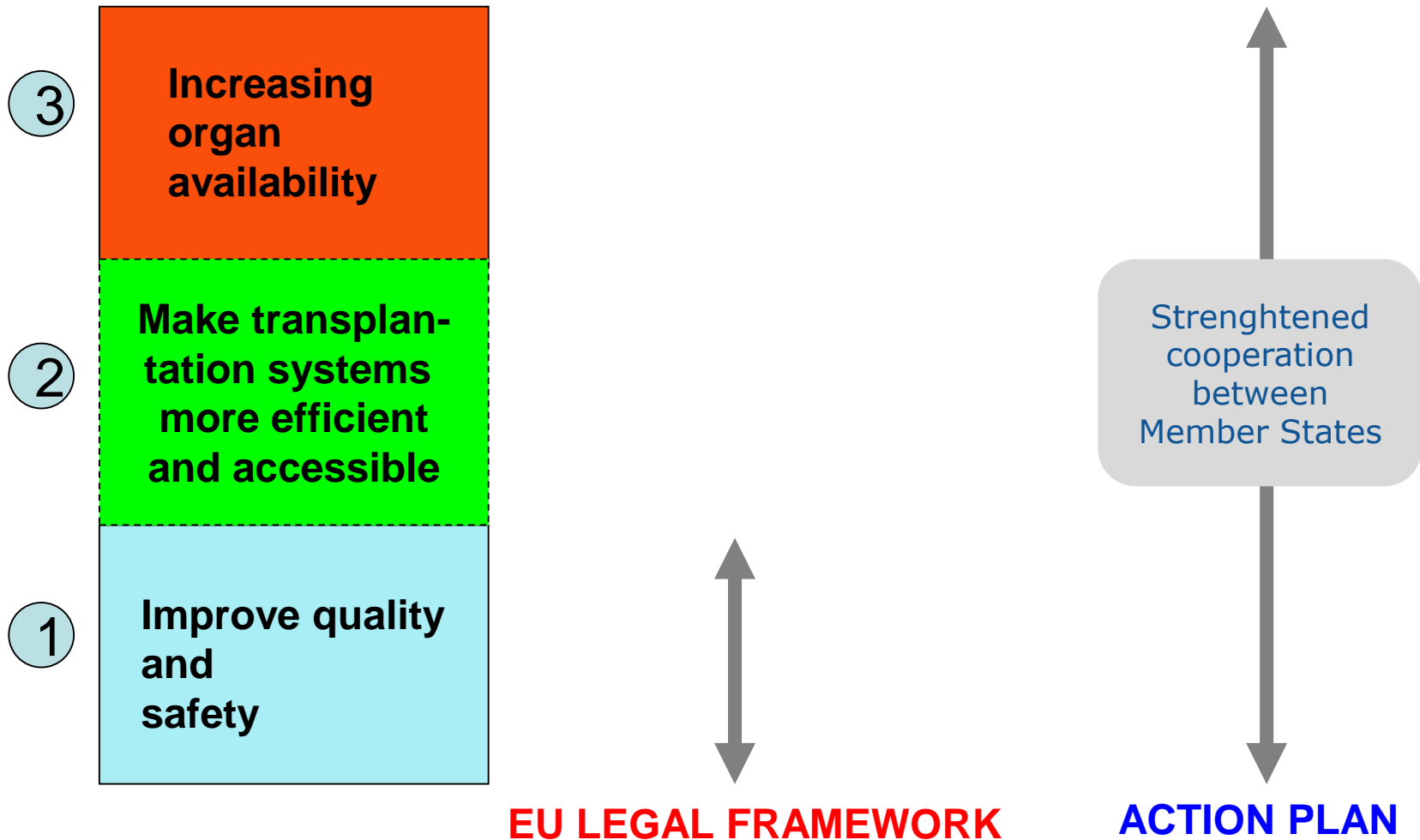
2010

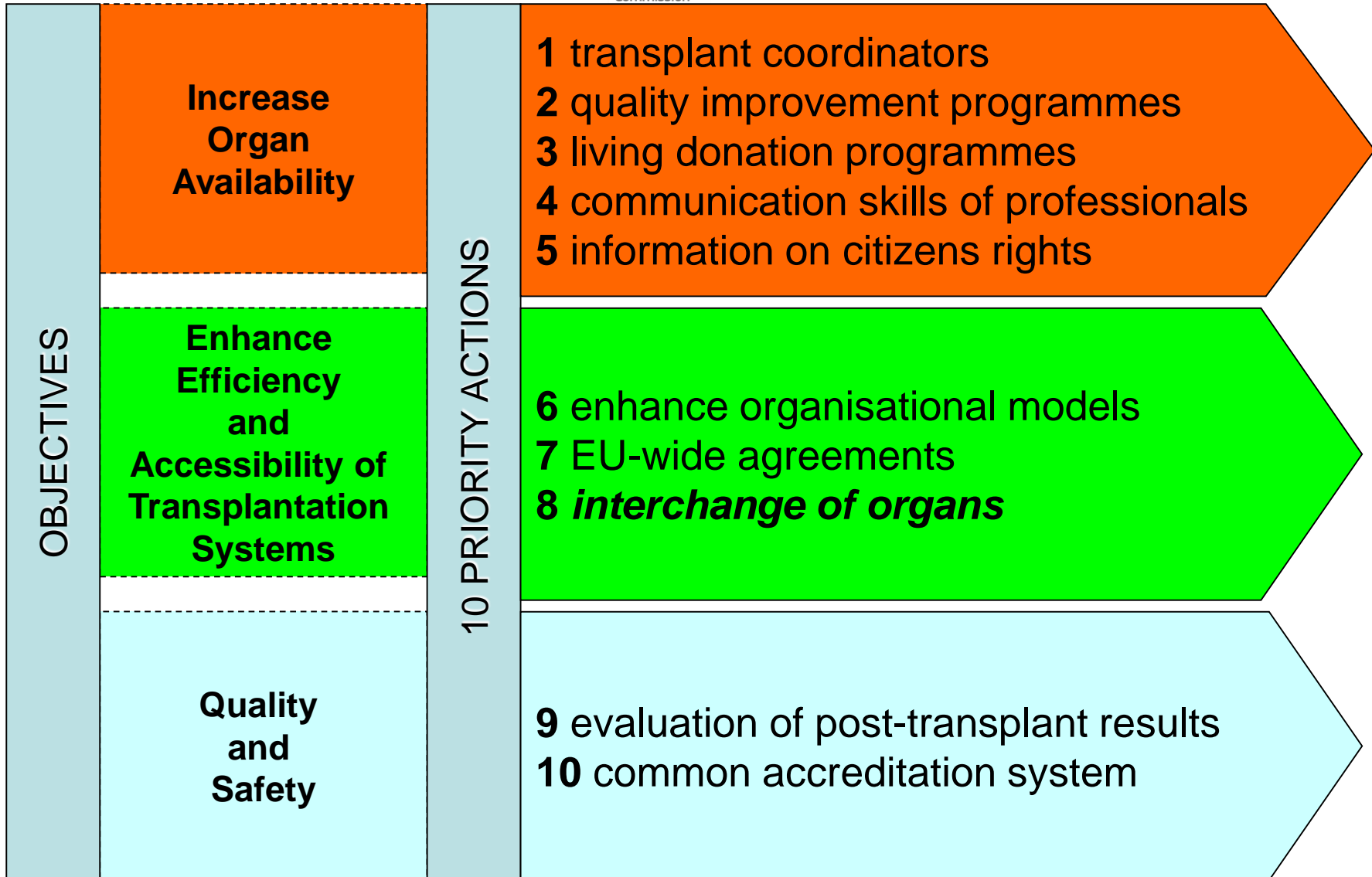
2012 Implementing Directive to support organ exchange between Member States







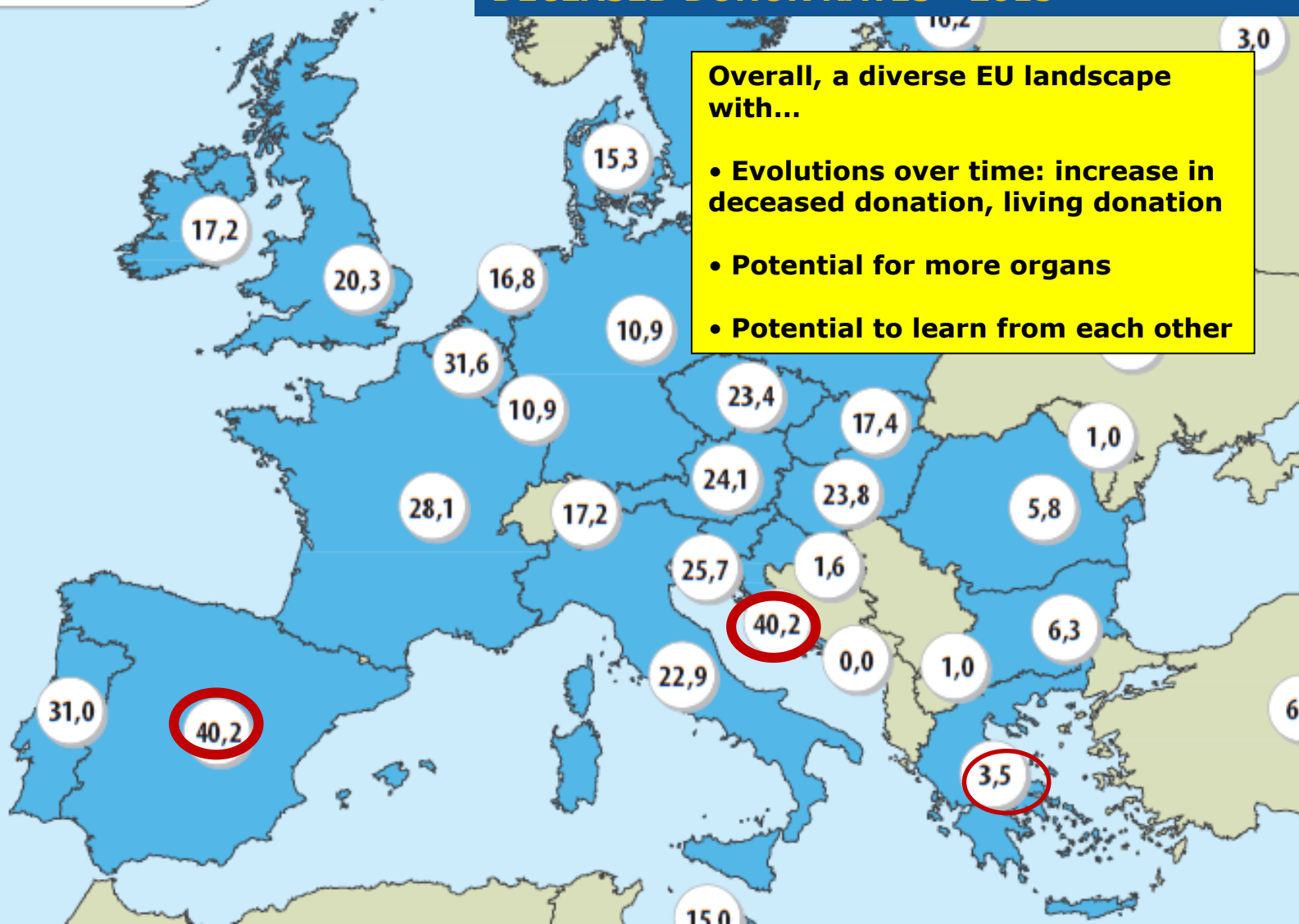




ACTUAL DECEASED ORGAN DONORS
-both DBD and DCD included-
Annual Rate p.m.p
2015

MEMBER STATE DIFFERENCES DRIVE OPPORTUNITIES

DECEASED DONOR RATES - 2015



Overall, a diverse EU landscape with...

- Evolutions over time: increase in deceased donation, living donation
- Potential for more organs
- Potential to learn from each other

EU supported Actions



- Alliance – O
- DOPKI
- **ETPOD**
- **EULID**
- **EDD**
- **ELPAT**
- **EFRETOS**
- **ELIPSY**
- **COORENOR**
- **EULOD**
- **ODEQUS**
- **Train the Trainers**
- **MODE**

- ACCORD
- **FOEDUS**
- EUDONORGAN
- EDITH
- **Direct Grants Council of Europe**
- HOTT
- LIDOBS
- ONE study
- Bio-DrIM
- COPE
- STELLAR

Joint Action, funded by Public Health Programme

Fit to Priority Action 8: Interchange of organs

Aim: Facilitation exchange of organ donated in European Member States

Developed IT-platform: pilot with 8 countries during 9 months (@10,000€/y)

Organs	Offers	Accepted	Transplanted
HEART	33	9	5
LIVER	25	14	9
SMALL BOWEL	23	1	1
KIDNEYS	23	7	4
LUNGS	23	6	4
PANCREAS	3	0	0
MULTIVISCERAL	1	1	0
Total	131	38	23

- Regular **meetings** of EU-28 National Competent Authorities for organ transplantation
- Commission-funded **projects (PHP)**: ex. on living donation
- Dedicated **working groups**:
 - E.g., WG on living donation (2012-3) developed a "toolbox on living kidney donation" – for authorities to support this activity
- *Since 2015: EP-funded* pilot projects !
 - Chronic Kidney Diseases - EDITH (MEP Karin Kadenbach)
 - Social awareness on organ donation *EUDONORGAN* - (MEP Gabriel Mato)



3-year project

Consortium

- *University of Barcelona - Fundació Bosch I Gimpera (UB-FBG), **Spain***

Partner /Country:

- *Donation and Transplantation Institute (DTI), **Spain**.*
- *Institute for transplantation of Organs and Tissues of the Republic of Slovenia (ITOT), **Republic of Slovenia***
- *Institute for Transplantation and Biomedicine (ITB), Ministry of Health, **Republic of Croatia***
- *Italian National Transplant Centre (CNT), **Italy***
- *Dinamia S.L. , **Spain***



1) To train health professionals and other relevant actors

2) To organize "awareness raising" events with the support of the trained professionals

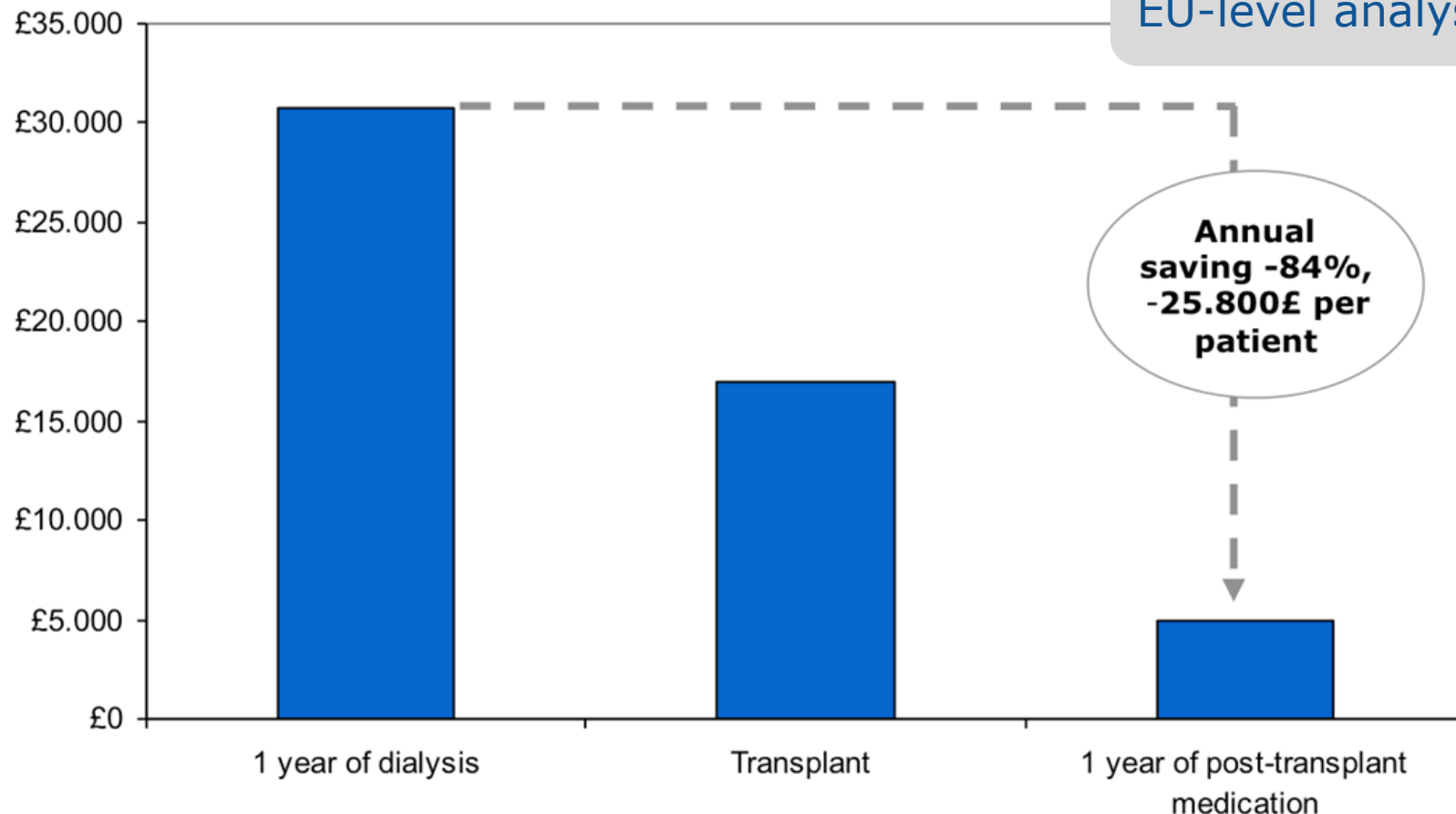
3) To propose and implement dissemination actions as well as monitoring and evaluation strategies

Kidney transplants offer annual savings (UK)

Costs per patient of treatment options for end-stage renal failure

European
Commission

EDITH is preparing
EU-level analyses



In 2009, 23.000 patients with a functioning kidney transplant were estimated to save 512million£ per year in dialysis costs



European
Commission

EVALUATION ACTION PLAN

Press release FACTOR

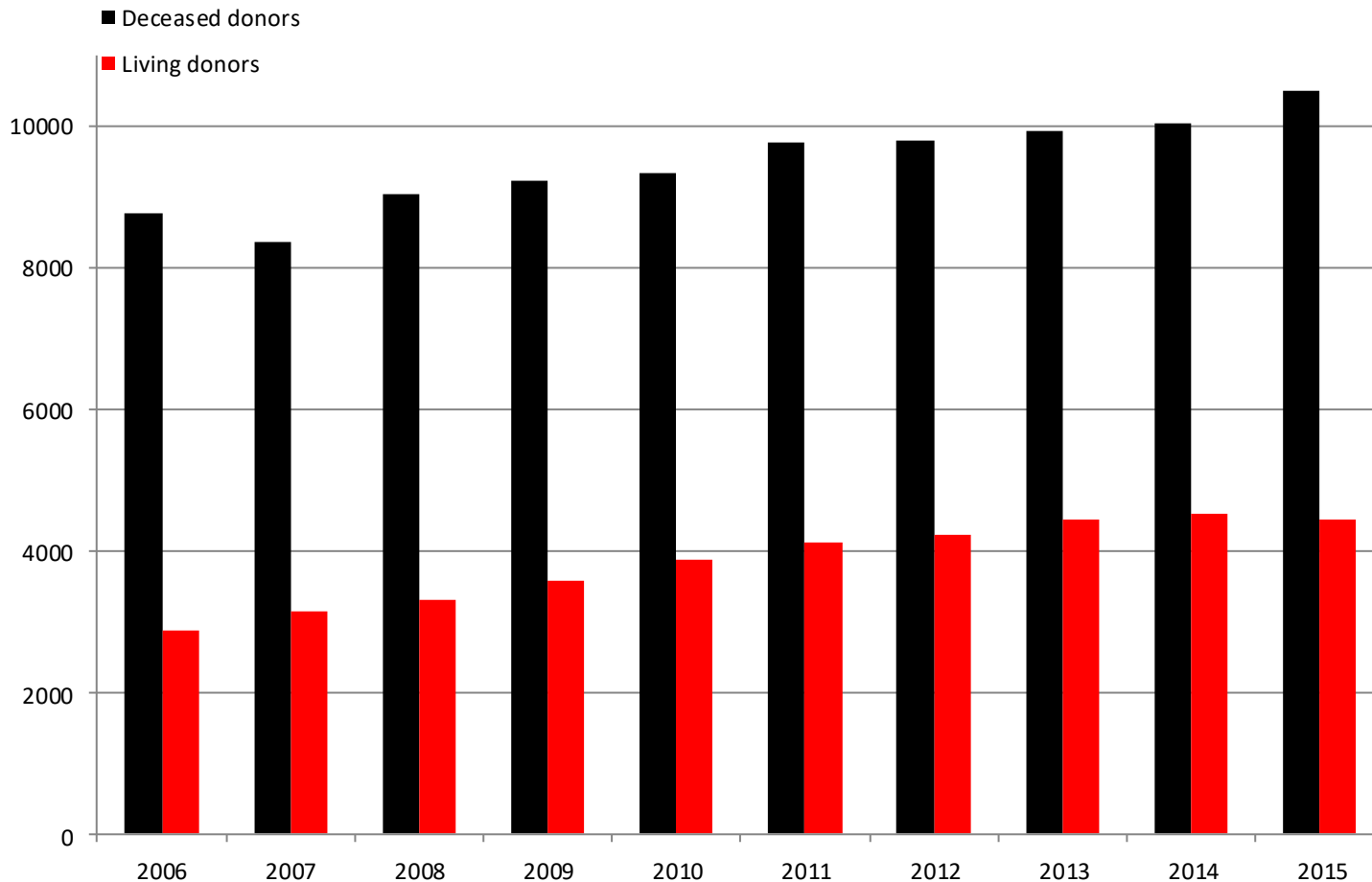
"EU Action Plan helped spur a 17% increase in organ transplants between 2008 and 2015"

- Increase in organ donors from 12000 to 15000
- 4600 additional transplants: from 28100 to 32700
- Kidneys (60%), Liver (24%), heart (11%)

- Spain, France, UK, Poland and the Netherlands five main contributors
- Bulgaria, Lithuania, Finland, Croatia, Hungary, Czech Republic, Slovenia, Latvia and Denmark with sharpest overall increase
- Some countries decline, like Germany where numbers fell with 20%

- Action Plan lead to appointment of local coordinators for deceased donation and registries for living donors

Increase in donation and (lung) transplantation



Deceased
donation
+ 21 %

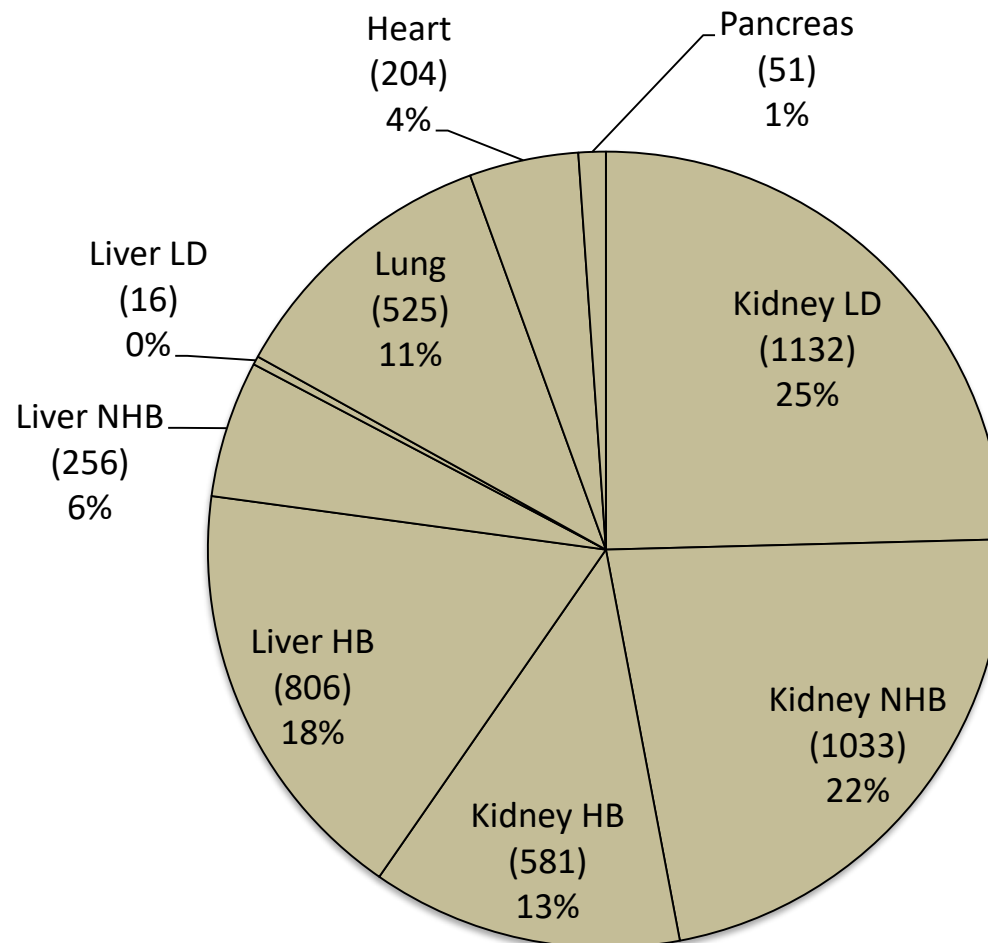
Living
donation
+ 56 %

Total
donation
+ 29 %



European
Commission

4604* additional transplants per type



- Reduction of 7 small bowel transplants is not reflected in pie chart
- Source: CoE Newsletters 2009 and 2016, ONT



Key benefits EU Action Plan

- A **shared agenda**, addressing issues with a common perspective
 - Helps obtaining political **support**
 - Alignment with other **international** positions (CoE, WHO)
- Facilitate EU-wide collaboration
 - **Exchange** best practices
 - Develop **new ideas/knowledge** and support tools through exchange
 - Overcome problems jointly
 - Build closer **relations** amongst MS
 - Allows to leverage potential of twinning and organ exchange

- Bottom-up agenda-setting, **engaging** professionals, administrations, politicians, public opinion
- Fewer **objectives**, with a stronger impact
- Clearly defined objectives, with tangible outcomes
- Bring together **groups** of countries with similar issues and situations.
- Learn from/collaborate with **adjacent areas** of expertise (e.g., tissues&cells, devices)
- More focus on MS with **less developed** transplant systems
- Reflect on **implementation** and sustainability, including IT

SoHO team members



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