

Publishable executive summary

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ALLIANCE-O <http://www.alliance-o.org>

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

ALLIANCE-O ERA-NET Coordination Action: description and objectives

The severe shortage of donors across all organ categories remains a major public health issue the Member States of the European Union are faced with, at the same level as the other countries worldwide. The ALLIANCE-O consortium is built on an already existing collaboration. Indeed, the partners are also involved in different groups working on organ transplantation (OT) issues, including within the Council of Europe. The group then decided to focus on the organ transplantation policies and planned to apply for an ERA-NET.

The ERA-NET ALLIANCE-O coordination action has been established to coordinate the efforts of countries on organ transplantation, each of them having different approaches and programmes to tackle OT issues. The project is coordinated by the Agence de la biomédecine, France, and involves partners from six other countries: Germany, Hungary, Italy, Portugal, Spain and United Kingdom. They are represented by national public bodies involved in the organisation of OT.

ALLIANCE-O project lasted three years and was granted € 2 million by the European Commission.

The **objective** was to identify existing organisations and programmes and propose strategies for improving coordination including joint activities between several countries with a national public body in charge of organ transplantation. Research programmes for improving OT efficiency concern many activities from donor to the follow-up of the patient. They are described in our workpackages.

Results of ALLIANCE-O

The six technical workpackages (WP) allowed us to go into details on each step of the organ transplantation process, from donation, allocation, safety and quality to methods for the evaluation of results, fundamental research programmes and ethical concerns. Each partner country participated in each WP: the proposals reflect a consensus between all of them. The “State of the Art” analysis generally reveals big differences and discrepancies among partner countries. Some are due to the size of the country or the number of transplantation teams, but many of the differences cannot easily be explained.

Our observations allowed us to make proposals or recommendations to strengthen the activity

- Some of those proposals involve the national or regional funding (obviously a priority factor) required to optimise the organisation of organ transplantation and organ retrieval activities, including training, quality and safety management, information systems, evaluation of results and organ allocation procedures.

The huge amount of money spent to provide dialysis for patients with end-stage renal disease in all of our countries, must be considered *per se* as the strongest incentive to organise organ retrieval with the most relevant efficacy, kidney transplantation being the most cost-effectiveness treatment.

- Many of the proposals imply collaboration between member states. The goal is not to obtain a unique uniform system, but to allow more powerful strategies:
 - common definition of terms is mandatory to share experience and results
 - common approach in tools used for organisation, training, education, allocation, safety, quality and evaluation, could avoid duplication of work and save time.

Many of these already existing tools that have been developed by one or the other countries must be now better translated and disseminated. Their improvement could also be shared to increase their pertinence and decrease the need for investments in each country.

These proposals concern all steps of activity for heart beating and non-heart beating and living donors. Some of them are immediately applicable; some others require additional implementation work.

Organ transplantation is a success story but organ shortage leaves people dying in all countries, with an important discrepancy between national rates.

The different state of the art studies carried out proved that we generally knew what direction should be taken, and allowed us to make practical recommendations. It is also clear we already have tools to improve the activity, the results and monitoring. However, the first step in any country is the sufficient funding of hospitals and a dedicated organisation for creating or reinforcing the human and technical resources.

Future perspectives for Alliance-O efforts

The consortium is now eager to implement the actions after this first step of coordination, analysis and proposals.

Finally, the consortium examined the proposed actions for each WP in order to define what kind of actions should be pursued at the Alliance-O group level, avoiding actions already

taken in charge by other organisations. The main goal remains to avoid the duplication of work. In this purpose we will exclude actions already undertaken by organisations such as the Council of Europe: (*Ethics, Guide on safety and Quality*), the European Union (*Proposal on cooperation and safety directive, cooperation with new or future member states*), or EOEO* (*logistical cooperation*).

Our proposal is to pursue the work initiated by most of our workpackages. Each organisation member would participate in one of the working groups, to make proposals and recommendations of the Alliance-O project on a voluntary basis. The overall objective is to share expertise and capitalize knowledge about Organ Transplantation by setting up technical groups for relevant topics.

Section 1 – Project objectives and major achievements during the reporting period

The severe shortage of donors across all organ categories remains a major public health issue the Member States of the European Union are faced with together, with the other countries in the world. Cooperation between the Member States should focus on identifying the most efficient systems, sharing experience and promoting best practice as well as supporting Member States whose transplantation systems are not yet sufficiently developed. The ERA-NET ALLIANCE-O project has been established to coordinate the research efforts of countries on organ transplantation, each of them having different approaches and programmes to tackle the issues of organ transplantation.

The project was coordinated by the French partner, Agence de la biomédecine, and involved partners from six other countries: Germany, Hungary, Italy, Portugal, Spain and United Kingdom.

These seven partners are represented by national public bodies involved in the organisation of OT:

- Agence de la biomédecine in France,
- Deutsche Stiftung Organtransplantation (DSO) in Germany,
- Hungarotransplant (Hu-T) in Hungary,
- Centro Nazionale Trapianti (CNT) in Italy,
- Organização Portuguesa de Transplantação (OPT) in Portugal,
- Organización Nacional de Trasplantes (ONT) in Spain,
- UK Transplant (UKT) in the United Kingdom.

ALLIANCE-O project lasted three years and was granted 2 million Euros by the European Commission.

The overall objectives of ALLIANCE-O were to set up cooperation and coordination of national and regional research activities through networking of programmes in the field of OT.

Knowing that several countries have a national public body in charge of organ transplantation, the aim was to identify existing programmes and to propose strategies for better coordination and cooperation including joint activities. Research programmes for improving OT efficiency concern many activities but can be categorised on a step-by-step basis as follows:

- Expanding donor pool (heart beating, non heart beating donors, living donors)
- Improving allocation rules
- Improving safety and quality of OT

- Improving evaluation methodology
- Improving fundamental research
- Improving coordination on ethical and legal issues raised in the field of OT

Three specific objectives were considered:

a) The activities of the Consortium have addressed, for each step mentioned above, questions at the coordination level of Research programmes. The identification and comparison of the respective national/regional programmes, their methodologies (aims, organization, evaluation, funding, benchmarking) and their results have been performed.

The aim of this benchmarking was:

- to improve, set up and coordinate the exchange of information, good practices and results of research programmes led by the different members among partners;
- to enhance research relevance and validity, and maximise research utility by avoiding duplication;
- to develop, in a coordinated way, an applicable common methodology that could be used (through joint actions) to improve the potential for organ donation, the allocation, quality and safety of organs, and the evaluation of OT.

b) From these different benchmarking analyses, relevant recommendations and position papers were discussed

c) For some of these programmes, joint pilot actions focused on specific questions for which some of the partners are already involved in identified comparable objectives and for which joint activity were already obviously desirable. This has led mainly, in the frame of the WP4, to the design of a proposed common European Donation Form that would include the same data set all over Europe and in WP 3 in the exchange of data for simulating a modification of allocation rules.

Major achievements

The major achievements were:

- The publication of a final report (called **White Paper**) summarising the actions conducted during the whole life of the Alliance-O project and including recommendations to strengthen the transplantation activity in the European Union. These recommendations were gathered by workpackages.
- The organisation of a final workshop, held on 24 October 2007, presenting the work done by the partners in the frame of the project to an European audience of

representatives from competent authorities and from research bodies, transplant professionals and journalists.

- The decision, taken by all partners, to go ahead with the Alliance-O initiative, in order to implement some of the recommendations issued in the white paper and to develop further some of the tracks for research that have been opened by the ERA-NET Alliance-O project.

Difficulties

Most of the difficulties encountered have been related with the provision of the administrative and financial documents, which resulted in a considerable delay in having the European Commission approval of the mid-term report (see section 3 – Consortium management).

The delay in meeting deadlines for some of the workpackages, especially the WP2, has also been a difficulty. Nevertheless, the dedication of the entire consortium to overcome some disagreements on the methodology, have been remarkable. This could also be considered as a major achievement of the project.