Bioethics

Newsletter issued by the Bioethics Consultative Committee

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The Worlds Largest Gene Database

We have heard recently that Britain is to go ahead and house the largest gene data base. This consists of DNA samples from 500,000 individuals of both sexes in the age group 45- 64 years, which will be worked out in great detail to determine their genome. This information will then be linked with history of disease, lifestyle, etc. The aim is to see if there is some linkage between genome and any of these expressed characteristics.

The ethical issues relating to these studies have been well aired, particularly with respect to the first such data bank which was given the go-ahead in Iceland a couple of years ago. Unlike that data base, however, the British study will ensure that all specimens are voluntarily given. It is also ensures that police and insurance companies will specifically not have access to this information.

So who is going to benefit from this database? One expects that new links will be established between genetic make-up and health and disease. This would be of considerable importance to the pharmaceutical industry which are already negotiating access to the gene database. The individual DNA donors are specifically excluded from receiving any information resulting from this research.

These advances have been criticised as "commercialising the human genome". The Convention of Bioethics makes a specific injunction against using the human body and its parts for commercial gain, and one could argue that this research could fall under that category. A fine balance needs to be made between allowing science to advance and ensuring that human rights are not eroded.

The Council of Europe has issued a Recommendation concerning the protection of personal data, which was adopted by the Committee of Ministers in 1997 (copies available).

Cloning no panacea for Infertile Couples

The novel techniques of cloning have been hailed in some quarters as the answer to fertility problems. However, further developments have sounded alarm bells that cannot be ignored. New research around the world has shown that cloned cells may harbour minute genetic changes not easily recognisable but which lead to fetal losses or major abnormalities.

Several investigators working in experimental systems have shown that these techniques needed much further study before they could be applied to human beings.

Rudolph Jaenisch, of the Whitehead Institute for Biomedical Research, Cambridge, Massachusetts, and Ryuzo Yanagimachi's laboratory at the University of Hawaii, Honolulu, who are working on producing clones from embryonic stem cells to produce various body tissue warn that: "even apparently normal clones may have subtle aberrations of gene expression that are not easily detected in the animal clone," and add that attempts to clone human beings were "dangerous and irresponsible". Ian Wilmut, whose name has been linked with the first cloned sheep "Dolly" warned fellow scientists against attempting to apply this technique to the human situation. "The most likely outcome of any attempt to do that would include late abortions, birth of children who would die, and worst of all the birth of children who would survive but would be abnormal."

"There is an unusual pattern of loss of foetuses and unfortunately the death of offspring that are produced by cloning." He continued, "This is the reason why lots of labs, including our own, have called for a moratorium on the use of cloning with humans on safety grounds alone."

It is to be noted that human cloning has been interdicted by the Council of Europe [See Protocol on Cloning, Convention of Bioethics, Council of Europe]. On the other hand, President Bush has allowed limited stem cell research to be funded by US health funds.

From the Council of Europe, Bioethics Committee: Interim Report on the Use of Human Biological Materials and Personal Data in Biomedical Research

This topic has become a hot issue and needs to be addressed. Biological material, whether left over from diagnostic procedures or donated for the purpose of research or other reasons has to be processed carefully to ensure that informed consent for its use is always available. In relation to personal data, distinction is to be made between data that is anonymised (linked or unlinked) and coded. The rights of the individuals and the adequate safeguards in relation to research were also stressed. Further discussion highlighted the importance of informed consent and procedures for feedback of information resulting from research findings.

The Council of Europe is in the process of preparing an extensive protocol in relation to the performance of research in member States. Currently in Malta, the decision whether to submit a research protocol to a Research Ethics Committee is left to the whims of the individual researcher. There is moreover very little supervision by such Committees, and no reports relating to progress of the research are requested or submitted.

All this will change when Malta signs the Convention of Bioethics and its related Protocols. Strict regulation is made relating to what procedures have to be adhered to. In particular, there are detailed requirement for submitting a research protocol.

No research is to be allowed unless it has been approved by a scientific/ethical body to ensure the acceptability of its scientific merit. Such a Committee has to ensure its independence, and in particular, no member of the committee can have a direct interest in the research programme being examined. Detailed requirements about informed consent for the participants is also made clear. It is, moreover, the onus of the researcher to ensure that the participant are in a position to give informed consent. Research in special situations, particularly where one is not capable of giving consent (e.g. research involving patients with a mental disability, or patients below the age of consent), as well as research in pregnancy and that involving the embryo and fetus is subject to special considerations.

Unforeseen complications may arise during the course of research. Such incidents are to be reported and the research protocol re-examined. Certain articles of the Protocol deal with the safety and supervision of the research programme. This may include the need for suitable insurance cover in case of complications.

In Malta we are still working under outdated conditions, where research ethics committees are not given due importance. In fact it is not an exaggeration to say that the vast majority of research done never comes under the scrutiny of a Research ethics Committee. This is obviously an unsatisfactory situation.

It is also envisaged that the requirements imposed by this Protocol are likely to increase the difficulties associated with the performance of a research programme. While this is unfortunate, it is to be appreciated that the aims promulgated here will ensure that there is no possibility of performing research that has not been scrutinised properly, or using patients without their knowledge or through lack or adequate information.

Xenotransplantation: What is its status?

Transplantation across a species barrier has the theoretical aim of providing a limitless supply of organs and tissues. However, this practice has been under considerable criticism, not least because of the perceived danger associated with the transfer of organs from an animal to the human. Hence the continued controversy relating to the desirability of developments in this area. On the one hand, transplantation of items like pigs' heart valves is an established procedure. On the other hand, the risk involved in transfer of animal viruses to human beings is an unknown quantity, and needs further elucidation. The transplant of cell lines derived from animals is still under active research. Transplant of organs from animals is the least acceptable procedure, particularly in view of the lack of convincing evidence relating to its long-term safety.

Ethical Aspects of Fee-Splitting

The AMA Code of Medical Ethics makes it quite clear where it stands on this matter (Opinion 6.02):

"Payment by or to a physician solely for the referral of a patient is fee splitting and is unethical."
Arnold Relman, MD, editor emeritus of the New England Journal of Emergency Medicine, reminds us that :

"Medicine is a profession and should remain so. In the practice of medicine it is unprofessional and unethical to make money from services not directly provided or supervised."

New draconian regulations are being introduced in the US in an attempt to stamp out fee-splitting. The Federal Fee-Splitting/ Kickback Statute provides for severe penalties for those falling foul of this legislation. It states that "Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both."

Fertilising Eggs With Somatic Cells - A Revolutionary Process

Scientists in Australia have found a way to fertilise eggs using genetic material from any cell in the body - and not just sperm.

The technique could potentially help infertile couples to have children. It has been developed by Dr Orly Lacham-Kaplan, from Monash University in Melbourne. She said that her team had been able to successfully fertilise mice eggs in lab cultures using other cells in the body known as somatic cells. Until now this has not been possible because somatic cells contain two sets of chromosomes, while sperm cells only contain one set. The Monash team used chemical techniques to get rid of the spare set of chromosomes. To do this they mimicked the process that takes place during normal fertilisation when two sets of chromosomes in an egg are separated and one is ejected, leaving the remaining set to combine with the single set from the sperm. However, they will not know if the embryos were viable until they were transferred to foster mothers for further development.

"We will then have to wait to see if any live and healthy babies are born following those transfers. Within the next six to eight months I believe we will have the answer, and see whether this technology can go further and be used maybe in clinical aspects", she said.
Fertility expert Professor Robert Winston commented: "The beauty of this technique is that it makes cloning completely unnecessary. This actually is a much better technique and ethically much more acceptable because you have chromosomes from two partners."

On the other hand, The Society for the Protection of the Unborn Child (SPUC) was outraged by the technique. A spokesman said: "The proliferation of novel ways to produce embryos is increasingly reducing the human being to a commodity in many people's eyes.

"We believe the interests of the child come before the wishes of anyone else, including the parents. We shall be calling for a moratorium on this kind of development."

International Ethical guidelines for Biomedical Research Involving Human Subjects

Extensive documentation relating to conducting medical research has been released by the Council for International Organizations of Medical Sciences (CIOMS). It revises and updates the guidelines published in 1993. Research workers and others interested in this aspect are encouraged to peruse this extensive document. It is available on the website at: www.cioms.ch

Pulications by The Bioethics Consultative Committee

Bioethics: Responsibilities and Norms for those involved in Health Care (Ed. T. Cortis, 1989)

Informed Consent: Proceedings of a Symposium for Medical and Paramedical Practitioners. (Ed. M.N. Cauchi), 1998. ISBN 99909-68-68-3

Proceedings of the Conference on Bioethics and Disability (Ed. M.N. Cauchi) 1999. ISBN: 99909-993-0-9.

Patients' Rights, Reproductive Technology, Transplantation. (Ed. M.N. Cauchi), 2000. ISBN: 999009-993-1-7

Interprofessional Ethics in Health Care. (Ed. M.N.Cauchi, 2001) ISBN: 99909-993-2-5

BEGINNING AND END OF LIFE ETHICS: CONFERENCE October 26/27 7.30 pm

Ethical issues surround us throughout life, but they are nowhere so evident as at the beginning and at the end.

Modern molecular genetics has opened up a Pandora's box - issues which are far from being settled. Techniques which are particularly relevant in diagnosis of genetic disorders have proliferated, making urgent the need for analysis of ethical issues that they raise.

At the other end of life we see an ever-increasing proportion of people reaching the age of three score and ten. Ethical issues become very significant in this age group as well.

These issues will be discussed at the Conference to be organised by the Bioethics Consultative Committee
Further Details will be available in the next Newsletter.

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