



Animal-to-Human Transplants

**A policy statement
with background paper
adopted at the April 2002
General Council Executive Meeting
of the United Church of Canada**

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Background Paper

The Division of Mission in Canada Church-in-Society Co-ordinating Group has been addressing issues of biotechnology and genetic engineering for the past several years. In 1999, the Division commissioned the Taskforce on the Churches and Corporate Responsibility to prepare a study resource as an overview and introduction to the ethical dimensions of biotechnology. The following year the DMC published that study along with reflections by four Christian ethicists in the booklet *Biotechnology and Genetic Engineering: Current Issues, Ethics and Theological Reflections*.

The Division has begun a process to develop a policy statement on biotechnology related to agriculture. A small consultation of United Church people from across the church (including farmers, ethicists, clergy) was gathered by the Division in June 2001 to begin a drafting process. By the fall, a preliminary draft of this policy had been compiled. An educational resource is currently being developed to stimulate study on the issue and a more formal consultation process will take place during the fall of 2002. It is hoped that a policy proposal will be presented to the 2003 General Council.

Another biotechnology issue has arisen, however, which seems to call for a faster articulation of United Church policy – i.e. animal-to-human organ transplants or “xenotransplantation.” A petition on this theme entitled “A Study to Promote Informed Public Consultation on the Use of Animal Organs” was submitted at the last General Council and referred to the Division of Mission in Canada for consideration during the biotechnology policy development process. When the June 2001 biotechnology consultation participants examined this in more detail, they rapidly came to a general consensus that the United Church of Canada should draft a policy on xenotransplantation given the dangers it poses; several members then undertook to prepare an initial draft that was reviewed by the full group as well as an expanded circle of United Church ethicists and theologians over the summer and early fall of 2001. This draft policy was approved by the Division of Mission in Canada and sent to the fall meeting of the General Council Executive.

The fall 2001 General Council Executive considered the first policy draft but felt it needed more work before it could be approved. In January of 2002, the Canadian Public Health Association issued the report of its national public consultation on xenotransplantation recommending that human trials should not proceed at this time.

Following additional consultation and work by a biotechnology advisory committee, a revised, more concise version of the background paper and modified policy resolutions on Animal-to-Human Transplants were submitted to the April 2002 meeting of the General Council Executive. The policy statement was approved at that meeting following some final revisions.

Organ Transplants in Canada

More than 3500 Canadians are now waiting for vital transplants of tissues and organs. Up to 30% of these may die waiting for a suitable transplant to become available. Even those who eventually receive an organ often experience months or years of suffering and disability while they wait for a suitable transplant. Meanwhile, the need for organ transplants continues to rise and is expected to increase by 200% by 2020 (due in part to an aging population). Worldwide there are 180,000 people waiting for an organ transplant, but only one third will receive one.

The United Church of Canada feels a deep pastoral concern for those waiting for these vital organ and tissue transplants. We believe that our society has an ethical obligation to do what it can to ensure that essential transplant procedures take place in a timely fashion. At the same time, we

believe that we must seek a solution to the shortage of transplants that ensures a high quality of life for transplant recipients, that affirms our respect for the integrity of other species, and that exercises careful stewardship by using our healthcare resources wisely and responsibly.

Xenotransplantation

One of the solutions that modern biotechnology proposes to this problem is the use of animal-to-human transplants, or *xenotransplantation*¹. Until recently, this approach seemed to present nearly insurmountable hurdles – any organ or tissue transplanted from another species was quickly rejected by the recipient, causing rapid death². Even powerful immunosuppressive drugs were insufficient to prevent organ rejection.

Recently, however, genetic engineering techniques have enabled scientists to alter the DNA in an animal's tissue sufficiently to make xenotransplantation more feasible. Human DNA is inserted into a specially developed transgenic animal – usually a pig – (and other native genes are eliminated from the animal's genome) to produce a source of organs and tissues that can be more easily accepted by the human body. While still experimental and fraught with difficulties, it seems likely that xenotransplantation will become increasingly viable in the upcoming years. Indeed, formal clinical trials of xenotransplants could begin in the near future.

Already, research and development of xenotransplantation is proceeding rapidly. Several hundred xenotransplants involving transgenic animal cells have taken place globally over the past decade. Transgenic pigs containing human DNA are already being raised. Pig organs have been transplanted into baboons – albeit with limited survival times. As well, in 1997 genetically modified pig livers were used to temporarily cleanse the blood of several patients waiting for liver transplants. (The livers, however, were never actually transplanted into the patients' bodies.)

Concerns

In theory, transgenic animals could eventually produce a virtually unlimited supply of organs and tissues for human transplant. At the same time, though, xenotransplantation raises very real concerns.

1. Theological concerns

A key theological principle in reflecting on xenotransplantation must be that of living with respect in Creation. In reflecting on xenotransplantation, the opening lines of the creed seem especially poignant: “We live in *God's* world.” The world ultimately belongs to God, not to humanity. We are part of creation and thus are called to live with respect for the other beings that inhabit our world – and for the complex and mysterious dynamics of the Earth and its ecosystems.

What does living with respect in creation mean when applied to the question of animal-to-human organ transplants? Certainly our interdependence on other forms of life means we may – and indeed must – make use of other living things in order that we ourselves may live. Yet, the principle of respect places limits on this privilege: We are allowed to take what we truly need to support life with dignity, but we must not abuse or misuse other creatures.

¹ From the Greek “xeno” meaning “stranger.”

² It should be noted that, while pig heart valves have long been used to replace human heart valves, and while pigskin has been used for skin grafts, neither of these constitute xenotransplants. Heart valves use dead, sterile tissue that does not cause rejection concerns. Skin grafts are temporary in nature and do not have a direct blood supply, and this present minimal risks. Neither makes use of genetically engineered animals.

Similarly, living with respect for the weak and the suffering in the case of xenotransplantation means respect for the quality of life for patients requiring transplants. It also means advocating for their plea for vital human organs and tissues transplants.

Respect for creation also urges us to exercise caution when the common good of all creatures is threatened. Xenotransplantation clearly transgresses the boundaries of species integrity that have evolved over the course of Earth's history, creating "in-between" species that are neither fully animal nor fully human. We must admit with humility that this could have dangerous, even catastrophic effects, as the risk of diseases crossing the species barrier illustrates (see point #2 below).

A further theological principle to have in mind in considering xenotransplantation must be our confident trust that ours is a God of life who triumphs over death. While our faith in Jesus the healer calls us to look for ways to respond to the need for vital organ and tissue transplants, we also know that we cannot seek to evade death at all costs – especially if this means endangering the health of society as a whole or incurring high expenditures that threaten our public healthcare system. Instead of fearing death, let us remember (again in the words of the New Creed) that, "In life, in death, in life beyond death, God is with us."

2. Safety concerns

One of the key concerns about xenotransplantation is the very real possibility of diseases crossing the species barrier, possibly causing new epidemics. Despite the rigorously qualified pathogen-free breeding condition for genetically engineered pigs, it is currently impossible to remove porcine endogenous retrovirus (PERV) contamination from pigs because PERVs are incorporated into the pig's genome³. The dangers of retroviruses – such as HIV and Simian Foamy Virus (SFV) – as well as prion diseases like Creutzfeld-Jacob-Disease (CJD, the human form of BSD or "mad cow disease), and others simply cannot be overstated. These are capable of "jumping" natural species barriers via animal tissues, permanently infecting the genome of their new hosts. Infected humans can then infect other humans "horizontally" (via blood transfusions, sexual contact, etc.) as in AIDS or transfer their infection "vertically" to their offspring. This risk is further multiplied by the fact the xenotransplant recipients will take immunosuppressive drugs for life – leaving them with virtually no defence against any new diseases that might be transmitted.

3. Concern for the recipient's health and welfare

There are also high risks for the human recipient of a xenotransplant. The patient would require pre-treatment with high doses of immunosuppressive (anti-rejection) drugs, at least one expensive and life-threatening surgical procedure, and post-surgical immunosuppression for life. As soon as the xenotransplant would show lost function – possibly after mere days or weeks – another xenotransplant would be "harvested" and this cycle would be repeated (in which case the rejection of the new organ would probably be more rapid and severe) – unless a suitable human organ was found. The recipient could also be subject to unforeseen complications such as infections, severe rejection reactions, organ failure, psychological stress and trauma, and probable early death⁴. Given

³ Some estimate that hundreds of endogenous retroviruses may be present in a given animal. Most of these are not dangerous to their "native" host species – but they are potentially lethal when they cross to another species. Studies sponsored by biotech giant Novartis have shown that 30 patients who had their blood "filtered" through pig spleens later tested positive for pig PERV DNA. (This problem is not unique to pigs – the example of pigs is used here because they are the most probable source of xenotransplants.)

⁴ Because successive organ transplants introduce new foreign genetic material with each new transplant, it is currently rare for human kidney transplants to be practicable more than two or three times. Thus, it is quite doubtful

all these concerns, some doctors and medical ethicists believe that xenotransplantation may well be contrary to the non-maleficence principle (i.e. “do no harm”).

There are also serious concerns regarding the physiological suitability of organs from another species for humans. For example, a heart from an animal living on four legs is in many respects unsuited for the circulatory system of upright-positioned humans. Similarly, pig kidneys lack the ability to regulate drug levels in the blood and cannot tolerate the high levels of uric acid found in the human bloodstream.

4. Concern about costs and sustainability

With limited financial resources and increased pressures on the existing health care system, both health and research communities must ask themselves how they can most efficiently use available funding to assist the needs of society. At all times, the priority must be to benefit transplant recipients without overburdening society with new costs. The disproportional support of a high-risk procedure like xenotransplantation with huge inherent biomedical risks could place a considerable burden on the healthcare system, and might divert resources from safer and more viable alternatives. We must exercise particular caution because – even though xenotransplantation is likely to produce relatively few benefits for patients – it does have a great potential to benefit investors, biotechnology corporations, and privately-funded researchers.

Alternatives

While xenotransplantation raises very serious concerns, it is by no means the only means available to address the critical shortage of human organs and tissues available for transplant. Indeed, there are many safer, less expensive, and more effective strategies for addressing this problem:

1. Increasing the supply of human organs for transplant

Canada’s organ donor rate is one of the lowest in the industrialised world at approximately 14.4 donors per million and this rate has not increased significantly for some time⁵. This compares very unfavourably with Spain, for example, that has increased its organ donation rate to 31 donors per million. In the United States, too, the rate of donation is significantly higher than in Canada at over 21 per million.

Many experts estimate that Canada could increase the rate of organ donations by as much as 80%⁶-effectively eliminating the organ shortage, at least in the shorter term. Ways to accomplish this include publicity and education campaigns, making donor cards more generally accessible, and creating specially-trained teams of health professionals to counsel families of accident victims who are potential donors (the approach that proved so successful in Spain). As well, changes to organ donation legislation could facilitate organ donations.

There are also ways to considerably increase the “pool” of potential transplant donors. Some options include improving the system for collecting and distributing organs, improving the success rate of human-to-human transplants through increased research in this area (currently, 50% of

whether successive xenotransplants could ever work – especially given that the genetic material involved is even less acceptable to the recipient.

⁵ In 1997, the Atlantic provinces had the highest organ donor rate with 19.5 donors per million population, while Saskatchewan had the lowest rate at 11.7 donors per million population.

⁶ Less than 1% of deaths are likely to result in good transplant donors, at least given current practices and technology. Still, donor rates could theoretically reach much higher levels than the current rate of 14.4 per million.

transplanted organs fail or are rejected within five years of transplant), using both living and non-beating heart donors for kidney and liver transplants, and changing the age criterion for organ donors.

2. Disease prevention

In the longer term, preventative strategies like improving diet, promoting exercise, reducing the consumption of alcohol and tobacco, and similar measures could significantly reduce the need for organ transplants.

3. Other avenues of scientific research

Artificial organs may in time become viable as a way of maintaining patients alive while they wait for a suitable human transplant. As well, human stem cell research may – in the longer term – make it possible to use a patient’s own stem cells to grow replacement organs and tissues that would be a perfect genetic match for the recipient⁷. These approaches, however, may prove to be very costly.

In sum, then, there seem to be many safer, more effective, and more economical options for addressing the shortage of transplantable organs. Indeed, a recently-concluded national consultation by the Canadian Public Health Association concluded that “Canada should not proceed with clinical trials involving the transplantation of live animal organs, tissue or cells into human patients” at this time.

As a church seeking the common good and endeavouring to live with respect for all creation, we therefore believe that the wisest and most ethical course is to refrain from pursuing xenotransplantation as a way to address the shortage of organs and tissues for transplants. Instead, public resources should be used to increase the supply of human organs available for transplant, work to prevent diseases that make transplants necessary, and to fund research of more promising future alternatives.

⁷ While some concerns have been raised about the ethics of using human embryos in stem cell research, it should be noted that embryos are not the only source of stem cells. Stem cells are found in placental tissue that is readily available. As well, the stem cells found in the bone marrow and skin of all humans may well prove to be appropriate for tissue and organ replacements. See <http://www.wired.com/news/technology/0,1282,42761,00.html> for more details.

Animal-to-Human Transplants Policy
The United Church of Canada
Approved at the General Council Executive of April 2002

1. Prohibition on Animal-to-Human Transplants and Clinical Trials

WHEREAS animal-to-human organ and tissue transplantation poses significant risks both to transplant patients and to society at large - including the possibility of new diseases crossing the species barrier and causing future epidemics, and,

WHEREAS the quality of life for animal-to-human organ transplant recipients is likely to be much lower than those receiving transplants from human donors, and

WHEREAS the cost of xenotransplants will be very costly, putting additional strains on our public health care system,

THEREFORE BE IT RESOLVED that the Executive of the General Council of The United Church of Canada:

Support a complete and immediate prohibition on animal-to-human organ and tissue transplantation, including any proposals to begin human clinical trials. It is to be noted that such procedures as heart valves and temporary skin grafts do not have their own blood supply and do not raise issues of rejection by the recipient, and therefore, are in a different category in terms of risk, and are not subject to this prohibition.

2. Supporting Alternatives to Animal-to-Human Transplants

WHEREAS viable alternatives exist to xenotransplantation - both in the immediate and long-term - that could more effectively address the shortage of organs and tissues for transplant with significantly fewer risks and costs;

THEREFORE BE IT RESOLVED that the Executive of the General Council, through the appropriate units and courts of the United Church:

- a) Advocate for a more effective donor registry or card program, ensuring that donor consent is indicated directly on health cards;
- b) Actively solicit participation in the organ donor registry or card program at a congregational level;
- c) Advocate for a national publicity/educational campaign in support of organ donation, living wills, and instruction to proxy or substitute decision makers, as well as for education in schools on organ donation;
- d) Advocate for preventative health measures, aimed at reducing the need for organ and tissue transplants;

- e) Advocate for programs designed to train teams of health professionals to counsel the families of potential organ donors;
- f) Encourage the study of changes to the current legislative framework for organ donations that might further facilitate organ and tissue donations.

3. Research

WHEREAS animal-to-human organ and tissue transplantation poses significant risks both to transplant patients and to society at large - including the possibility of new diseases crossing the species barrier and causing future epidemics, and,

WHEREAS the quality of life for animal-to-human organ transplant recipients is likely to be much lower than those receiving transplants from human donors, and

WHEREAS the cost of xenotransplantation research is very high, uses valuable scientific resources, and could in itself introduce unacceptable risks related to cross-species disease transmission, and

WHEREAS viable alternatives exist - both in the immediate and long-term - that could more effectively address the shortage of organs and tissues for transplant with significantly fewer risks and costs,

THEREFORE BE IT RESOLVED that the Executive of the General Council:

- a) Call for increased funding for medical research into alternative ways of addressing the organ transplant shortage, particularly research seeking ways to expand the potential pool of human organs available for transplant.
- b) Call for the suspension of both government and corporate funding - direct and indirect - for xenotransplantation research.