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BIOETHICS, MEDICAL TECHNOLOGIES AND THE HEALTH OF CANADIANS: SOME POLICY CONSIDERATIONS

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BIOETHIC, MEDICAL TECHNOLOGIES AND THE HEALTH OF CANADIANS: SOME POLICY CONSIDERATIONS

BACKGROUND

Canadians are confronted almost daily by media stories about technological interventions in medical science and their potential or actual effect on the health of human beings. Each story alerts the general public to some dilemma resulting from increased understanding of human biology and raises questions with respect to decisions on applying technology to people. "Human Trials of Gene Therapy Begin" opens a story about Canada's first trials to insert altered genetic material into human subjects in an attempt to battle two deadly forms of cancer. "A Gift of Life – and Death" headlines an article examining the ethical dilemmas surrounding the use of fetal tissue transplants to treat Parkinson's disease, Alzheimer's disease, diabetes and AIDS. A column entitled "Can Anencephalic Babies Be Used As Organ Donors?" asks whether an infant born without a brain but with other viable organs can be medically defined as dead.

In general, the application of technology to human beings has given society the ability to create life, to improve life, to sustain life and to prolong life. In Canada, as in many parts of the world, it is now accepted as routine that human infertility can be bypassed, genetic defects detected, organs transplanted, and individuals kept alive. These powers have inevitably led to questions about when and how and for whom life will be created, improved, sustained, and prolonged. Canadians are beginning to ask about the impact – short-term and long-term, negative and positive – of such practices for individuals, communities, and the broader society. In all of these areas, consideration of the human dimension of the decisions is vital.

Public discussions regarding the use and potential misuse of biological knowledge frequently seek to link the use of medical technologies with individual and societal values. Efforts to ascertain what social, cultural and legal values are common among the numerous groups comprising Canadian society are ongoing. It is recognized that there are various views of the significance of birth and death and of when it is appropriate to begin or to end treatment. As the following paper suggests, Canadians are beginning to assess the particulars of their cultural milieu, to identify the diverse concerns and to develop approaches that reflect a broad consensus.

The link between human values and medical applications dates back several thousand years. More recently, there have been systematic efforts to study human conduct in the area of life sciences and the ethical problems arising from biological research and its applications in areas of human health. In particular, the moral values and principles supporting or refuting the application of certain technological practices to human health care are increasingly being examined in public debates, in parliament and in the courts. This paper focuses on some Canadian approaches to related policy questions on practices affecting various stages of life, from genetic testing and organ transplantation to euthanasia and assisted suicide.

BIOETHICAL PRINCIPLES AND TECHNOLOGY

Discussions of the ethics of human biology used to be largely the preserve of physicians and academics. Now, ordinary members of the public are increasingly involved in assessing how bioethical principles affect decisions respecting technology use and people. While many continue to talk about microethics or "bedside ethics," where individual patients and families make decisions in conjunction with individual physicians, there is growing recognition that these decisions within Canada's health system are affected by the macro, or wider social ethic.(1)

Within Canada as elsewhere, these discussions are guided by certain principles. Many participants refer to the so-called "trinity" of principles: autonomy, beneficence and justice. Autonomy is seen as encompassing self-determination, personal liberty and freedom of choice. Justice is tied to the overall question of fairness, of equitable distribution of scarce resources. Beneficence seeks to ensure that any intervention is for the benefit of the patient and that a technological procedure is being done out of concern for the patient's welfare and not for experimental, economic or other reasons.

In 1993, the Canadian Royal Commission on New Reproductive Technologies (RCNRT) identified eight principles that it argued should guide public policy decisions that go beyond a doctor and patient relationship. The RCNRT list included individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability, balancing individual and collective

(1) Nuala Kenny, Chairperson, Values Working Committee, National Forum on Health, *Minutes of Proceedings and Evidence of the Standing Committee on Health*, Issue 23, 21 February 1995, p. 7.

interests.(2) While all the principles are relevant to both the individual and the broader society, the first four principles are situated more in the realm where individuals exert an influence on policy while the last four have broader societal implications for health policy.

Although these principles were developed in relation to reproductive technologies, they could apply to many other areas of intervention in health and medical care policy. For the RCNRT, individual autonomy means that people are free to choose how to lead their lives; equality means that every member of the community is entitled to equal concern and respect; respect for human life and dignity means that all forms of human life, including human tissue, should be treated with sensitivity; and protection of the vulnerable means that those less capable of looking after themselves or open to exploitation should be given special consideration.

With respect to the second four RCNRT principles: non-commercialization of reproduction means that it is wrong for decisions about human reproduction to be determined by a profit motive; appropriate use of resources recognizes the existence of diverse needs and finite resources and refers to the need to provide programs, procedures and technologies according to clearly defined public policy priorities; accountability means that those holding power have a responsibility to regulate and monitor technologies in a way that ensures respect for societal values, principles and priorities; and balancing individual and collective interests emphasizes that both these interests are worthy of protection, with one not automatically taking precedence over the other.

This list of RCNRT principles confirms that decision-making in areas affecting human biology requires careful and thorough deliberation by those who develop policy. Various organizations have been established in Canada, mostly in the last decade, to advance the understanding of ethical questions prompted by biological research as awareness of the issues has moved beyond the academic and professional sphere into the broader public.

The first bioethics centre in Canada, the Centre for Bioethics at the Clinical Research Institute of Montreal, was established in 1976. Since that time, other centres, such as the Westminster Institute for Ethics and Human Values associated with the University of Western Ontario and the Centre for Medicine, Ethics and Law at the University of McGill, have been founded. In 1987, the Medical Research Council developed guidelines for research involving human subjects. By 1988, the Canadian Bioethics Society, was created by a merger of

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(2) Royal Commission on New Reproductive Technologies (hereafter RCNRT), *Proceed with Care: Final Report,* Government Services Canada, Ottawa, 1993, p. 52-58.

two existing groups to promote research and teaching in the area. In the same year, the National Council on Bioethics in Human Research was created under the sponsorship of the Royal College on Physicians and Surgeons to interpret and promote all existing guidelines on the ethics of biomedical and health-related research involving human subjects.

BIOETHICAL ISSUES FOR ALL LIFE STAGES

As biological and social research has developed, a wide range of ethical questions has arisen, affecting all stages of human life. At the beginning of life there are issues of conception, use of embryo and fetal tissue, abortion, prenatal diagnosis, genetic counselling and screening, fetal therapy, and neonatal care. At the end of life are issues such as care of the dying, termination of treatment, and assisted suicide. In the middle stages of life, topics raised include organ transplantation, contract motherhood or surrogacy, genetic screening and access to various procedures.

Canadian writers have outlined more fully the areas during a person's life when bioethical considerations would need to be addressed.(3) At the beginning of life, concerns arise when people cannot conceive a child and reproductive technologies are available; when people fear giving birth to a malformed child and genetic counselling, prenatal diagnosis, and fetal therapy are available; when people do not want a child and abortion or adoption are available; when people are unable to look after children because they are intellectually disabled and sterilization is available.

At other stages, when human health and life are threatened, concerns arise when a new epidemic such as HIV/AIDS appears; when people are diagnosed as mentally ill and undergo psychiatric treatment; when patients are old, and caring becomes problematic; when the effects of new treatments are unclear; and when limited resources must be fairly allocated.

At the end of life, the use of life-prolonging treatment may be questionable and decisions to withhold or withdraw treatment may be necessary; people may ask for death through euthanasia; and, as in organ transplantation, the death of one person may mean life for another.

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(3) David Roy, John Williams, Bernard Dickens, *Bioethics in Canada*, Prentice Hall Canada, Scarborough, Ont., 1993.

In the sphere of public policy, many biomedical practices are currently the focus of attention. Some of these involve the use of technology to sustain or to change an individual's health status. Of these, some, like those involving genetics, are fairly new, while others have either become routine or have been discussed for many years. The following discussion explores some of the difficult questions surrounding euthanasia, particularly when medical technologies can be used to continue or to terminate life. In addition**,** it looks at the more routine practice of organ transplantation and the newer practices of prenatal genetic testing**.**

A. Towards the End of Life

1. Euthanasia

Many types of intervention may affect the end of life. In past generations, both children and adults usually died at home, often in the full knowledge that they were going to die. Now, they are more likely to die in hospitals or other institutions where drugs, medical devices, and procedures for prolonging life are readily available and where decisions about dying are often removed from their control. Decisions about when to extend, when to withhold and when to withdraw treatment to sustain or prolong life now involve the affected individuals, family members, health care professionals, and, increasingly, lawyers.

Euthanasia has become an important element of discussions about dying. While generally described as an act of mercy, as "the practice of putting to death persons who are suffering from incurable or malignant diseases," it has various dimensions depending on who carries out the action that causes death.(4) Others have categorized euthanasia as active or passive, voluntary or involuntary and as involving different decisions revolving around the principle of free and informed consent. Thus, in involuntary euthanasia someone is put to death without his or her consent, for example when life-sustaining treatment is withheld or withdrawn. Voluntary euthanasia takes place when a person requests that life-sustaining treatment or life be ended. Active euthanasia involves performing a deliberate death-inducing act, and passive euthanasia involves the cessation or withdrawal of life-prolonging treatment or nourishment.

For many, withholding or withdrawing treatment is not the same as euthanasia and assisted suicide. The Special Senate Committee on Euthanasia and Assisted Suicide advanced the following definitions. Assisted suicide is "the act of killing oneself intentionally with the assistance

(4) Margaret Smith and Sandra Harder, *Euthanasia and Cessation of Treatment*, CIR 91-9E, Research Branch, Library of Parliament, Ottawa.

of another who provides the means, the knowledge, or both."[5] Euthanasia is defined as "the deliberate act undertaken by one person with the intention of ending the life of another person in order to relieve that person's suffering where that act is the cause of death."[6] Euthanasia was seen as being voluntary when done in accordance with the wishes of a competent person, non-voluntary when the person's wishes have not been made known, and involuntary when done against the wishes of a competent person.

The populations generating the focus on euthanasia are varied. They include critically injured patients who, because of emergency response services, have survived traumas that would otherwise have killed them but have been left with permanent brain damage or paralysis. They include people suffering from chronic or incurable diseases such as Alzheimer's Disease, AIDS, or cancer, adult individuals with congenital defects that are no longer tolerable to them, and afflicted infants and children whose parents recognize the real and potential difficulties in their lives.

Four factors at the base of current policy are seen as contributing to support for euthanasia. These include the tendency of the medical community to accept a simple biological paradigm in dealing with death; the emphasis on health promotion over care of the sick individual; the increased focus on efficiency and cost containment; and the failure of medicine to help survivors of debilitating illness and their families. According to one physician, these factors allow euthanasia to be seen as simple, painless to the patient, economically efficient, liberating of society's resources for health promotion, and a way of providing an escape hatch for individuals saved by medicine and subsequently entrapped in unbearable lives.[7]

For policymakers as for the general public, euthanasia in any form poses many questions pertinent to the rights of individual patients. The need to serve the public interest by providing a high standard of care to the community may simultaneously conflict with the need to protect individual patients and their right to control their own treatment. Health care professionals and family members can easily find themselves promoting a situation considered undesirable by the affected individual.

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(5) Senate of Canada, *Of Life and Death: Report of the Special Senate Committee on Euthanasia and Assisted Suicide*, Ottawa, June 1995, p. 51.

(6) *Ibid.*, p. 75.

(7) James Gordon, "Describing the Slippery Slope," Presentation to the Senate Committee on Euthanasia and Assisted Suicide, 1994.

Certain rights to refuse life-prolonging medical treatment have become established in Canadian law, reflecting a greater emphasis on dignity and quality of life than on the rigid insistence on sustaining life at all costs. The distinction has narrowed between the "extraordinary" life-prolonging measures such as cardiopulmonary resuscitation, respiratory support, chemotherapy, haemodialysis and the more "ordinary" provision of food and water. It is argued that "the real issue is whether any intervention, regardless of its being a measure of basic or advanced life support, is proportionate to the goals of each individual patient."(8)

The goals of the individual and the goals of the larger society may still be at odds, however. In a case where an individual demands rare and costly treatment to sustain life, a publicly funded health care system like Canada's would decide whether the demand exceeded the ability of the system to meet it. Questions may arise about whether a societal consensus must be upheld over certain individual rights. In the case of Sue Rodriguez, a woman suffering from amyotrophic lateral sclerosis (Lou Gehrig's disease) who challenged the prohibition against assisted suicide, the majority of judges at the Supreme Court of Canada argued that the prohibition reflected a consensus in Canadian society that respect for life must be supported over individual choice.(9) In the case of a newly born and very fragile infant in a neonatal intensive care unit, the question arises as to who has the right to decide a course of action or inaction; hospital administrators, physicians, nurses and parents may reach different conclusions over what is in "the baby's best interest."

2. Specific Responses to Euthanasia

Responses to this issue have come primarily from the medical and legal communities and, more recently, from parliamentarians. In addition to the 1993 Rodriguez case in the Supreme Court, other cases have been decided at the provincial level. Through the Canadian Medical Association, Canadian physicians in 1995 developed a policy position on physician-assisted death. In the 1990s, several Private Members' Bills were introduced in the House of Commons asking for amendments to the *Criminal Code* to allow assisted suicide and from February 1994 to June 1995, a Senate Committee studied euthanasia and assisted suicide.

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(8) Roy, Williams, Dickens (1993), p. 384-392.

(9) Smith and Harder.

For physicians, several questions arise. Does a patient, after being properly informed of a proposed treatment, have the right to accept it or reject it in order to die a dignified death? Should a doctor help a person who is incapacitated and in pain to die? For many observers, making death a treatment option for physicians changes the whole patient-doctor relationship. The Canadian Medical Association in 1993 provided guidance to its members in a series of papers that examined some of the ethical, legal and social concerns from a physician's perspective. In 1995, the CMA published a policy statement summarizing the position of its members on physician-assisted suicide. It urged them to adhere to the principles of palliative care and not to participate in euthanasia or assisted suicide.(10)

For the legal profession, one issue is the need to protect vulnerable groups while at the same time defending the right of individuals to make their own decisions. The Law Reform Commission of Canada in a 1983 report identified widespread consensus on three basic principles reflected in law: the protection of human life, the right to autonomy and self-determination in decisions about medical care, and the recognition that human life has both quantitative and qualitative aspects.(11) On the question of legalization of active euthanasia, the Commission identified a number of problems, including the possibility of incorrect diagnosis, the possible discovery of a cure, and the possibility of abuse. It also noted that procedures developed to allow people with terminal illness to end their lives could also be used to remove those considered to be a burden on society. A major concern was the difficulty in ensuring that a person's consent to euthanasia was free and voluntary. Similar views were expressed by the Canadian Bar Association in its submission to the 1995 Special Senate Committee on Euthanasia and Assisted Suicide.

When the Special Senate Committee on Euthanasia and Assisted Suicide studied this issue, it received testimony from a wide range of groups and individuals representing palliative care specialists, medical ethicists, health care professionals, social workers, lawyers, and affected individuals. It examined the issue from various perspectives looking at physical, psychological, and financial reasons for euthanasia; at methods such as withholding treatment, withdrawing treatment, and self-induced death; at the issue of competency and at advanced directives or "living wills." It urged all levels of government to make palliative care a priority. It argued that the practices of withholding and withdrawing life-sustaining treatment should be

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(10) "CMA Policy Summary: Physician-Assisted Death," *Canadian Medical Association Journal,* 15 January 1995, 152(2), p. 248A-248B.

(11) Law Reform Commission of Canada, *Euthanasia, Aiding Suicide and Cessation of Treatment,* Report 20, Ottawa, 1983.

clarified in law. On assisted suicide, the majority of the Committee favoured retaining the provision of the *Criminal Code* that proscribed aiding and abetting suicide. It recommended that voluntary euthanasia and non-voluntary euthanasia remain as criminal offences but with imposition of a less severe penalty where mercy or compassion was an element. Involuntary euthanasia was to continue to be treated as murder under the *Criminal Code*.(12)

In Canada, euthanasia has been addressed in legislative prohibitions, in various court cases and in policy statements by professionals. Such considerations as informed consent to medical treatment, the right to refuse medical treatment and the right to privacy are part of broader public discussions. The question of whether the courts are the best arena to deal with general standards relating to "best interests" is still subject to debate. Some have argued that even when euthanasia is prohibited as a criminal offence, it could be practised if certain guidelines developed through court decisions were followed. It is suggested that legislation on the reporting procedure for euthanasia could guarantee immunity from prosecution to physicians following specified procedures.(13)

Canadians pondering the relationship between the value of life and the reality of death must take into account the influence of our current publicly financed system of health care on end-of-life decisions. On the question of withholding or withdrawing life support, differences between attitudes in Canada and the United States have been subject to scrutiny. It has been suggested that in Canada, where resources are allocated on the basis of medical need and potential benefit, physicians have a stronger say in the final decision. Conversely, in the United States, where the Intensive Care Unit is a major source of income for hospitals, patients and families have the stronger voice in choosing extraordinary care and also in withdrawing life support if they desire.(14) As the rationing of health care services comes more to the fore in health policy discussions, the implications of decisions made towards the end of a person's life deserve full and informed consideration by the public.

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(12) Senate of Canada (1995).

(13) Smith and Harder.

(14) A. Whittaker, letter on withdrawing life support in Canada and the United States, *American Medical Association Journal*, 2 August, 1995, p. 5.

B. Continuing Life

1. Organ Transplantation

Organ transplantation is now carried out on a routine basis in all major medical centres in North America and Europe. In organ transplantation, tissues are removed from one human body and implanted in another, where the transplanted tissue is expected to perform its previous function. The most common organic materials donated or sold by people are the renewable ones of blood and sperm. In terms of non-renewable organs, the kidney, being bilateral, was the first to be transplanted from a living subject. Preservation techniques have now made it possible to establish banks for bone marrow, eyes, and embryos.

As the demand for donated organs grows, so does the expense of the medical procedures involved. In the United States, it is estimated that a transplant procedure can cost $200,000 or more and the continued use of anti-rejection drugs following the procedure add even more costs. This has led to major international debate concerning "the justice of major publicly supported investment in transplants while a more significant public health result would be yielded by investing in disease prevention, health promotion, and supplying basic care for large populations."(15) Thus, ways to reduce the demand for organ transplantation through health promotion and disease prevention becomes important to any policy examination of scientific and medical developments in this area.

Different concerns arise when donations are generated by the death of a person, by removal of healthy organs from a living person, or by an aborted foetus. On the bioethical considerations surrounding organ transplantation, it is argued that "they concern every step of the process from donor recruitment to recipient selection and involve issues of justice (equitable treatment), beneficence (for whose good is the procedure carried out) and autonomy (the preservation of free choice for all concerned)."(16)

On autonomy rights, such as self-determination, personal liberty, and freedom of choice, it has been noted that the next of kin must make decisions for the recently dead adult donor, and the recently pregnant woman must make decisions for the aborted fetus; such decisions must be made free of undue persuasion or coercion. Organs or tissues taken from any source raise the

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(15) Eugene Brody, *Biomedical Technology and Human Rights,* UNESCO and Dartmouth Publishing, Aldershot, England, 1993, p. 97.

(16) *Ibid.*, p. 99.

prospect of commercial gain and possible exploitation. Stories of Canadians who have paid cash for organs from individuals in less developed countries emerge from time to time and prompt questions about how such practices can be controlled. Even though buying human organs is outlawed in most countries, it continues as a lucrative underground practice. In British Columbia, the provincial Transplant Society, which coordinates organ transplants and distributes anti-rejection drugs, has argued that the province should force any person who bypasses the provincial system in order to obtain an organ to pay for the necessary anti-rejection drugs.(17) It argues that such sanctions are needed to give policymakers a role in controlling the collection and distribution of body parts.

Justice rights are viewed as tied to the overall question of equitable distribution of scarce resources. They include the right of equitable or just access to organs or tissues, whether adult or fetal, that is needed to sustain life. These rights also include equal freedom from coercion in obtaining necessary organs or tissues. Given the high costs associated with extending life through organ transplantation, access is often beyond the reach of individuals in many parts of the world. One question is whether age is in itself an acceptable reason for refusing organ transplantation to a patient. Another concern is whether people who have adopted a lifestyle that damages their organs should be allowed to be candidates for replacement organs. For policymakers, who are obliged to be both humanitarian and financially responsible, assuring unlimited provision of such medical care is fraught with pitfalls.

Beneficence rights seek to ensure that the procedure is for the sole benefit of the patient, in other words is motivated by concern for the patient's welfare and not by experimental, economic, public relations or other interests. In the case of organs or tissues obtained from living donors, the question of different needs for different patients is problematic. The conception of a child for the express purpose of providing potentially life-saving tissue for a child already living raises questions about which patient's welfare is to be the primary consideration. Use of fetal tissue has generated widespread public discussion about whether and how a decision for abortion can be separated from decisions about the use of the fetal tissue.

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(17) Holly Horwood, "Buyers of Organs May Get Drug Bill," *The Province* (Vancouver), 31 January 1995, p. A6.

2. Specific Responses to Organ Transplantation

Internationally and nationally, responses to the issue of organ transplantation have taken various shapes. In most studies, legislative solutions are seen as an essential component of protecting the rights of both donor and recipient. Legislative questions include whether individuals should be permitted to decide the disposition of their own organs after death and, in the absence of such a decision, whether the family can decide. Should donation of fetal tissue or organs be allowed? Should the sale, purchase or brokerage of certain adult organs and of fetal tissue be prohibited? Should legislation or codes of conduct be developed to address the issue of transplantation of cadaveric organs and tissues? Should every country have comprehensive regulations to cover such issues as delays in organ retrieval, donations from minors, commercialization, and compensation of donors for related costs?

The development of guidelines has also been explored. At the international level, in 1987 the World Health Organization recognized the need to develop guidelines on organ transplantation and called for a study of the associated legal and ethical issues. The concern was to ensure the rights of both donor and recipient. The Guiding Principles endorsed in 1991 prohibit giving and receiving money, except for payment of expenses incurred in organ recovery, preservation and supply. The Principles prohibit removal of organs from the body of a living minor except for regenerative tissues. They emphasize the need for freedom from coercion and for informed consent. Reproductive tissues (ova, spermatozoa, ovaries, and testicles), embryos, blood and blood constituents are not covered by the guidelines.(18)

In Canada, organ transplantation is fully funded by provincial health insurance plans. In June 1995, controversy erupted in Alberta when it was learned that Alberta Health had paid about $500,000 for a baby to have a heart transplant in the United States although a pediatric transplant service existed in Edmonton. Most provinces have policies that out-of-country funding for such procedures will be covered only if the service does not exist within the province. In the Alberta case, procurement of organs was problematic as it has been in other provinces. In 1989, the *Uniform Human Tissue Donation Act* was developed by the Conference of Commissioners on Uniformity of Legislation in Canada. The provinces have equivalent Acts to regulate procurement and use. In 1992, the Law Reform Commission of Canada issued a working paper on the

(18) Brody (1993), p. 115.

procurement and transfer of human tissues and organs.(19) The focus was on questions about legal reforms that might alleviate perceived tissue scarcity and on whether selling body parts or substances was an acceptable means of increasing the supply. At the data collection level, the Canadian Organ Replacement Register, a joint project of the federal and provincial governments, provides statistics that allow comparisons among provinces and facilitate decision-making in health care.(20)

One barrier to increasing the supply of donated organs is the difficulty of obtaining consent. "Presumed consent," the idea that, unless donation has expressly been refused, organs are considered to be available, has been suggested as a possible method of increasing the supply of organs. It has been noted that countries such as Belgium, France, Austria, which have presumed consent laws, transplant more organs per million people than do Germany, the Netherlands, and the United Kingdom, countries seen as culturally, socially and economically similar, but that lack presumed consent laws.(21) To consider organ donation as a routine procedure was seen as possibly reducing autonomy and altruism but as alleviating the current burden of decision borne by relatives and physicians.

Recently, Organ Sharing Canada, a body set up by the Canadian Transplant Society and the Canadian Association of Transplantation, called for a national agency to coordinate the distribution of donated organs.(22) This could ensure uniform standards for donor screening, standard guidelines for listing transplant patients, and equal access to available transplants on a national, rather than the current provincial, basis. In response, the provincial deputy ministers of health have asked their advisory committee on health services to review the situation in relation to organ transplants.

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(19) Law Reform Commission, *Procurement and Transfer of Human Tissues and Organs*, Working Paper #66, Ottawa, 1992.

(20) Pauline Copleston *et al*., "The Canadian Organ Replacement Register," *Health Reports,* 6(4), March, 1995, p. 457-68.

(21) Aaron Spital, "The Shortage of Organs for Transplantation, Where Do We Go from Here?," *New England Journal of Medicine*, 325(17), 24 October 1991, p. 1245.

(22) Clare Mellor, "National System Urged to Coordinate Organ Transplants," *Chronicle Herald* (Halifax*),* 1 November 1995, p. 4.

C. Beginning Life

1. Prenatal Genetic Testing

Genetic research and its applications have evolved rapidly over the last few decades. The human genome project is one endeavour that demonstrates the nature of movement in the area. It is a major international attempt to determine the structure and the location of an estimated 100,000 human genes. In 1992, Canada joined the project, which already involved the United States, Japan, France, Britain, Germany, Denmark and Italy. The goal of research teams around the world is to collect information on DNA in human cells with the hope that it will provide an understanding and eventual cure of many genetic diseases. When the information is collected, policy makers must understand how and when any applications of the information will be used and who will be involved.

For the Canadian public, there is a concern that the complexity of the area, combined with limited interaction between researchers and practitioners, will restrict any efforts to have public input into articulating and acting on the ethical concerns. In consultations, individuals and groups "expressed fears about what the rapidly increasing capacity to detect genetic make-up would mean for their work opportunities, how they live, and particularly, the health care they receive and their options with respect to reproduction."[23] The use of genetic knowledge and technology in relation to human reproduction is a major area of concern, particularly with respect to prenatal diagnosis of disorders that are present at birth or begin in childhood and presymptomatic or predictive testing for genes that may affect a person's health later in life.

In Canada, prenatal diagnostic services are provincially funded. In 1990, more than 22,000 women were referred for prenatal diagnostic tests at the 22 genetic centres. About 78% of the referrals were made because the woman was over 35 years of age, a factor associated with increased risk of chromosomal disorder.[24] While the exact cost of these procedures is not known, they do involve expensive highly specialized equipment and personnel. One of the pieces of information provided through the testing is the sex of the developing fetus.

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(23) RCNRT (1993), Vol. 2., p. 733-734.

(24) *Ibid.*, p. 757.

In considering, prenatal diagnosis for congenital anomalies and genetic disease, two terms require clarification. Congenital anomalies are those evident at birth, or now, with the use of imaging and diagnostic techniques, that are evident *in utero* and are linked to chromosome or genetic defects resulting from external environmental influences passed on through the father or mother at conception or while *in utero*. Genetic disease, on the other hand, is present at conception and is inherited from one or both parents as a result of derangement of the hereditary material of chromosomes and their genes.(25)

The diagnostic tests or techniques developed to determine whether the fetus has a congenital anomaly or genetic disease include amniocentesis, chorionic villus sampling (CVS) and specialized ultrasound. Amniocentesis, the most common procedure , is normally carried out between 15 and 17 weeks of pregnancy, when fluid containing fetal cells is removed from the uterus and analyzed for chromosomal disorders, genetic metabolic disorders or neural tube defects. In chorionic villus sampling, a sample of the fronds extending from the fetal membranes into the uterine wall are extracted and analysed. Specialized ultrasound involves a detailed examination of the fetus lasting up to an hour and can diagnose many congenital anomalies. Before these procedures were introduced into obstetrical use in the 1970s and 1980s, accurate diagnosis of congenital anomaly or genetic disorders was not possible. Now, new PND technologies, including methods that involve diagnosis at the preimplantation stage and diagnosis using fetal cells found in the blood of the pregnant woman, are rapidly being developed.

For prenatal diagnosis for late-onset single gene disorders and for susceptibility genes there are two different types of testing. Late onset single gene disorders, which may be recessively or dominantly inherited, include Huntington Disease, a disorder resulting in progressive mental and physical deterioration; adult polycystic kidney disease, leading to a progressive reduction in kidney function; and retinitis pigmentosis leading to progressive loss of vision. Susceptibility genes are those whose presence suggests that an individual may be more susceptible than others in the general population to a certain disease such as cancer, cardiovascular disease and mental illness. The Royal Commission on New Reproductive Technologies noted in 1993 that "no such prenatal testing for susceptibility genes is being done in Canada at present, but there is a limited amount of adult testing of members of families with a history of a disorder."(26)

New developments in DNA technology have made it possible to determine whether a fetus carries a particular gene responsible for genetic disorders. This presymptomatic testing can

(25) *Ibid.*, p. 746.

reveal whether a person is destined or is highly susceptible to a disease many years before symptoms appear or a clinical diagnosis is made. Thus, people who inherit the defective gene for Huntington's disease, a condition that shows up between 30 and 45 years of age, females with a predisposition for breast cancer, and African-American sickle-cell carriers can all be identified early in life.

Prenatal diagnosis will not provide all the answers about the present condition or the future health of a developing fetus but as a technology it has a powerful influence on people's decisions. Some authors have argued that this early knowledge and identification can lead to a greater emphasis on preventive measures and interventions. Thus, people with a genetic susceptibility to coronary heart disease could alter their diets, increase their physical activity and have their cholesterol levels checked regularly. The question of what form the prevention will take becomes very important, however. Cancer provides one important example. Prevention for females with a breast cancer gene might mean removal of all breast tissue in early life before any cancer manifests itself; if links are made between the cancer and exposure to certain chemicals present in workplaces around the world, prevention might mean exclusion from employment. These different possibilities for prevention reveal that presymptomatic testing might be applied in potentially negative as well as positive ways. The potential for genetic discrimination through breaches of individual privacy and confidentiality is also a concern.

2. Specific Responses to Prenatal Genetic Testing

Canadian efforts to assess the safety and effectiveness of new prenatal diagnostic technologies used in genetic centres took place at an early stage. In 1974, a joint effort on the part of the Genetics Society of Canada, the Canadian Paediatric Society and the Society for Obstetricians and Gynaecologists of Canada resulted in the first national guidelines for the delivery of prenatal diagnostic services. In 1976, the Medical Research Council supported a collaborative multicentre trial of amniocentesis that demonstrated its safety and effectiveness and contributed to the establishment of international standards for the procedure. Continued efforts to collaborate on clinical trials have been successful.

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(26) *Ibid.*, p. 871.

However, this type of effort on the part of professional organisations was not enough to satisfy the Royal Commission on New Reproductive Technologies, which raised many questions in its Final Report and in the accompanying research documents. It concluded that the federal government as the guardian of the national public interest must put boundaries around the use of new reproductive technologies. It recommended the establishment of a regulatory and licensing body – a National Reproductive Technologies Commission – composed of 12 individuals from a broad range of backgrounds. Under this system, prenatal diagnosis services would be provided only by licensed facilities with national standards established and monitored through the licensing system. Thus, Canadians would be assured that genetic knowledge applied to human reproduction would be applied in an accountable way and within acceptable limits.

In June 1995, the federal Health Minister took a tentative step when she called for a voluntary moratorium on nine reproductive and genetic technologies and practices, including several that relate to prenatal diagnosis.(27) She argued that it was ethically wrong to carry out procedures for non-medical purposes, such as performing chorionic villus sampling, embryonic biopsy, amniocentesis or ultrasound after conception in order to determine the sex of the fetus, which might then be aborted if the sex was not satisfactory. Similarly, she opposed the performance of germ-line genetic alteration of a fetus diagnosed as having a severe single-gene disorder or in an attempt to alter or enhance particular desired qualities, such as intelligence. According to the Health Minister, using genetic technologies in this way does not reflect Canadian values; threatens human dignity; represents serious health risks; and treats women and children as commodities. She proposed an interim moratorium until a permanent management regime could be implemented.

CONCLUSION

Biomedical research and its technological applications have the potential to change the face of society, to affect not just health but also access to a high quality of life. This is particularly the case if the research and applications provide knowledge that sets certain individuals off as being different from others and provokes measures that may exclude them from receipt of certain services. For legislators and policymakers concerned about the way scientific and medical

(27) Health Canada, "Health Minister Calls for Moratorium on Applying Nine Reproductive Technologies and Practices in Humans," 27 July 1995.

discoveries are applied to human biology in the name of better health, many dimensions must be taken into account when developing relevant administrative and legislative initiatives.

Full articulation of bioethical principles, including an understanding of autonomy and justice, freedom from discrimination and from harm, and the balancing of individual and collective interests, is an important first step. But it is only a beginning. Initiatives that allow for extensive public debate on the relevant medical, social, economic, and legal implications of biological developments must be encouraged and supported. Many participants focusing on separate areas have recommended a national approach and in particular a national agency that would coordinate and monitor developments in the application of medical technology to human beings. Whether a single agency would be capable of covering the numerous concerns raised by the use of scientific and technological interventions is not yet clear.

In a country like Canada, where both the development and the application of biotechnologies are tied to a publicly funded health care system, several questions arise. How do we decide which technological practices to support? Can we distinguish between practices that are truly preventative and aimed at overall personal well-being and those that are curative and aimed at repairing something that has gone wrong. How do we ensure that people of every socio-economic status and ethnic origin have access to valuable medical practices? What potential battles may develop between individual and collective rights? Canadians will grapple with these questions as they apply their collective wisdom to deciding on the role they want technology to play in their health and their lives.