ERA-NET SCHEME

COORDINATION ACTION

ALLIANCE-O

European Group for Coordination of National Research Programmes on Organ Donation and Transplantation

Project/Contract Number: 0011853

Work Package 4:
Increase safety and quality of organ transplantation

Deliverable 4.4: Common best practices for organ transplantation quality systems

Work Package Leader: Istituto Superiore di Sanità - Centro Nazionale Trapianti - Italy

Participant name	Abbreviation	Country
Agence de la Biomédecine	ABM	France
Deutsche Stiftung Organtransplantation	DSO	Germany
Hungarotransplant	Hu-T	Hungary
Organizaçao Portugesa de Transplantaçao	OPT	Portugal
Centro Nacional de Trasplantes y Medicina Regenerativa	CENATMER	Spain
UK Transplant	UKT	United Kingdom

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1 INTRODUCTION

1.1 Task 4.2: Scope of the task

The scope of WP4 – Task 4.2 "Quality Management Systems" is to develop a coordinated approach on Quality Management Systems to achieve through the following major objectives:

A) Drawing up of an inventory and analysis of existing quality systems;
B) Elaborating common best practices, standard operating procedures, for organ transplantation quality systems.

The objective of point A) was achieved in the first part of this work, as it was deeply described in the deliverable 4.3. This second deliverable is aimed at illustrating the outcomes resulting from the second part of the task and how the final objective of this WP was achieved.

1.2 Task 4.2: Participants

All partners participated to this second half of the Task and contributed to the activities necessary to define the best practices in a Quality Management System (QMS). Representatives of each organization attended the workshop and the three technical meetings organized for this purpose. Partners worked together to share a final common approach to this issue.

1.3 Task 4.2: Work approach

Starting from the results of deliverable D4.3, the group defined the approach to apply in the following phase, in order to achieve the final objective of identifying common best practices in a QMS. The steps of this process were the following:

1. A workshop was organized to agree the definitions, objectives and requisites of each sub-process;
2. Each partner presented at the following meeting the practices applied in their respective countries in response to the agreed requisites;
3. This information was analysed by the WP leader to draft a proposal of common position paper containing the minimum common requisites for a QMS;
4. The draft paper was analysed by the consortium during a technical meeting organized at this purpose. The common best practices were approved and it was decided to carry out a pilot action on one of the given requisites: analysis and identification of common data items of the donor forms utilized by the represented countries;
5. All partners contributed to this additional action by providing the local or national donation forms utilized for HBD. The work package leader carried out an analysis on the information collected and identified the categories and the respective data items for each country.
6. This analysis was presented during the last meeting, where the group identified the data items collected by most of the countries and drafted a first version of a common and essential donation data set.

2 DEFINITIONS, OBJECTIVES AND REQUISITES OF THE SUB-PROCESSES

The two days workshop ended with a final common document agreed by all partners and utilized for developing the work of the following phases.
For each sub-process the consortium identified the definitions, objectives, input, output and the main requisites to achieve the objectives. The phases of the sub-processes were slightly revised during the workshop, therefore we report here below the final agreed version.
Some general remarks were fixed as a preamble to the working paper and as a key of understanding of the work carried out all through this work package. This was done mainly to explain the context of these outcomes for any future need of utilization of the definitions or objectives here provided. The two major preliminary remarks are the following:

- Definitions used along the text were decided just for the purposes of this project: the quality analysis of the processes that make a "Transplantation Process", therefore they might not be applicable to all cases;
- The phases of the sub-processes identified in this work package are not necessarily applicable to all cases.

Some more preambles were given for the same reasons, to some of the donation to transplantation sub-processes.

<u>Allocation Sub-Process:</u>

- Organ Allocation as a whole is a complex socio-technical process including allocation principles and policy definition, allocation methods specification and implementation, allocation realizations and organ allocation evaluation.
- Organ Allocation interfaces Organ Donation and Organ Transplantation which are not sequential processes but interacting and concurrent processes
- WP4 only addresses (Brain-dead Donors) Allocation realizations by coordinating offices and/or transplant centres, some of its preconditions (WL registration, HLA typing) and Organ Allocation Quality Management System.

<u>Follow-up and Quality of Life Sub-Process:</u>

- All objectives and activities included in the follow-up process refer to both live donors and organ recipients

Here below we report the common position of the consortium in relation to the sub-processes and their analysis from a quality system point of view.

DONATION Sub-Process

Definition:

All the tasks carried out with the aim of obtaining human organs for transplantation. This starts with the donor identification and includes all the phases that are listed below

Phases:

- Identification of Potential Donor
- Diagnosis of cerebral death
- Consent or objection to donation
- Legal authorization
- Maintenance of the donor
- Donor suitability
- Notification of allocation agency (ET)
- Feed-back and support to families
- Organ suitability
- Coordination of safety
- Coordination of transport
- Retrieval and preservation of the graft

Input:

Possible donor (person with a severe brain damage/ any cardiac arrest / person who volunteers to donate an organ)

Output:

Organs

Objectives:

- Identify the Potential for Donation (donors & organs);
- Analysis of the outcome of the donation process;
- Identify any difference between actual and best practices;
- Identify and implement the monitoring procedures: corrective and preventive measures and actions;

- Continuous evaluation and improvement of the process

Requisites:

- Education and Training;
- Data validation: definition of the methodology and the indicators;
- Internal and external audits: definition of the methodology;
- Comparability system: identification of best practices, compatibility of information tools, etc;
- Accountability for performance;
- implementation of monitoring procedures;
- Stakeholders Surveys to test the perception of the service (including donor hospitals, retrieval teams & Relatives/society)

ALLOCATION Sub-Process

Definition:

Allocation is a process by which an organ from a donor is identified for transplantation to a recipient selected from a waiting list according to predefined criteria.

Phases:

- Coordination of offers
- Documentation / Administration
- Management of waiting lists
- Allocation at national level
- Allocation at regional level
- HLA Typing and matching

Input:

Evaluated organ and patients on WL

Output:

Acceptance of the organ as valid for a selected patient

Objectives:

- To offer all suitable organs in view of a final acceptance:
  - to (and/or):
    - each potential recipient (patient-based allocation)
    - each potential transplant team (centre-based allocation)
  - in conformance with:
    - predefined offer specifications (± predefined safety specifications)
    - predefined allocation specifications
  - with the purpose to reach a set of predefined valuable allocation end-points
- To guarantee transparency and traceability with the registration of proposals, refusals and final acceptation;
- To evaluate and optimize the allocation sub-process

Requisites:

- Registration of all potential recipients on the Waiting List(s) according to predefined waiting list registration specifications;
- Allocation guidelines defining:
  - Valuable allocation end-points
  - General and organ specific offer & allocation specifications
  - Develop standards and policies for exceptional circumstances or organizational constraints
  - Allocation procedure
- Registration of proposals, refusals and final acceptance;
- Organ Allocation Quality Management System;

TRANSPLANTATION Sub-Process

Definition:

The process of grafting a suitably matched organ from a donor to a specific recipient. The process includes the following phases: registration and care of the patient on WL, the surgical procedure. The process ends when the grafting is completed.

Phases:

- Assessment of candidates
- Admission to the waiting list
- Management of patients on waiting lists
- Evaluation of offers
- Transplant

Input:

A patient requiring a transplant and a donated organ

Output:

Grafted patient

Objectives:

- Save the life of a patient or improve a patient's quality of life;
- Reduce general morbidity and mortality;
- Minimize the waiting time and reduce the number of patients on waiting list;
- Guarantee Safety and Quality of the transplant process;
- Ensure transparency of criteria used for patient registration or removal from waiting list;
- Guarantee the accessibility to transplantation;
- Optimize the number of organs from a donor that are available for transplantation

Requisites:

- Standard criteria for registration and removal from waiting list;
- Best practice and professionalism of health care workers involved in the transplant process;
- Policy to ensure cold ischemic time is minimized;
- Quality in data collection and validation;
- Audit to inform future development;
- Continuous provision of information to patients;
- Education and training

FOLLOW-UP and QUALITY of LIFE Sub-Process

Definition:

All activities developed after the surgical procedure with the aim of maintenance of health through clinical care and the quality of life of the transplanted patient and live donors.

Phases:

- Clinical follow-up
- Quality of life follow-up
- Adverse events

Input:

Live donor / transplanted patient

Output:

Irreversible graft failure, loss to follow-up or death

Objectives:

- Evaluation of "transplant therapy": organ and patient survival, graft function, quality of life and socio-economic impact;
- Validation of allocation criteria;
- Identify factors associated with graft and patient survival, differences between centres and take appropriate actions;
- Monitoring, vigilance and traceability of post transplant events;
- Evidence based analysis to improve clinical practice

Requisites:

- Data collection standardization;
- Minimum data set and common methodologies;
- Definition and identification of post transplant adverse events and reactions;
- Standardization and sharing of best practice for follow up of recipients and living donors;

- Provide relevant information to society and all stakeholders

3. COMMON BEST PRACTICES RELATED TO THE REQUISITES

Once agreed the objectives and requisites for a QMS, all partners provided a description of the actions carried out in their respective countries for each requisite reported in the section above. This information was used and analysed by the work package leader to make a proposal with minimum common standards. The work package leader compared the information requisite by requisite and drafted a document reporting the essential and shared practices that should be present in the transplant system of one Country. The document was deeply analysed during the following meeting, it was improved and agreed by everybody. During this analysis the group realized that a revision of some requisites was necessary. This was the case of two requisites: "information system" and "standards for safety criteria". The group decided to keep them out of the sub-processes and to treat them as independent requisites that shall be applied in each sub-process and not only in one of them. This decision was due to the fact that the consortium realized that these two have an impact in each phase, therefore it was preferred to treat them not as requisites of the single sub-processes, but as requisites of the Process as a whole.
Here below we report the common best practices as they were agreed. It's important to clarify that these are not exactly best practices in terms of selection of the best ones among others, while they are the results of a mix of good points taken from the actions of the different countries and then put together. As a result, the best practice of the given requisite is the result of a combination of different aspects pertaining to one or more Countries. To the view of the consortium this was the most effective and fruitful way to achieve the final objective. As a consequence in this piece of work, there won't be any highlight to one practice of one Country as best practice compared to the others, while the best practices were agreed for each requisite with the following approach:

I. The selection of the common elements applied in each Country;
II. The selection of innovative and outstanding elements applied in one or more countries;
III. The ideal elements that should be applied in each Country, but that are still missing everywhere.

The latter bullet point represented the means of discussion and planning of future shared activities for the improvement of the services given by the single Country and for setting the grounds of a wider cooperation among the European Member States on more specific aspects related to the transplant field. Moreover, the consortium decided to highlight all the action resulting from this document that could be developed in the future as common actions between EU Member States.

DONATION Sub-Process

1. Education and Training

I. Education and Training Programme on the donation phases:

- Identification of the Potential Donor
- Diagnosis of cerebral death
- Consent/Authorisation or objection to donation
- Legal consent/authorization
- Maintenance of the donor
- Donor suitability
- Notification of allocation agency (ET)
- Feed-back and support to families
- Organ suitability
- Co-ordination of safety
- Co-ordination of transport
- Retrieval and preservation of the graft

Characteristics of the programme:

- Theoretical and practical
- Certificated
- Accredited by the national transplantation authority
- Customized to different categories of professionals (workers of ICU, coordination, etc) and to competencies
- Final assessment of competence
- Initial programme plus continuous education
- Mutual recognition of the programme in the different EU countries

II. Specific courses on the single phases of the donation process

2. Data collection and validation

Existence of:

- national donation form containing all data related to the donation process
- Data validation procedure compliant with the organizational structure (H, regional, national levels); the procedure shall be based on recommended/standard/operative procedures
- Data should be comparable in the different countries allowing collaborative studies; minimum set of data shall be defined

3. QMS and auditing

QMS should be implemented in all organizations involved in donation activities

Internal and external auditing:

- of all units involved in the process: local, regional and national coordination.
- all phases of the process shall be audited.

- periodical scheduling of audits
- auditing and follow-up procedures shall be validated at the national level and shared at the EU level
- The existence of a document that shall contain all audit procedures according to national and European standards
- Every audit has to define the geographical level of the action, the author of the results and the objective of the actions. Results of the audit should be analysed at a regional and national level

4. Accountability for performance

- Quality programme with a monitoring system of the phases (quality indicators)
- A minimum indicator set shall be defined at a national level; this should be shared and comparable at the European level (see DOPKI)

5. Stakeholders Surveys to test the perception of the service

Identification of the stakeholders, health care professionals, donor families, patient associations, Institutions, etc.
Identification of the tools to measure the perception of the service for example: questionnaires sent to health care professionals involved in the process, donor action survey, etc.
Internal/external communication of data and indicators of donation activity.
Regular reports.

6. Information and public communication

Continuous information based on a strategic national information programme that defines:

- Target (general public, opinion leaders, minorities, religious leaders, professionals)
- Tools (National campaign, information day, website, free toll number, press communication etc)
- Monitoring tools (press release analysis, donor card, opinion polls)

See WP7 (ethical aspects) for a further analysis

ALLOCATION Sub-Process

1. Registration of all potential recipients on the Waiting List(s)

Existence of a public document reporting the procedures and criteria of registration on national waiting list according to the health status of the potential recipient.

All patients awaiting for a transplant shall be registered on waiting list, patients awaiting for a living donation included.

2. Allocation rules:

Existence of a policy for the definition of allocation rules
Rules covering all organ allocation should include and define:

- methods to define, verify and revise the allocation criteria
- methods of communication and dissemination of the rules to all structures involved in the donation to transplantation process and to the public (transparency)
- methods to apply the allocation algorithms (es. priority of assignment for urgencies, paediatrics, etc; methods of geographical assignments)

3. Registration of proposals, refusals and final acceptance

Procedures for the registration of all offers for each type of organ that could show the results of the offer (accepted, refused, allocated, retrieved, transplanted) in order to ensure the traceability and transparency of the allocation process

4. Organ Allocation Quality Management System

QMS should be implemented in all organizations involved in allocation activities and auditing shall be developed including the application of rules.

TRANSPANTATION Sub-Process

1. Standard criteria for registration and removal from waiting list

Transparent procedures for registration, maintenance and removal from waiting list, including appropriate medical criteria of the recipient on the waiting list

2. Policy to ensure cold ischemic time is minimized

Procedures and surveys to ensure an efficient organ distribution and allocation to allow optimal ischemic time.

3. QMS and auditing

QMS should be implemented in all organizations involved in transplant activities

Transplant centres auditing on:

- all phases of the process shall be audited (including acceptance, declination of organs)
- every audit a priori has to define the geographical level of the action, the author of the results and the objective of the actions; results of the audit should be analysed at a regional and national level

4. Continuous provision of information to patients

Information shall be given to patients on the waiting list, this information should include:

- The registration on waiting list
- Status on waiting list plus any change or removal
- Mean time on waiting list (including regional waiting list for some countries)
- Mean waiting time of transplanted patients

5. Education and training

Ensure professionalism and competency of all health care professionals who work with recipients:

- Identification of the education program
- Definition of the competency levels
- Hospital, team or individual certification/authorization of competencies
- Mutual recognition between EU Countries should be developed

FOLLOW-UP and QUALITY of LIFE Sub-Process

1. Data collection standardization

Data collection shall be carried out in the framework of a national standardization program with the aim of assessing at least the following outcomes:

- Patients survival
- Organs survival
- Quality of life

Data collection shall be performed all through the lifetime of every transplant.

2. Minimum data set and common methodologies

The national program shall include:

- Definition of the objectives of the analysis
- Minimum data set agreed with clinicians

- A methodology for the calculation of the patient and graft survival that could ensure the results comparison
- Regular reviews
- The participation to the programme shall be mandatory
- Methods for the use and the publication of the results

Data should be comparable in the different countries allowing collaborative studies; standardized data set and a shared methodology should be defined

3. Definition and identification of post transplant adverse events and reactions

Presence of a "vigilant monitoring system" including:

- Identification of the competent authority
- Policy and protocols for the reporting of adverse reaction/events
- Appropriate advisory group for discussion and decision
- Policy and protocols for the actions

4. Provide relevant information to society and all stakeholders

There should be tools for the provision of information to the general public and all stakeholders available at the national level and managed by professionals of the field. Some communication tools include:

- Report (at least on an annual basis)
- Website
- Information material
- Free toll number
- Scientific publications
- National Meetings

Information should be customized for each category of user. Specific attention should be given to the mass-media with regard to communication by appropriately trained personnel.

Requisites for the whole Process (all sub-processes included)

1. Information System

There is a need for the existence of an information system for data collection, management and processing. This should include donation, allocation, transplantation and follow-up process namely:

- national transplantation form containing all data related to the donation and to transplantation;
- data collection and management on organ allocation to support the organ allocation system in compliance with the allocation guidelines

The information system should be shared by all stakeholders involved in the processes, and it should be adapted to the organizational model of the Country (local, regional, national organization). Moreover it should be compliant with the rules, guidelines and procedures that regulate the single sub-process.

The information system should allow the traceability of the whole process, together with the management of the severe adverse events and reactions.

The information system should ensure the data quality in terms of completeness and coherence through dedicated validation procedures and auditing. Moreover, it should ensure the capability to create activity indicators regarding each sub-process.

2. Standards of safety criteria

Safety standards including:

- risk / benefit evaluation for recipient / graft and extended donor criteria guidelines
- traceability rules
- safeguards concerning the procedures (i.e. recipient consent, etc)
- definition of specific risk follow-up
- management of adverse events

4 CONCLUSION

The consortium worked successfully in developing the activities foreseen in this WP4 – Task 4.2. A very high level of cooperation and agreement was needed to reach the final objective of this task, which was extremely challenging for all members.
A very good consensus was achieved in each phase of the work plan that included:

I. The identification of the sub-processes and the respective phases;
II. The definition of the objectives of the sub-processes;
III. The detection of the requisites useful to reach the objectives;
IV. The selection of the common best practices shared by all members.

The selection of common minimum practices revealed that most of the tools were already known and applied by the majority of the countries, although with slightly different methods. Through this work it was possible to highlight the different aspects that could be shared at a European level and agreed by the different countries. The activities developed and the issues introduced in this workpackage represent a preliminary workplan for launching future actions shared by the European Countries. Following a detailed analysis of the practices laid out in the present document, the members of this working group highlighted the actions with priority to be carried out in the near future in terms of sharing and agreement on a single action recognised by all countries. The main suitable actions agreed by the consortium are the following:

1. Standards for a continuous education on donation and transplantation and standards for the certification of the education;
2. Standardization of the donation form;
3. Transversal auditing model defining the auditing procedures (certification of the procurement centres)
4. Transversal auditing model defining the auditing procedures (certification of the transplant centres)
5. Definition of transparency and communication principles of the allocation criteria;
6. Methods and criteria for the evaluation of results (Alliance-WP5)
7. Bio-vigilance model: a system to report, investigate, register and transmit information about serious adverse events and reactions (See Eustite project);
8. Ensuring safety standards throughout the process
9. Cooperation among the information system for data exchange (see Eurocet project)

The consortium also decided to develop one of the above mentioned actions during this project, to be considered as a pilot action for the future work. The group decided to work on a single European donor form that would include the same data set all over Europe.

3.1 Pilot Action

The working group decided to start developing one of the future actions identified as thank to the final outcomes of the work package activities. The group decided to work on the standardization of the donation form at a EU level. It was decided to produce a first draft with the minimum data recorded by the majority of the organizations.
All partners provided the electronic version of the donation forms utilized in their respective countries. The WP leader processed this information by categorizing all data in a single chart and by specifying what Country collected what data. During the last WP technical meeting the group discussed these elements and it was decided to produce a first draft of the donation form with the following criteria:

1. Harmonization of the top categories;
2. Selection of the data items both essential and collected by the majority of the represented countries;
3. Creation of sub-categories, where necessary. This was the case of the laboratory test data;
4. Units of measurements of the single data were not taken into account in this first phase.

The first draft was produced and it is reported here below. Nonetheless, it is important to underline that this table should be considered as a preliminary working document to be further analysed and revised by the key professionals of the field.
This initiative put in evidence that the seven countries already utilize quite similar donation forms, in other words they collect, for the majority of the categories, the same data from the donor and the donation side. As a result, 114 out of 174 data items provided by the partners were identified as minimum data set, which corresponds to the 65% of the total.

CATEGORY	SUB-CATEGORY	ID	ITEM	ACRONYM
GENERAL DATA		01	donor_code	
		02	date_time_notification	
		03	hospital	
		04	local coordinator	
		05	contact person	
ICU ADMISSION		01	date_time_icu	
		02	date_time_intubation	
DONOR DATA		01	donor type	
		02	date_birth	
		03	age	
		04	gender	
		05	weight	
		06	height	
		07	chest perimeter	
		08	abdomen perimeter	
		09	ab0	
		10	cause_death	
		11	date of death	
OBSERVATION CEREBRAL DEATH		01	date_time start	
		02	date_time end	

CONSENT		03	opposition	
		04	type opposition	
		05	legal authorization	
DONOR MEDICAL HISTORY		01	neoplasia	
		02	nephropathology	
		03	epathopathology	
		04	cardiopathology	
		05	pneumapathology	
		06	pancreaspathology	
		07	parasitaire	
		08	diabete	
		09	Hypertension	
		10	Neuropathology	
		11	other pathologies	
		12	previous_oper	
		13	trauma	
		14	alcohol	
		15	smoking	
		16	drugs	
PHYSICAL / CLINICAL DATA		01	blood_pressure	
		02	hypotension (duration)	
		03	temperature	
		04	diuresis	
		05	diuresis last h	
		06	Cardiac arrest (time - duration - irreversible)	
		07	Cardiorespiratory reanimation (duration)	
		08	CVP	
		09	Heart rate	
LABORATORY		01	Date_time values	
	HEMATOLOGY	15	Prothrombine	PT
		18	White blood cell count	WBC
		19	platelettes	
		20	haemoglobin	Hb
		24	Haematocrit	PCV
	BIOCHEMISTRY	02	Na+	
		03	K+	
		04	Ca2+	
		05	Cl-	
		06	Alk. Phos.	AP
		07	Glucose	
		08	Bilirubine Tot_Dir	
		09	Amylase	
		10	Lipase	
		11	Glut oxalacetic trans(GOT).	AST
		12	Glut pyruvic trans (GPT).	ALT
		13	Gamma glutamil trans(GGT).	GGT
		14	Creatinine	
		16	Troponine	
		17	Urea	BUN
		21	LDH	

		22	TOTAL Protein	
		23	Albumin	
	MICROBIOLOGY	34	blood colture	
		35	urine culture	
		36	trach_secr	
	SEROLOGY	25	HIV 1-2	
		26	HBsAg	
		27	AntiHbs	
		28	AntiHbc	
		29	HCV	
		30	Anti CMV IgG	
		31	Anti CMV IgM	
		32	Syphilis	
		33	HTLV I II	
	URINE	37	Glucosio	
		38	Protein	
		39	Sediment - RBC	
		40	Sediment - WBC	
		41	Sediment - Casts	
DIAGNOSTICS		01	Abdominal echography	
		02	Chest X Ray	
		03	ECG	
		04	Cardiac ECHO	
BLOOD GAS AND VENTILATION		01	FiO2 %	
		02	PEEP	
		03	PaO2	
		04	PaCO2	
		05	PH	
		06	HCO3	
		07	Sat O2	
		08	FiO2 1,0 / PEEP 5	
		09	PaO2	
		10	PaCO2	
		11	PH	
		12	HCO3-	
		13	Sat O2	
THERAPY		01	Antibiotics	
		02	Diuretics	
		03	Adrenaline	
		04	Dobutamine.	
		05	Noradrenaline.	
		06	Blood transfusion	
		07	Dopamine.	
		08	Plasma expander	
		09	Other medication	