



An Agency of the French Ministry of Health



**Transparency,
Equity,
Ethics:** Improving
access to care
and patients'
quality of life

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AGENCE DE LA BIOMÉDECINE

PROFILE

The “Agence de la biomédecine” is a French national public agency created by the 2004 Bioethics law.

It provides information on, supervises, supports and evaluates healthcare activities in the areas of:

- ↳ Organ, tissue and haematopoietic stem cell transplantation;
- ↳ Assisted Reproductive Technology (ART);
- ↳ Prenatal Diagnosis (PND) and Preimplantation Genetic Diagnosis (PGD);
- ↳ Human embryo and embryonic stem cell (hESC) research.

The General Director of the Agence de la biomédecine is directly supported by a communication department and an “inspection” department.

The general Director has two deputies: one is in charge of the medical and scientific policies, and the other one is in charge of administrative, legal issues, human and financial resources and information system.

The agency also provides training for healthcare professionals and a documentation centre.

The Agence de la biomédecine is guided in all its decisions by the board of directors and an ethics board.

A budget of
95,6
million Euros
in 2013

276
people
in 2013



NB: the figures in this report concern France only.

Head Office of the Agence de la biomédecine

AGENCE DE LA BIOMÉDECINE

MISSIONS

General Missions

- ↳ Supervision of all aspects of organ, tissue and cell procurement and transplantation, at every stage from donor to recipient;
- ↳ Management of the French bone marrow donor Registry, the organ transplant waiting list, organ donation refusal Registry, the French national *in vitro* fertilisation register and the national registry of dialysis and transplanted patients;
- ↳ Monitoring studies and research on embryos, authorisation of preimplantation genetic diagnosis centres and multidisciplinary centres for prenatal diagnosis;
- ↳ Accreditation of practitioners for preimplantation genetic diagnosis and human genetics;
- ↳ Implementation of vigilance systems for ART and transplantations;
- ↳ Promotion of the donation of bone marrow, gametes, organs and tissues, through national campaigns and in collaboration with healthcare professionals and patients' associations.

In addition, the 2011 French Bioethics Law mandates the Agence de la biomédecine to inform the French Parliament and Government about developments in the field of neurosciences.



International Action

Under the authority of the French Ministry of Health, the Agence de la biomédecine contributes to the development of EU legislation and international agreements.

The agency both monitors and contributes to international scientific research, presenting at international conferences and publishing in international peer reviewed medical journals.

In the context of international cooperation, the agency works with multiple French and international professionals and institutional partners to develop transplantation in several countries.

VALUES

Transparency

The Agence de la biomédecine ensures transparency regarding its role, its operating methods and the rules applied within its different fields of competence. It scrupulously publishes declarations of financial interest online in order to guarantee the independence of its expertise, and produces numerous reports. It ensures that patients and user associations are included in its various bodies and involved in decision making processes. Transparency is also enforced by information systems – especially Cristal that makes the organ allocation processes and decision making available to all concerned professionals.

Equity

The Agence de la biomédecine guarantees an equal access to care for everyone in conformity with Health care legislation and regulation. It works with professionals to develop rules for the allocation of organs and monitors application of the principle of equity.

Ethics

The use of the human body parts for therapeutic purposes raises ethical questions which the Agence de la biomédecine must resolve in strict compliance with the bioethics law. It also ensures the respect of the three main principles of the donations that it supervises i.e. unpaid, voluntary and anonymous.

DONATION, PROCUREMENT AND TRANSPLANTATION OF ORGANS AND TISSUES

Organ transplantation saves lives and improves quality of life of many patients.

The main organs transplanted in France are the kidneys, the lungs, the livers and the hearts. The transplant of tissues mainly concerns the cornea (fine membrane on the surface of the eye).



Preparation of the operating unit before a multiple organ procurement

18,976

people were on the organ transplant waiting list at year-end in 2013

5,123

people were transplanted in 2013

13% of

kidney transplants were performed thanks to a living donor in 2013

INCREASING THE NUMBER OF PATIENTS TRANSPLANTED

Because the number of patients on the transplant waiting list increases each year, the Agence de la biomédecine is seeking to increase the number of donors by encouraging everyone to let their closest relatives know whether they wish to donate their organs or not. In France, the law presumes that everyone consents to procurement (opt out). As such if medical teams have no information about the wishes of the deceased they always ask the next of kin what the position of the dead person about organs and tissue donation prior to initiating procurement.

ORGANISING AND IMPROVING THE CHAIN FROM PROCUREMENT TO TRANSPLANTATION

The agency works closely with healthcare professionals to help improve the organisation of procurement, allocation and quality of organs. In addition, the agency is active in providing a large number of training programmes designed to improve practices in the field.

ENCOURAGING KIDNEY DONATIONS FROM LIVING DONORS

A close relative or friend can donate a kidney. When a person with end stage kidney failure has the chance of being able to benefit from it, this type of graft provides excellent results.

DONATION, PROCUREMENT AND TRANSPLANTATION OF HAEMATOPOIETIC STEM CELLS (BONE MARROW, PERIPHERAL BLOOD STEM CELL AND CORD BLOOD)

INCREASING THE NUMBER OF HAEMATOPOIETIC STEM CELL TRANSPLANTATION

A HSC transplant gives patients with serious blood diseases, such as leukaemia, an additional chance of being cured. There are three possible sources of HSCs:

- ↳ bone marrow (collected under general anaesthesia);
- ↳ peripheral blood stem cells (HSCs from bone marrow, mobilized and collected while circulating in the bloodstream);
- ↳ cord blood.

It is very difficult to find a compatible donor outside the close family circle (brothers or sisters). It is, therefore, very important that the number of donors registered on the *France Greffe de Moelle* registry managed by the Agence de la biomédecine be increased and that international solidarity be brought into play.

SEARCHING FOR A COMPATIBLE DONOR

The transplant physicians register their patients on the French registry by entering the name, medical and biological characteristics of the patient, including their HLA typing. The search for a compatible donor is launched in France and on the international registries. When a potential donor is identified and after the compatibility verification tests have been carried out, the Registry coordinates with the donor centres the organization of the stem cell procurement. All HSC donors receive a medical follow-up.

STORING CORD BLOOD UNITS

In some cases, a complementary source of HSC, such as a cord blood unit, can be provided. The cord blood is collected from the umbilical cord immediately after the birth of a child. This collection is painless and does not endanger neither the mother nor the child.



221,460
voluntary donors
were registered
on the French Bone
Marrow donors
Registry in 2013

Patients who have received an allotransplantation of bone marrow



31,230
cord blood units
were stored
in banks at the
end of 2013

Appointment prior to a donation of cord blood

ASSISTED REPRODUCTIVE TECHNOLOGY AND GAMETE DONATION

In vitro fertilisation carried out with ICSI



23,887
children were
born *via* ART
in 2012

There were
422
ovocyte
donors
in 2012

2,110
couples were
waiting for an
ovocyte donation
in 2012

AUTHORISING THE TECHNIQUES FOR ASSISTED REPRODUCTIVE TECHNOLOGY (ART)

The different ART (assisted reproductive technology) techniques for couples with infertility problems or diseases that may be transmitted to their children are as follows: artificial insemination, *in vitro* fertilisation (IVF) and embryo donation.

IMPROVING ACCESS TO ART AND PRACTICE EVALUATION

The Agence de la biomédecine is fully focused on improving the treatment and monitoring of the couples who turn to ART. It manages the Registry of IVF attempts and proposes good practice rules with the help of healthcare professionals. It gives an opinion to regional Healthcare Agencies which issue authorisations for the activity of clinical and biological ART centres. It collects the data from all the centres to evaluate their activity and their results. It has also implemented a vigilance system to communicate serious adverse events and prevent them from recurring. Finally, it issues import and export authorisations for gametes and embryos.

ENCOURAGING THE DONATION OF OVOCYTES AND SPERM

The recourse to a gamete donation (sperm or ovocytes) may be necessary for many infertile couples. The Agence de la biomédecine communicates about the donation of gametes since, the number of ovocytes donated is not sufficient to meet the needs of the couples concerned in France. Embryo donation is intended for couples who have double infertility or risk transmitting a genetic disease to the child.

The Agence de la biomédecine monitors the health of the people who undergo ART, the children born from it, and of ovocyte donors.

PREIMPLANTATION GENETIC DIAGNOSIS, PRENATAL DIAGNOSIS AND POSTNATAL GENETICS

PREVENTION OF A RISK

The **preimplantation genetic diagnosis (PGD)** may allow parents who have a serious and incurable genetic disease to have a child free of that disease. This technique consists in testing the embryos conceived *in vitro* for the disease that could be transmitted by the parents and reimplanting a disease-free embryo in the mother's uterus. The Agence de la biomédecine certifies the practitioners, authorises, and monitors and evaluate the activities of the PGD centres.

DIAGNOSIS SCREENING

The **prenatal diagnosis (PND)** serves to detect particularly serious diseases in the embryo or the foetus *in utero*. The most common PND carried out is the ultrasound. The multidisciplinary centres for prenatal diagnosis authorised and monitored by the Agence de la biomédecine, bring together all the healthcare professionals who perform this activity.

AVOIDING SITUATIONS CAUSED BY DIAGNOSTIC ERROR

Most **genetic** diseases are detected at birth or during childhood, but some are diagnosed in adults. Medical supervision is essential for the provision of these results, which is not the case of genetic tests purchased on Internet. The Agence de la biomédecine aims to harmonise practices and improve the quality of treatment in this activity.

More than **80%** of pregnancies examined by a multidisciplinary centre for prenatal diagnosis led to the improvement of the treatment of the mothers and babies in 2012.

Approximately **20%** lead to a medical termination of pregnancy

91
births
occurred
after PGD
in 2012

1,538
tests of different
genetic diseases
were available
in 2013

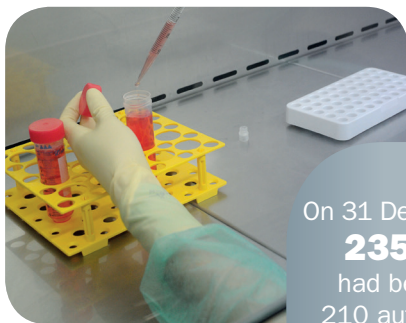


Chromosome capture and analysis

RESEARCH ON HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS

In France, research on the embryo is authorised, under certain conditions, by the bioethics law of 7 July 2011, modified by the law of 6 August 2013.

hESCs washing before centrifugation



On 31 December 2013,
235 decisions
had been issued:
210 authorisations,
27 authorisation
renewals

On 31 December 2013,
38 teams were
carrying out research
on hESCs or embryos



Change in hESC Environment

FACILITATING MAJOR MEDICAL PROGRESS

Embryo research studies the mechanisms of the development of the embryo up to several days after fertilisation.

The researchers authorised by the Agence de la biomédecine work on embryos that have been conceived and conserved within the framework of *in vitro* fertilisation, which are no longer the subject of parental project and which the parents have chosen to give to research.

The embryonic stem cells (hESCs) come from the human embryo at the very first stage of its development. Their ability to generate all types of human cells carries a potential for advances in the knowledge of human development and understanding the biological mechanisms which characterise these cells and also open new paths for treatment, for example regenerative medicine.

THE AGENCE DE LA BIOMÉDECINE ONLINE



www.agence-biomedecine.fr/About-us

The screenshot displays the website's interface for the 'ABOUT US' section. At the top, there is a navigation bar with the agency's logo and name, followed by links for 'Sites pour le grand public', 'Site institutionnel', 'Site des professionnels', and 'International website'. A search bar is also present. Below the navigation, a purple header contains the main menu items: 'ABOUT US', 'THE BIOETHICS LAW', 'OUR INTERNATIONAL ACTIVITIES', and 'COLLABORATIONS WITH INTERNATIONAL ORGANISATIONS'. The 'ABOUT US' page features a sidebar with a 'Home' link and a list of sections: 'The missions of the Agency', 'Our values in action', 'Organisation of the Agency', 'Expert Advisory Bodies', 'Our work and areas of expertise', and 'Key figures'. The main content area includes a large image of a woman speaking, with the text: 'ABOUT US The French Agence de la biomédecine, established by the bioethics law in August 2004, oversees four key areas of human biology and medicine: organ tissue and cell transplantation, assisted reproductive technology, prenatal and genetic diagnosis and human embryo and embryonic stem cell research. These medical activities all share major therapeutic, health and ethical issues. The Agence de la biomédecine is the only agency in Europe that brings together the four areas of transplantation, procreation, embryology and genetics. The Agence, on a national level, provides professionals and researchers with collective answers, guarantees equity of access, ethics and transparency of these activities, organises information and awareness campaigns, and evaluates and publishes its activities in an annual report. Additionally, the head office operates a training and information centre.' Below this, there are four columns of content: 'THE MISSIONS OF THE AGENCY' (with an image of a building), 'ORGANISATION OF THE AGENCY' (with an image of a person), 'OUR WORK AND AREAS OF EXPERTISE' (with an image of a microscope), and 'KEY FIGURES' (with a colorful graphic). To the right, there is a 'QUICK ACCESS' section with links to the 'Annual report (in french) (pdf, 7.1 Mo)', 'Press (in french)', and 'Legal texts (in french)'. Below that is an 'AGENDA' for February 2014, showing a calendar grid with the 27th highlighted.

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The Agence de la biomédecine is a national public agency created by the bioethics law of 2004, modified in 2011 and 2013. It carries out its missions within the field of the procurement and transplantation of organs, tissues and cells, as well as in the fields of procreation, embryology and human genetics.

The Agence de la biomédecine does its best to ensure that each patient receives the care it needs, in respect of the healthcare safety and ethics rules. Owing to its expertise, it is the reference authority for the medical, scientific and ethical aspects of such questions.



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