Data Protection and Medical Research in Europe: PRIVIREAL

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PRIVIREAL, Sheffield Institute of Biotechnological Law and Ethics

PRIVIREAL (Data Protection and Medical Research in Europe) is a European Commission funded project (Contract No. QLRT-2001-00056) examining the implementation of Data Protection Directive 95/46/EC in relation to medical research and the role of ethics committees in European countries. PRIVIREAL members and authors are national experts in their fields, and the project is coordinated by Professor Deryck Beyleveld, Faculty of Law at the University of Sheffield.

The PRIVIREAL series consists of five separate volumes following the development of the PRIVIREAL project, from first assessments of the implementation of the Directive with a particular focus on medical research, to consideration of the role of research ethics committees as regards data protection, leading to recommendations on the implementation of the Directive and the remit which should be given to RECs to protect research participants’ rights.

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Edited by

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ASHGATE
Chapter 12

Research Ethics Committees in Hungary

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Introduction

According to Hungarian health administrators, the monitoring of public health and medical activities within the Hungarian health system is one of the oldest models of its kind in Europe. The history of the Health Science Council,¹ the main review body operating at the national level, goes back to the nineteenth century. Questions of medical ethics, of course, were interpreted differently at that time than today: concerns about the public good had higher priorities in designing and implementing new medical services than, say, focusing on the rights of the patient. Nevertheless, issues of consent already appeared in the lectures of a famous medical doctor at the beginning of the twentieth century.²

Though the current model of ethical supervision of medical activities was first adopted in 1951 when the Health Science Council was established in its present form, this body may be considered as a legitimate successor to the National Public Health Council, which was formed in 1868.³ Since then the composition, name and function of the Council has been through numerous changes. After the Second World War, the main function of the body was to provide professional guidelines and opinion in important matters of health and science and to provide education in health. However, explicit reference to ethics in science appeared in 1977, when a

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¹ In Hungarian this is the Egészségügyi Tudományos Tanács, hereinafter the ETT. In 2001 the chairman of the Council was Prof. Szilveszter E. Vizi, Chair of the Hungarian Academy of Sciences. Since 2002, the chairman of the ETT has been Prof. Péter Sótonyi, a pathologist and rector of the Semmelweis University of Medical Sciences. More information on the Council can be found in Hungarian at the website http://www.ett.hu (last accessed on 16 May 2005).
² A Professor of medicine, Dr. József Imre, collected and published his lectures on medical ethics in 1925. The Professor studied Hungarian and German legal literature, and it is surprising even today to see the degree to which the necessity of informing the patient, and receiving his or her permission before carrying out medical procedures, was recognized and considered ethical at the start of the twentieth century.
³ The King appointed the first members of this Council in 1868. See the brief history of the Health Science Council, available in Hungarian at the website http://www.ett.hu (last accessed on 16 May 2005).
new committee was established within the Council—the research ethics medical committee (Tudományos és Kutatásügyi Bizottság, ETT TUKEB).

The first specific law on biomedical research was adopted in the form of a Ministry Decree in 1987. In the same year the text of the Helsinki Declaration was published in the Official Gazette.

The general rules for conducting biomedical research were laid down in the Health Care Act of 1997, while conditions for research on human beings were specified in a Ministry Decree issued in 2002.

Today research ethics committees operate on three levels in Hungary: on the national level, the regional level, and the level of healthcare institutions (such as hospitals).

Institutions

Definition of Ethics Committees under the Hungarian Law

Under the Ministry of Health Decree on Medical Research on Human Beings, ethics committees are defined as ‘independent bodies that are responsible for protecting the human rights, safety, and well-being of the research subjects, by means of, among other things, evaluating and assessing, from a scientific and ethical perspective, the research plan, conditions of the research, the methods applied in the research, and the information given to the participants’.

As the above citation reveals, these ethics committees safeguard not only human rights and safety concerns, but are also responsible for assessing the scientific and professional merits of newly proposed research plans or protocols. Thus, these committees have the combined function of evaluating both the ethical and scientific aspects of new research proposals in a single procedure.

As already mentioned, these ethics committees operate at national, regional, and institutional levels.

Central Research Ethics Committees

The Health Science Council is the advisory, opinion making, and policy preparing body of the Minister for Health, Social and Family Affairs. The Council consists of seven board members (medical doctors and academic scholars), two chairman emeriti, five chairmen of the committees (see below) operating within the ETT,

and eleven ex officio members (as specified by the law). The members of the Council are appointed for three years.

The Law on the Health Science Council specifies five committees of the Council:

- Scientific and Research Ethics Committee (with the Hungarian acronym, ETT TUKEB);
- Clinical Pharmacology Ethics Committee (ETT KFEB);
- Human Reproduction Committee (ETT HRB);
- Forensic Committee; and
- Research and Development Committee.

Members of the Council and the Committees are appointed by the Minister for Health. There is no rotation, though the appointment has a fixed term.

The Scientific and Research Ethics Committee (ETT TUKEB) plays a principal role in the ethical review of new medical technologies based on a protocol submitted to the Council. Most members of this Committee are prominent medical professors. As the Committee operates within the Health Science Council, formally an advisory body for the Minister of Health, it is not entirely independent from the government.

The ETT TUKEB provides ethical and professional opinion on:

- the introduction of new preventive, therapeutic or diagnostic methods and procedures in Hungary, if those involve invasive treatment of the patient;
- the clinical applicability of medical technologies and equipment, and the effectiveness of them in the treatment of the patient;
- research projects concerning the development and characteristics of genetically determined illnesses, research in the fields of population genetics, somatic genetics and genetic epidemiology;
- research that does not belong to the categories described in the previous points but falls under the competence of more than one regional research ethics committee due to its multi-centred organization;
- any other research where the regional ethics committee forwards the application to the highest authority.

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4 Ministry of Health Decree No. 11 of 1987 (VIII.19) on Biomedical Research (EüM rendelet az orvosiológiai kutatásokról), amended by the Ministry of Welfare Decree No. 31 of 1998 (VL24).
5 Act No. CLIV of 1997 on Public Health (also referred to as the Health Care Act) and Ministry of Health Decree No. 23 of 2002 (V.9) on Medical Research on Human Beings (EüM rendelet az emberen végzett orvostudományi kutatásokról).
6 Ministry of Health Decree on Medical Research on Human Beings, n. 5 supra, Article 2(b).
7 Ministry of Health, Social and Family Affairs Decree No. 34 of 2003 (VI.7) on the Health Science Council (ESzCsM rendelet az Egészségügyi Tudományos Tanácsról).
8 The head of the Commission is Prof. Zoltán Papp, a gynaecologist and obstetrician. Among the members of this Commission, there are two legal scholars: Ágnes Döss and Judit Sándor.
10 Ministry of Health Decree on Medical Research on Human Beings, n. 5 supra, Article 9(2).
The Committee on Human Reproduction (ETT HRB)

provides professional and ethical opinion on specific procedures that are targeting human reproduction; on research and invasive treatments involving the use of embryos and embryonic stem cells; and on research and treatments involving a study of the human genome in relation to reproduction.\textsuperscript{11}

The Committee on Clinical Pharmacology (ETT KFEB) ‘provides professional and ethical opinion on medicinal products and on the clinical applicability of pharmacological products’.\textsuperscript{12} Evaluation of procedures and protocols before the KFEB are based on the Law on Clinical Trials of Medicinal Products for Human Use.\textsuperscript{13}

Regional Research Ethics Committees

There are 13 regional research ethics committees (Regionális Kutatásértékelő Bizottság, RKEB) in Hungary.\textsuperscript{14} The main role of the regional ethics committees is to formulate ethical and scientific opinion on any research that does not fall within the special competence of the central or national committees (TUKEB, KFEB, HRB).

The composition and procedures of the regional ethics committees are subject to the approval of the Scientific and Research Ethics Council. Members of the regional ethics committees are appointed by the heads of the health institutions involved.

\textsuperscript{11} Ministry of Health Decree on Medical Research on Human Beings, n. 5 supra, Article 9(3).
\textsuperscript{12} Ministry of Health Decree on Medical Research on Human Beings, n. 5 supra, Article 9(4).
\textsuperscript{13} In full: Ministry of Health Decree No. 24 of 2002 (V.9) on The Implementation of Good Clinical Practice in the Conducts of Clinical Trials on Medicinal Products for Human Use (EúM, rendelet az emberi felhasználásra kerülő vizsgálati készítmények klinikai vizsgálatáról és a helyes klinikai gyakorlat alkalmazásáról).
\textsuperscript{14} In addition to the six geographic-administrative regions (grouping two or three counties), the Semmelweis University of Medical Science and its institutions together with three central counties form one region; the health institutions under the direct supervision of the Ministry of Health, Social Affairs and Family form another; the health institutions in Budapest are grouped into two additional regions (the health institutions on the Buda and Pest sides of the Danube are separated); hospitals of the Hungarian Military Forces form their own region; the health institutions of the Ministry of Internal Affairs form yet another region, and the hospitals of the National Railways form the last one. See Annex to the Ministry of Health Decree No. 23 of 2002 (V.9) on Medical Research on Human Beings, amended by the new Ministry of Health, Social Affairs and Family Decree No. 34 of 2003 (VI.7) on the Health Science Council (see n. 7 supra).

Research Ethics Committees at Health Institutions

Every health institution in which biomedical research is conducted has to have an institutional research ethics committee (Intézményi Kutatásértékelő Bizottság, IKEB).\textsuperscript{15} The composition and procedural rules of the committee have to be approved by the competent regional ethics committee. The main task of these local research ethics committees is to check whether the personal and technological conditions at the health institution are adequate for organizing and conducting research and to monitor the research procedure once the research protocol is approved.

The chairman, the secretary, and the members of the institutional research ethics committees are appointed by the head of the health institution. The chairman of the committee may nominate the members. The committee has to have at least five members including the chairman and the secretary. It is recommended that the membership include professionals who do not have a labour contract with the health institution. It is also recommended (thus, unfortunately, not mandatory) that there is a member in the committee who has some legal expertise in the field of research on human beings.\textsuperscript{16}

Procedures

Meetings of the Committees

The Central Research Ethics Committees (TUKEB, KFEB, HRB) have regular meetings at least once every two months. The meetings are organized on the invitation of the chairman of the committee. An irregular meeting can be initiated by two thirds of the members. The chairmen, deputy chairmen, and members of the committees are based on the nomination of the Council Chairman appointed by the Minister for Health. Selection should take into account the age and gender composition of the committee.

The agenda for meetings is drafted by the secretary of the given committee. Members of the committees should receive the invitation at least ten days prior to the meeting.

On the level of hospitals and health institutions, ethics committees review research protocols. Each healthcare institution where research is conducted has to set up a research ethics committee. In addition there are some institutions where regional research ethics committees have to be established as well.

\textsuperscript{15} Ministry of Health Decree on Medical Research on Human Beings, n. 5 supra, Article 12.
\textsuperscript{16} See Guideline Number 2 on the ‘Operation of the regional and institutional health committees’, included in the Annex to the Ministry of Health, Social Affairs and Family Decree No. 34 of 2003 (VI.7) on the Health Science Council (see n. 7 supra).
Conflict of Interest

Based on Article 11 of the ETT Decree, if any member of the research ethics committees has a conflict of interest for either legal, ethical or economic reasons, the person has to reveal this fact to the committee. Members of the committee may also claim that another member has a conflict of interest. In the latter case the committee decides on the conflict of interest by vote.

Basic Rules of Biomedical Research

General rules and the content of research protocols are regulated in a Ministry Decree.

Biomedical interventions can only be carried out with authorization and with the research purpose of developing diagnostic, therapeutic, preventive and rehabilitation procedures, for working out new procedures, and for a better understanding of the aetiology and pathogenesis of illnesses.

Within the meaning of this decree the term biomedical intervention covers the following: human genetic research carried out on living human beings and human genetic material, or other human genetic research; trying new, not yet applied, medical and treatment procedures, interventions, tools, equipment, applying medicines on the basis of new recommendations, or using other substances; for public health purposes—epidemiology and environmental healthcare research carried out on human beings; and research carried out on embryos and stillborn foetuses.

Biomedical intervention has to be based on appropriate and satisfactory laboratory and animal experiments and a deep understanding of relevant professional literature. Biomedical intervention can only be carried out in the institutions defined in the Health Care Act. In the process of biomedical intervention, the scientifically proven diagnostic and therapeutic procedures accepted in practice must be provided for the persons participating in the intervention, including those in the control group.

The biomedical intervention—including the interventions not carried out for therapeutic and preventive reasons—can only be carried out within the framework of Chapter VIII of the Health Care Act (Act CLIV of 1997) if:

- it is in the public interest and is scientifically sustainable;
- the expected results can be verified;
- the professional, personal and material circumstances necessary for careful preparation and verification of the evaluation are satisfied.

The health and the personal rights of the healthy person or the person under medical treatment involved in the biomedical intervention (in the following: the person involved in the research) must be secured. The biomedical intervention cannot endanger, without justification, the health condition of the person involved in the research.

The head of the research has the obligation to put together a detailed research plan and individual data-files about all the persons involved in the research. The data-file has to contain all data, facts, and events that are connected to the intervention and that may respectively influence the outcome of the research. The head of the research must send the research plan and the data-file to the director of the institute—non-affiliated doctors must send them to the director of the capital or county hospital with responsibility for their area.

If the authorization for the biomedical intervention is not from the director of the institution, then, before starting the intervention, the consent of the director of the institution is required as well. Biomedical intervention—unless laws provide differently—can only be carried out on patients or healthy persons who undertake it voluntarily. Carrying out biomedical intervention requires the preliminary written consent of the person involved in the research.

Biomedical intervention can, even if ethical-scientific approval is given, only be started if the person involved in the research or respectively his or her legal representative has been informed in detail, by the director of the research or based on his or her authorization, by another doctor participating in the research, about all the facts, circumstances or events that are connected or could be connected to the intervention.

Information has to be provided especially about the purpose and the course of the research, the interventions necessary for the research, the frequency of the interventions, the possible and expected effects and side effects connected to the research, possible advantages and risks and possible consequences. Information must also be given concerning the fact that the consent to participate in the research can be withdrawn any time, including orally, and that in case of any damage to their health condition, they may ask for compensation of damages. This information has to include explanation of any medical terminology.

Such information has to be included in the document referring to the consent, including withdrawal of consent. Reimbursement of expenses can be given to the

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18 Ministry of Health, Social Affairs and Family Decree No. 34 of 2003 (VI.7.) on the Health Science Council (see n. 7 supra).


20 Ministry of Health Decree No. 24 of 2002 (V.9.) on The Implementation of Good Clinical Practice in the Conducts of Clinical Trials on Medicinal Products for Human Use (see n. 13 supra).

21 Health Care Act, Article 161(4), see n.5 supra.
person involved in the research—unless the intervention was made for therapeutic purposes. The interests of the persons involved in the research are represented—for medical purposes—by a doctor who is not participating in the research and is appointed by the director of the institution (appointed doctor of the institution). If more than one doctor is needed, he or she can be appointed. In selecting the appointed doctor of the institution, the preference of the patient has to be considered. The appointed doctor of the institution has to be informed regularly—without special request—about the standing of the biomedical intervention, and any occurring problems. Information must be given immediately if the appointed doctor requests it.

It is the task of the appointed doctor of the institution to monitor the health condition of the research participants. For this purpose they keep in touch regularly with them, provide information for them, initiate professional help, examine them regularly, in the case of a complaint immediately report this to the director of the institution, and take part in the supervision and evaluation of the research.

**Ethical Monitoring of Research Projects**

Biomedical intervention is continuously supervised from a professional, scientific and ethical point of view by the director of the institution and by the chief doctor of the department professionally in charge. The appointed doctor of the institution also has to be involved in the supervision.

The health condition of the person involved in the research has to be observed and documented carefully before starting the research, continuously during the research and after the research.

**Informed Consent Process**

Written information required under the Decree\(^{22}\) should include the following elements:

- data on the scope of the research;
- the experimental nature of the research;
- the object of the research;
- the expected duration of the research;
- the number of research subjects;
- biomedical interventions and their frequency;
- other available treatments;
- information about changes in therapy and its impact on the research subjects’ health;
- the expected consequences of the research;

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\(^{22}\) Decree of the Minister of Health No. 23 of 2002 (V.9) on Biomedical Research on Human Beings, n. 5 *supra*, Article 4(4).

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- the benefits of the research (if no benefit is expected then it has to be stated why the research is necessary), the method of selecting different research groups, compensation for potential damages and a statement describing any compensation for study participation (including expenses and access to medical care) must be given to research participants;
- data protection; and
- the name of the ethics review committee.

Research subjects should receive special information on the handling of their personal data.\(^{23}\)

**Minimal Content of the Consent Form**

The written consent form that should be signed by each of the research subjects should include at least the following elements:\(^{24}\)

- the name of the health institute where the research will be conducted;
- the name of the head of the research and names of the staff members who will provide information on the research;
- personal data of the research subject (name, mother’s maiden name, date and place of birth, social security number, address);
- statement of the consent;
- date of signature;
- signature of the researcher who provided the information;
- list of any relevant research conducted on animals.

**Mandatory Elements of the Research Project**

The following data are considered as data of public interest:

- the purpose and relevance of the research including a description of the expected results;
- the background and justification of the scientific research;
- an evaluation of the anticipated benefits and requirements, including bibliography;
- arrangement for the recruitment of the research subjects, selection criteria, projected number of research subjects and their distribution by gender and age;
- research methodology and the medical interventions to be applied;
- procedures in case of adverse events and injuries, provisions for indemnity or compensation in the event of injury;

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\(^{23}\) Ministry of Health Decree on Biomedical Research on Human Beings, n. 5 *supra*, Article 4(2)(i).

\(^{24}\) Ministry of Health Decree on Biomedical Research on Human Beings, n. 5 *supra*, Article 4(5).
the protocols on processing the personal and health data of the research subjects;
- guidelines for the statistical processing of research data;
- a statement made by the chief researcher on the compatibility of the research with the Hungarian laws and with the Helsinki Declaration.25

Data related to scientific hypotheses and the pre-clinical trial are not considered data of public interest.

Termination and Suspension of the Research

The researcher has to terminate the biomedical intervention immediately if he or she perceives that its continuation could be damaging to the person involved in the research.

In the case that an adverse effect occurs that justifies the interruption of the biomedical intervention, or an important change occurs in the circumstances on which the ethical-scientific opinion was based, the director of the institution must immediately suspend the intervention and notify the committee which gave the ethical-scientific opinion. The director of the institution must also suspend the research if more than one fifth of the persons involved in the research withdraw their consent.26

Criminal Sanctions

A new sub-section of the Criminal Code, effective from 1 July 1998, concerns biomedical ethics.27 Criminal activity classified here includes interference with the human genome,28 human gamete usage,29 the use of techniques that aim to select the sex of the unborn child,30 human experiment research protocols,31 embryo and gamete research protocols,32 violation of the rules of self-determination in the field of healthcare, and the sale for transplantation of human body parts and cadavers.33

Violations of these legal rules and norms is punishable by up to five years’ imprisonment, with the exception of when the right to self-determination has been violated or a human body or corpse used, where the punishment is up to three years. In some cases attempting to commit these crimes is also punishable.34

Any intervention in the human genome, including alteration of a human embryo, is punishable by up to five years’ imprisonment. If the alteration resulted in a change to the genome, the punishment is two to eight years’ imprisonment.35 Reproductive use of cadaver gametes, including the gametes of the dead embryo is punishable by up to five years’ imprisonment. Sex selection is punishable by up to five years’ imprisonment.36 The only exception to this is the case where the sex selection of the human embryo is conducted in order to avoid an inheritable disease (Health Care Act 1997 No. CLIV, Article 182).

Violation of the rules on human research is punishable by up to five years’ imprisonment.37 Research conducted on an embryo or gametes without permission issued on the basis of the Public Health Act is punishable by up to five years’ imprisonment.38

Data Protection in Biomedical Research

Research subjects have to receive information about the methods of data protection before consenting to research. A general rule of data protection can also be applied here. Under Article 16/A(1) of the amended Data Protection Act,39 the data subject may object to the data processing if the processing only serves the interests and rights of the data processor, except where it is prescribed by the Parliamentary Act.

Furthermore, the data subject may protest against processing or transfer of the data if it serves the purposes of marketing, opinion survey or scientific research. In addition to these instances, data subjects may protest against data processing if the law prohibits it in other cases.

25 Ministry of Health Decree on Biomedical Research on Human Beings, n. 5 supra, Article 8(3)(a)(i).
26 Ministry of Health Decree on Biomedical Research on Human Beings, n. 5 supra, Article 15(1).
27 ‘Crimes Against the Order of Medical Interventions and Medical Research, and Against Self-Determination Related to Health Issues’, Criminal Code, Title II, Chapter XII, Crimes Against Persons.
28 Criminal Code, n. 27 supra, Section 173/A.
29 Criminal Code, n. 27 supra, Section 173/B.
30 Criminal Code, n. 27 supra, Section 173/C.
31 Criminal Code, n. 27 supra, Section 173/D.
32 Criminal Code, n. 27 supra, Section 173/E–G. These Sections basically prohibit all forms of cloning for any reason except if done by, and strictly according to, a permission issued in line with the law on healthcare.
33 Criminal Code, n. 27 supra, Section 173/I. This Section prohibits the unlawful obtaining and any kind of sale of all parts of the human body from the genes to the whole body.
34 Criminal Code, n. 27 supra, Sections 173/B, E, F, G and I. Preparation is either a misdemeanor punishable by up to two years’ imprisonment, or a crime in itself, punishable by up to three years’ imprisonment.
35 Criminal Code, n. 27 supra, 173/A (1).
36 Criminal Code, n. 27 supra, Section 173/C (1).
37 Criminal Code, n. 27 supra, Section 173/D.
38 Criminal Code, n. 27 supra, Section 173/E.
39 Parliamentary Act No. XLVIII of 2003 on the amendment of the Act on the Protection of Personal Data, Article 16/A(1).
Conclusions

As we have seen above, the ethical and professional review of medical research and the implementation of new protocols operates on three different levels in the Hungarian health system. Ethics committees, due to the composition of their members and the by-laws regulating their operation, generally focus on the parallel aspects of scientific merit and ethical acceptability.

On the national level, specialized committees monitor new and particularly sensitive research, such as genetic research on either human reproduction or the human embryo.

One of the most problematic issues that may arise on all three levels is how to ensure professional and political independence. The law declares independence as a principle on which the operation of the ethics committees should be based. In practice, however, the ethics committees often neglect this principle by not involving patient rights representatives, ethicists, or other non-medical professionals in their work. There has been some change recently on the higher, national and regional levels—the committee membership now also includes highly educated professionals, often with two degrees, usually in medicine and law. This is very useful in many respects, but it may still be problematic in the case of representing the interests of research subjects. On the level of local ethics committees the problem is quite the opposite—there is a striking lack of expertise in ethics and ethical issues.

Ethics committees at the national level have a high prestige and they are often considered as the bearer of ultimate knowledge on almost any issue. This is partly due to the fact that the majority of the members are heads of university hospitals and senior professors who represent a variety of medical fields. Although ethics committees, even at the national level, may provide only scientific and ethical opinions on the implementation of new research projects, their opinions are often regarded as ultimate decisions in administrative licensing of the various new medical procedures and research protocols.

This widespread perception of the authority of the Health Science Council led to a rather unusual legal procedure in 2003. In this case, the Health Science Council was sued by a private company, and its clients, for the adverse consequences of the statements of the Council that collecting umbilical cord blood for storage and the future use of haematopoietic cells for the purposes of the therapy of the child constitutes research. Although the Council does not have an independent legal personality, it had to act as the defendant in the civil proceeding.

40 According to the World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research (Geneva: World Health Organization, 2000), independence is understood as independence from political, institutional, professional and market influences.

41 The use of umbilical cord blood stem cells for transplantation treatment holds exciting promise, but this area of medical science is still largely investigational. It was only in 1988 that French researchers performed the first successful stem cell transplantation using umbilical cord blood. The transplant was taken from a newborn and given to a five-year-old sibling with a severe anaemia syndrome that included skeletal defects.