

Standard Summary Project Fiche – IPA decentralized National programmes

1. Basic information

- 1.1 CRIS Number: TR2009/0328.01
- 1.2 Title: Alignment in Organ Donation (ALOD)
- 1.3 ELARG Statistical Code: 28
- 1.4 Location: Turkey

Implementing arrangements:

- 1.5 Implementing Agency: CFCU

The CFCU will be Implementing Agency and will be responsible for all procedural aspects of the tendering process, contracting matters and financial management, including payment of project activities. The director of the CFCU will act as Programme Authorizing Officer (PAO) of the project.

Mr. Muhsin ALTUN (PAO-CFCU Director)

The Central Finance and Contracting Unit

Tel: +90 312 295 49 00

Fax: +90 312 286 70 72

E-mail: muhsin.altun@cfcu.gov.tr

Address: Eskişehir Yolu 4.Km. 2. Cadde (Halkbank Kampüsü) No:63 C-Blok 06580 Söğütözü/Ankara Turkey

- 1.6 Main-Beneficiary (including details of SPO):

-GD of Curative Services / Ministry of Health of Republic of Turkey – Assoc. Prof. İrfan ŞENCAN – Acting DG

Tel: +90 312 585 14 50 / +90 312 585 14 51

Fax: +90 312 585 15 98

E-mail: irfan.sencan@saglik.gov.tr, organnakli@saglik.gov.tr

Address: Sağlık Bakanlığı Mithatpaşa Cad.No:3 B Blok Kat:2 Sıhhye/Ankara/Turkey

Financing:

- 1.7 Overall cost (VAT excluded)¹:

€3,700,000

- 1.8 EU contribution:

€3,330,000

- 1.9 Final date for contracting:

2 years after the signature of the FA

¹The total cost of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated (see Section 7.6)

1.10 Final date for execution of contracts:

2 years after the end date for the execution of contracts.

1.11 Final date for disbursements:

1 year after the end date for the execution of contracts.

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To contribute to the harmonization with and implementation of the EU *acquis communautaire* in the area of public health, specifically focusing on increasing cadaveric organ donation in Turkey.

2.2 Project purpose:

To ensure quality and safety standards for human organ donation and transplantation in medical treatment.

2.3 Link with AP/NPAA / EP/ SAA

Council Decision of 18 February 2008 on the principles, priorities and conditions contained in the Accession Partnership with the Republic of Turkey and repealing Decision 2006/35/EC (2008/157/EC) demands further align with the consumer and health acquis, including the areas of blood, tissues and cells and adequate administrative structures and enforcement capacity.

In the NPAA released in 2008 it has been stated under the priority 28.2 (Further align with the health acquis and ensuring adequate administrative structures and enforcement capacity) that “Law on the Organ, Tissue and Cell Transplantation Services” will be published between 2009 and 2010. The law regulates the procedures and principles of supply, donation, procurement, testing, processing, preservation, storage, transportation, distribution, implantation and transplantation of organs, tissues, cells, stem cells and cell components for treatment, diagnostic or scientific purposes. By-Law on the Tissue and Cell will be published in 2010. The By-Law regulates donation, procurement, testing, processing, preservation, storage, distribution, traceability requirements, notification and coding of serious adverse reactions and events of human tissues and cells.

On the other hand, “Proposal for a Commission Directive 2008/0238 of 8 December 2008 of the Commission of the European Communities as regards on standards of quality and safety of human organs intended for transplantation” has been promoted. The section 13 of the Proposed Directive mentioned that an organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Community system for tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported in the tissue vigilance system as provided for in the Directive 2004/23/EC.

The Article 11 of the Proposed Directive also mentioned that reporting system should be established in accordance with Article 11 of Directive 2004/23/EC.

The activities of the project will be beneficial in putting the draft law of organ donation and transplantation into practice.

2.4 Link with MIPD:

In Multi-annual Indicative Planning Document (MIPD) 2008-2010 for Turkey, in Component I-Transition Assistance and Institution Building, it is referred that "In addition to the above priorities, Institution Building support may also be provided in the following areas of the *acquis*, with more modest budgetary allocations: [...] Health Policy [...]".

This project aims to ensure effective implementation of organ donation and transplantation related EU *acquis communautaire* in Turkey within the framework of Health Policy.

2.5 Link with National Development Plan:

(TR) Grand National Assembly Decision, published in the Official Gazette, dated 01.07.2006, no. 26215

Priority No. 248 of the 9th National Development Plan sets improvement of health information systems.

Priority No. 603 of the 9th National Development Plan sets to improve accessibility to health services, the infrastructure and health personnel needs will be met and their distribution around the country will be balanced.

Priority No. 604 of the 9th National Development Plan sets to increase in-service training programs with the aim of improving the qualifications of health personnel.

Priority No. 608 of the 9th National Development Plan sets to increase service quality, national standards concerning service provision and personnel will be determined and the system for the accreditation of health institutions will be established.

Priority No. 609 of the 9th National Development Plan sets to strengthen the planning, regulatory and supervisory role of the Ministry of Health.

Priority No. 615 of the 9th National Development Plan sets to establish a health database compatible with international criteria.

Considering improving institutional capacity of MoH, activities mentioned in this Project addressing to improve the qualifications of health personnel, to increase the reliability of collected data, and to increase quality and safety of organs are in harmonization with the 9th State Planning Organization Plan.

2.6 Link with national / sectoral investment plans (where applicable)

N/A

3. Description of project

3.1 Background and justification:

The conclusions of the Helsinki European Council in December 1999 recognized Turkey as a candidate for membership to the European Union. In December 2004, the European Council concluded that Turkey sufficiently fulfils the Copenhagen political criteria to open accession negotiations. The EU opened accession negotiations with Turkey on 3 October 2005. Chapter 28 (Consumer and Health Protection) was opened at the fourth Accession Conference with Turkey on 19 December 2007.

Since 1999, Article 152 of the EC Treaty, as introduced by the Treaty of Amsterdam, has enabled the European Parliament and the Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted directives, on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004. It is recognised that organs need a different approach from blood or tissues.

Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells addresses the need to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme "we are all potential donors".

When adopting the Tissues and Cells Directive on 31 March 2004, the Commission committed itself to conducting a thorough scientific review of the situation regarding organ transplantation. On 31 May 2007, the Commission adopted a Communication on organ Donation and transplantation: Policy actions at EU level, Brussels – COM (2007) 275, 30.5.2007. This communication proposes what activities the EU should undertake in the field of organ transplantation. Three priority areas of action were identified: 1) improving quality and safety of organs, 2) increasing organ availability and 3) making transplantation systems more efficient and accessible. In order to respond to these objectives the Communication suggested two different mechanisms of action: an Action plan for strengthened coordination between Members States on organ donation and transplantation and an EU legal framework (Directive) on quality and safety of human organs.

On the basis of the above-mentioned Communication, the Commission adopted the "Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organ intended for transplantation"² in December 2008.

Due to rapid advances in transplantation medicine, the use of human organs for transplantation has steadily increased during the past decades. However, this advancement has led to a shortage in available organs and poses new quality and safety challenges. While the excellent results of transplants, in terms of life years gained and improvement in quality of life, have led to an increase in the demand for transplantable organs, the fact remains that demand far outstrips supply. In 2007, the

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0818:FIN:EN:PDF>

cadaveric donation rate³ was 33.8 in Spain, 23.2 in France, 21.7 in Italy, 15.3 in Germany, 12.9 in the United Kingdom, 1 in Romania and finally, the EU average was 17.8 per million populations⁴. Research by the World Health Organisation (WHO) has found that only one in ten people in need of a new kidney manage to get one. Turkey, unfortunately, achieved a cadaveric donation rate of 3.1 per million populations in 2007⁵.

The Ministry of Health (MoH), General Directorate for Curative Services (GDSCS) is the main authority regulating and supervising the organ donation and transplantation coordination services throughout the country. As regards the organ donation and transplantation services, the directorate is responsible for:

- 1- Preparation of the legislation related to organ donation and transplantation coordination services,
- 2- Improvement of quality, safety and adequacy of the organ supply,
- 3- Provision of training and certification to the personnel employed in National Organ and Tissue Transplantation Coordination Centre, Organ and Tissue Transplantation Regional Coordination Centres and hospitals,
- 4- Promoting public campaigns on organ donation.

In order to enhance productivity of organ transplantation activities and to ensure equitable and fair organ allocation, under the coordination and supervision of the MoH, the “**National Organ and Tissue Transplantation Coordination System**” has been established in 2001. The purpose of this system is to maintain relevant coordination between the institutions working in the field of organ and tissue transplantation services, and to assure the transplantation of donated organs and tissues in the most equal and fair way within the shortest duration to the most appropriate patients in accordance with scientific and ethical rules. With a view to conducting the National Coordination System and affiliated to the General Directorate of Curative Services, **National Organ and Tissue Transplantation Coordination Centre (NCC)** is established in Ankara. In addition, **Organ and Tissue Transplantation Regional Coordination Centres (RCC)** are opened in 9 provinces consisting of Ankara, Istanbul, Izmir, Antalya, Bursa, Erzurum, Samsun, Antalya and Adana. The other provinces are covered and managed under these 9 regional centres. NCC and RCC is available 24 hours a day, every day of the year, to facilitate organ sharing among transplant centres. NCC and RCC staff consists of doctors and nurses. One doctor and one nurse work as part of a 24-hour shift team. When there is a cadaveric donation in any hospital throughout the country, the organ transplantation coordinators of that hospital notify the RCC. Then, the RCC communicates the donor information to the NCC in a rapid way. The NCC ensures the delivery of donated organs and tissues of the donors to the organ and tissue transplantation centres where the most appropriate patients available according to objective medical criteria (i.e.

³ A cadaveric donor is a deceased person from whom at least one solid organ or part of it has been recovered for the purpose of transplantation. Cadaveric donation rate is the number of cadaveric donors per million of population.

⁴ http://ec.europa.eu/health/ph_threats/human_substance/oc_organ/docs/fact_figures.pdf

⁵ Ministry of Health Statistics

medical urgency, blood-type, tissue type, size of the organ, time already spent on the waiting list, distance between donor and recipient, etc.).

There are currently 5 scientific boards, including kidney, liver, heart and lung, intensive care and coordinators. Each of them is made up of 6 members, including professors from the universities and state education hospitals, and professionals. They are charged with considering medical, scientific, and ethical aspects related to organ procurement, allocation, and sharing. They meet periodically, and the main job of each scientific board is to review available policies, provide assessment, and propose new policies.

National Organ Transplant Computer System came into effect in 2008. Only cadaveric kidneys are allocated with this computer program. Liver, lung, heart, pancreas, intestine and cornea allocation is subjected to different rules. Licensed 41 kidneys, 24 liver, 16 heart and 1 lung transplantation centres are available in Turkey.

Each hospital with medical ventilator devices in its intensive care unit has a potential for cadaveric donation. The total number of the intensive care units with the respiratory devices in the hospitals of Turkey wide is 2727. Approximately, 40 % hospitals in Turkey have the potential for cadaveric organ donation in terms of human resources and equipment.

In the year of 2007, the number of brain death referrals is 680, cadaveric donor is 241, cadaveric kidney transplantation is 415, living kidney transplantation is 911, cadaveric liver transplantation is 209, living liver transplantation is 264, heart transplantation is 50, heart and lung transplantation is 1, pancreas transplantation is 9, intestine transplantation is 3.

In the year of 2007, the number of patients waiting for kidney transplants is 14450, liver transplants are 1165, and heart transplants are 172.

These numbers show us that only a small amount of patients is lucky enough to be transplanted. Nearly, 1 in 10 patients can have a renal transplant and those who aren't transplanted had to suffer dialysis therapy which lowers quality of life in a considerable magnitude. The number of patients waiting for heart and liver transplantation is low, not because of having few patients, but because of not having any other therapy method to save them.

The main factors affecting this shortage of organ donors in Turkey can be counted as follows:

- There are serious problems in donor detection, referral and data collection.
- Healthcare personnel, especially the donor coordinators, anesthesiologists, neurosurgeons, neurologists who take place in the different steps of the donation process don't have sufficient training opportunities concerning the subject.
- Family consent⁶ rates are also far from the desired level.
- The legislation concerning organ and tissue transplantation services needs to be updated according to actual and global standards.

Organ shortage, in turn, causes the following effects:

⁶ Legally valid permission given by the family of the deceased for removal of cells, tissues and organs for transplantation.

- Patient mortality and morbidity as well as healthcare expenses increase.
- Organ shortage has a major effect on quality and safety by causing an increased need to utilise expanded criteria donors⁷. In Turkey, there is no consensus on a standard level of donor safety and minimum set of examinations that should be performed in order to eliminate the risk of transmitting communicable or malignant diseases to the recipient. Therefore, it is crucial to build a system providing a standard in donor testing and traceability from the donor to the recipient in order to prevent the risks and in case, to detect complications and adverse events.
- Limited supply of and increasing demand for transplantable organs have been causing a potential threat of organ trafficking.
- Organ shortage is also a major obstacle preventing international cooperation. The organ donation and transplantation system in Turkey should be strengthened in order to overcome the shortage of organs which will have some positive consequences such as an international exchange of organs in urgent cases. In this way, the cooperation at the European level and strengthening of ties with neighbouring EU Member States might be achieved.

Considering that many times an organ donor is also a tissue donor, quality and safety requirements for organs should complement and be linked with the existing community system for tissues and cells. Implementation of the acquis will never be complete without taking the safety and quality of organs into account. The proposed directive which is mentioned above underlines the close connection of organs with tissues as: “As organ donors are often also tissue and cell donors, it is additionally important that information about adverse events and infections can be quickly traced to a donation and immediately relayed to the tissue vigilance system provided for by the Tissue and Cell Directive 2004/23/EC. Currently such a system does not exist.” Furthermore, another connection is the shortage of cadaveric donation which is the main source of transplantation for both organs and tissues. It is certain that safety and quality of both organs and tissues will increase when this problem is solved.

In the context of the alignment to EU legislation and preparing new guidelines, coordination with the **Tissues and Cells Transplantation Division (PF 44)** will be established especially on the issues of the quality and safety and notification of adverse events.

Being aware of the fact that organ shortage is an important problem of the society and transplantation is the best choice of therapy in chronic renal failure, **Turkish Society of Nephrology**, which is one of the stakeholders in this project, is trying to break prejudice on transplantation in the minds of health personnel and the public. A transplantation working group established by the society has been trying to develop public awareness campaigns and health personnel training on transplantation.

Transplant Coordinator’s Society which aims to increase cadaveric donation in Turkey is another non-governmental organization which is also a stakeholder in this project.

As mentioned in the linked activities, Akdeniz University Transplant Center’s partnership with European Training Program on Organ Donation (ETPOD) has

⁷ A donor that is not considered to be ideal or standard.

produced some good ideas for this project. Some health personnel, who still member of the Transplant Coordinator's society, have been receiving training in organ donation and transplantation in the scope of the above mentioned project. The ETPOD project's experiences have been used for establishing this project.

Above mentioned stakeholders are not completely involved in the project design, except their oral comments. They are being included in the preparation of the terms of reference, conducting of the project activities and implementation and monitoring phase.

General Directorate of Curative Services will be Centralized Competent Authority that would be charged with the task of authorising and monitoring and technical implementation of the project activities in the process of transition. Later, Centralized Competent Authority will be established according to EU Directives and under the new project prepared in the future

In the context of quality and safety of human organs, audit system will be established under the new project prepared in the future. Because of limited time and budget, only forms regarding quality and safety standards will be designed in the scope of this project.

3.2 . Assessment of project impact, catalytic effect, sustainability and cross border impact (Where applicable)

Assessment of Project Impact

The project is expected to increase cadaveric donation rate in Turkey. The increased rate of cadaveric donation, in turn, will enable more patients to receive organ transplants. This will produce the following outcomes:

- Waiting list deaths and waiting time will be reduced; the patients will have increased survival⁸
- Health-related quality of life of the patients will be improved⁹.
- Improved quality and safety of organs will reduce transplant risks such as transmission of infectious or cancerous diseases to the recipient.

Catalytic Effect

One of the potential consequences of the scarcity of organs is trafficking of human organs. Prohibition of organ trade and trafficking is a universally accepted fact which exists on "WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation"¹⁰ and the Council of Europe's "Convention on Human Rights and Biomedicine"¹¹. Increasing the cadaveric donation rate and public awareness of organ

⁸ Schnitzler MA: "The life-years saved by a deceased organ donor", Am J Transplant 2005;5(9):2289-96.

⁹ Ortega, F: "Quality of life after solid organ transplantation", Transplantation Reviews 21 (2007) 155-170

¹⁰ <http://www.who.int/transplantation/TxGP08-en.pdf>

¹¹ <http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=164&CL=ENG>

donation and transplantation will be helpful in preventing the imminent danger of trade and trafficking in human organs.

Kidney transplantation not only provides a better quality of life over dialysis, but also lowers healthcare expenses of end-stage renal failure patients¹². In long-term, as more patients receive kidney transplants, a substantial decrease in the costs is to be expected.

The project will improve patient safety by increasing the number of organs available, and enhancing and making more accessible the transplantation system.

Sustainability

Improved services in organ donation and transplantation are expected. Trainer teams will be set up and these teams will be responsible for vocational training and re-training. A trainer's guide and standard training materials will be prepared for long-term use.

International cooperation will be established to exchange knowledge and experience continuously.

Cross-border Impact

The cross-border exchange of organs has clear benefits. Given that donor and recipient have to be matched, a large donor pool which includes EU Member States is important to cover the needs of all the patients on the waiting lists. The waiting times will be reduced as much as the donor pool is expanded. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatments, hypersensitized patients or paediatric patients.¹³ A high-level of quality and safety of organs which is aimed to be maintained within this project, will facilitate Turkey's cooperation with the European countries and cross-border exchange of organs. Also, the increase in organ donation may possibly prevent the imminent danger of organ trafficking.

3.3 Results and measurable indicators:

Results	Objectively verifiable indicators
1. Turkish organ transplantation and donation legislation harmonized with that of EU.	Legislation for organ transplantation and donation published by the end of the project.
2. Healthcare personnel's knowledge and awareness on organ donation and transplantation improved.	Nearly 50 % of the physicians dealing with brain death identification and referral, and donor management in 245 hospitals which have high capacity ICUs and potential for identification of brain deaths will be trained.

¹² Schnitzler MA: "Economics of transplantation: a review of the literature", *Transplantation Reviews* 20 (2006) 61-75

¹³ Proposal for a "Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation",

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0818:FIN:EN:PDF>

	Additionally, 100 % the transplant coordinators in these hospitals, RCCs and NCC will be trained.
3. The safety and quality of human organs improved.	Increased amount and quality of produced data by the end of the project.
4. Public awareness of organ donation and transplantation improved.	Increased interest of public to the organ donation.
5. Bilateral agreements or protocols on organ transplantation and donation signed.	International cooperation strengthened and knowledge capacity of the Ministry's personnel in organ transplantation and donation increased.

3.4 Activities / Indicative:

The Ministry of Health, General Directorate of Curative Services will provide the national co-financing for the project, which amount to €370,000. This amount has already been included in the 2010, 2011 and 2012 budget planning of the above mentioned Directorate General.

The project includes one service contract. Activities 1.1 to 5.2 will be carried out through the service contract.

Details of the project activities are as follows:

Activities 1.1-1.3 aim to make a systematic and detailed analysis of the gap between the current legislation in Turkey and the European Union; and then to prepare the additional legislation which also includes collection of information provided in the Annex of the Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation. Guidelines on quality and safety and notification of adverse events of organs will be prepared jointly with the PF 44. These activities will be performed through experts' committee meetings.

Activities 2.1 aim to assure training on donor detection, brain death diagnosis, donor management and organ viability, family approach for organ donation, and legal, ethical and religious aspects related to health personnel such as anaesthesiologists, neurologists, neurosurgeons, doctors in charge of intensive care units, and also organ transplant coordinators. To provide the above-mentioned trainings, manuals will be prepared. Additionally, training of trainers will be provided to some health personnel specialized in the said topics. These activities will be performed through service contracts by people with proven experience in the field of organ donation and transplantation training.

Activity 3.1-3.3 aim to ensure collecting data such as waiting list number, transplantation number, rejection rate, patient survival, date of transplantation, kind of transplantation (cadaveric or living), tissue type of patient and donor, blood type of patient and donor, patient's current situation (alive, dead or retransplantation, date of

death, reason of death, date of re-transplantation), etc. Available statistical forms will be updated, if necessary, new ones will be generated. These activities will be performed through service contracts by people with proven experience in the field of organ donation and transplantation statistics.

Activities 4.1-4.5 aim to enhance knowledge and awareness of the public in the field of organ transplantation and donation. These activities will be performed through service contracts by people with proven experience in the field of public affairs and advertisement of organ donation.

Activities 5.1-5.2 aim to develop a reorganisation plan for organ donation and transplantation system in the country and to improve knowledge and experience of Ministry's managerial and administrative personnel in light of the data provided by these activities to strengthen international cooperation. The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Croatia, Germany, Luxemburg, the Netherlands and Slovenia. The Spanish National Transplant Organization (ONT) was the first European organization structured as directly depending on the Ministry of Health. Later on, this formula has been spread to many countries. Similarly, its organization model has been partially or completely adopted in other places. The ONT has played an essential role in the development of recommendations and regulations of the European Council and the European Union. Italy and France are forerunner countries in the organ donation system. Italy often conducts meeting with participation of Turkey to create Mediterranean Transplant Network.

Activities / Indicative	Means
1.1: Translating EU legislation on organ transplantation and donation into Turkish. 1.2: Conducting gap analysis between Turkish legislation in force and EU legislation. 1.3: Preparing draft texts of Turkish organ transplantation and donation legislation in conformity with relevant EU legislation.	1 Service Contract
2.1: Training of target groups which includes anesthesiologists, neurologists, neurosurgeons and transplant coordinators, etc.	
3.1: Updating of available statistical forms and creating new ones, where necessary. 3.2: To create audit forms. 3.3: Increasing capacity of data assessment.	
4.1: Preparation of communication strategy 4.2: Conducting of Organ Transplantation Week Events 4.3: Preparation and broadcasting of short television films, slogans or advertisements. 4.4: Printing of materials such as poster, brochure related with organ donation. 4.5: Distributing of the above-mentioned printed materials to the	

public places.	
5.1: Making study visits to France and Italy to exchange knowledge and experience and to establish cooperation on organ donation and transplantation.	
5.2: Making study visits to Eurotransplant and ONT to exchange knowledge and experience and to establish cooperation on organ donation and transplantation.	

3.5 Conditionality and sequencing:

The tender for this project can be launched on the condition that, by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s).

In terms of basic sequencing, the activities will shall proceed in the below order:

- Training-Legislation studies
- Statistical studies-public awareness-study visits

3.6 Linked activities

Akdeniz University Transplant Center has joined in European Training Program on Organ Donation (ETPOD) as a project partner. The activities of this project have been held only in Antalya and Izmir cities. Within these activities, a few health personnel stationed in Antalya and Izmir have been receiving training on donor identification, diagnosis of brain death, donor care, family consent, organ donation, organ extraction and organ allocation. These project activities cover only a very limited area of Turkey.

3.7 Lessons learned

Depending on previous experience of the MoH on Implementation of IPA/Financial Cooperation projects, the Ministry decided to set up a project coordination team composed of 3 MoH staff that would elaborate on coordination and technical implementation of project activities. This project coordination team will include 2 Ministry of Health's staff thus it aims to prevent possible delays during implementation period that may arise from lack of technical and procedural information and knowledge on the side of the beneficiary institution.

4. Indicative Budget (amounts in EUR)

			SOURCES OF FUNDING										
			TOTAL EXP.RE	TOTAL PUBLIC EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL PUBLIC CONTRIBUTION						PRIVATE CONTRIBUTION
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(e)	EUR (b)=(c)+(d)	EUR (c)	% (2)	Total EUR (d)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/ Local EUR (y)	IFIs EUR (z)	EUR (e)	% (3)
Activity 1													
Contract 1: Service Contract	X	–	3,700,000	3,700,000	3,330,000	90	370,000	10	370,000	0	0	0	0
TOTAL IB			3,700,000	3,700,000	3,330,000	90	370,000	10	370,000	0	0	0	0
TOTAL PROJECT			3,700,000	3,700,000	3,330,000		370,000		370,000	0	0	0	0

NOTE: DO NOT MIX IB AND INV IN THE SAME ACTIVITY ROW. USE SEPARATE ROW

Amounts net of VAT

(1) In the Activity row use "X" to identify whether IB or INV

(2) Expressed in % of the **Public** Expenditure (column (b))

(3) Expressed in % of the **Total** Expenditure (column (a))

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature contract	of	Project Completion
Contract 1 (Service)	2010 – 1 st Quarter	2010 – 4 th Quarter		2012 – 4 th Quarter

Duration of the project: 24 months

All projects should in principle be ready for tendering in the 1ST Quarter following the signature of the FA.

6. Cross cutting issues (where applicable)

6.1 Equal Opportunity

Equal participation of women and men will be secured through appropriate information and publicity material, in the design of projects and access to the opportunities they offer. An appropriate men/women balance will be sought on all the managing bodies and activities of the programme and its projects. Equal opportunities at participation to training activities will be assured.

6.2 Environment

Not applicable

6.3 Minorities

According to the Turkish Constitutional System, the word “minorities” encompasses only groups of persons defined and recognized as such on the basis of multilateral or bilateral instruments to which Turkey is a party. This project has no negative impact on minority and vulnerable groups.

6.4 Civil Society

Turkish Society of Nephrology and Transplant Coordinator’s Society are NGOs that will have contribution to the project. Turkish Society of Nephrology will take part in public awareness studies where Transplant Coordinator’s Society will play a role in training activities.

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number Alignment in Organ Donation (ALOD)	
	Contracting period expires 2 years after the signature of the Financing Agreement	Disbursement period expires 1 year after the end date for the execution of contracts.
	Total budget : €3,700,000	IPA budget: €3.330,000

Overall objective	Objectively verifiable indicators	Sources of Verification
To contribute to the harmonization with and implementation of the EU <i>acquis communautaire</i> in the area of public health, specifically focusing on increasing cadaveric organ donation in Turkey.	Turkish organ donation and transplantation coordination system is operational in line with EU standards.	-EU progress reports -Activity and progress reports of the project -Annual reports of the MoH

Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To ensure quality and safety standards for human organ donation and transplantation in medical treatment.	While cadaveric organ donation rate was 3 per million population (pmp) in 2007 in Turkey, this rate increased to 4.2 by the end of the project.	-EU progress reports -Activity and progress reports of the project -Statistical data of Council of Europe -Statistical data of the MoH -Annual reports of the MoH	
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
1. Turkish organ transplantation and donation legislation harmonized with that of EU.	-Legislation harmonized with EU for organ transplantation and donation published by the end of the project.	-Official Gazette	
2. Healthcare personnel's knowledge and awareness on organ donation and transplantation improved.	Nearly 50 % of the physicians dealing with brain death identification and referral, and donor management in 245 hospitals which have high capacity ICUs and potential for identification of brain deaths will be trained. Additionally, 100 % the transplant coordinators in these hospitals, RCCs and NCC	-Activity and progress reports of the project -Annual reports of the MoH	

	will be trained.		
3. The safety and quality of human organs improved.	Increased amount and quality of produced data by the end of the project.	-Activity and progress reports of the project -Statistical data of the MoH -Annual reports of the MoH	
4. Public awareness of organ donation and transplantation improved.	Increased interest of public to the organ donation.	-Activity and progress reports of the project -Annual reports of the MoH	
5. Bilateral agreements or protocols on organ transplantation and donation signed.	International cooperation strengthened and knowledge capacity of the Ministry's personnel in organ transplantation and donation increased.	-EU progress reports -Activity and progress reports of the project -Foreign Affairs Ministry records -Annual reports of the MoH	
Activities	Means	Costs	Assumptions
1.1: Translating EU legislation on organ transplantation and donation into Turkish. 1.2: Conducting gap analysis between Turkish legislation in force and EU legislation. 1.3: Preparing draft	1 Service Contract	€3,700,000	

texts of Turkish organ transplantation and donation legislation in conformity with relevant EU legislation			
2.1: Training of target groups which includes anesthesiologists, neurologists, neurosurgeons and transplant coordinators etc.			1- Health personnel high interest in the trainings and positive approach to the diagnosis of brain death.
3.1: Updating of available statistical forms and creating new ones, where necessary. 3.2: Creating audit forms. 3.3: Increasing capacity of data assessment.			Transplant centers and other health institutions high interest in filling out the forms and notifying the MoH regularly.
4.1: Preparation of communication strategy 4.2: Conducting of Organ Transplantation Week Events 4.3: Preparation and broadcasting of short television films, slogans			1- Positive family approach to the cadaveric organ donation. 2-High public interest to the printed

<p>or advertisements.</p> <p>4.4: Printing of materials such as poster, brochure related with organ donation.</p> <p>4.5: Distributing of the above-mentioned printed materials to the public places.</p>			<p>advertisement materials.</p> <p>3- High public interest to take organ donation card.</p>
<p>5.1: Making study visits to France and Italy to exchange knowledge and experience and to establish cooperation on organ donation and transplantation.</p> <p>5.2: Making study visits to Eurotransplant and ONT to exchange knowledge and experience and to establish cooperation on organ donation and transplantation.</p>			<p>Host countries and organizations' high willingness to cooperate.</p>

Pre conditions

The tender for this project can be launched on the condition that, by submitting a formal Declaration of Assurance, showing that the beneficiary has sufficient staff in a list for technical implementation and monitoring of the contract(s)

