Survey on human organ donation and xenotransplantation

Introduction

The transfer of viable animal cells, tissues, or organs into humans, known as xenotransplantation, offers the possibility of overcoming the severe shortage of human organs available for transplantation. Xenotransplantation may also be useful in treating patients whose organs are not functioning properly. Some examples include the use of pancreatic cells from a pig to treat patients with diabetes or the transplant of a kidney from a pig into a human. However, the potential benefits of this medical technology do not come without risks, both to the transplant recipient and the general public. Xenotransplantation also raises fundamental ethical issues.

Xenotransplantation currently is not a recognized medical practice in Canada or in other industrialized countries. However, some countries have allowed limited and controlled clinical trials, in which medical scientists are trying out some promising procedures on informed patient volunteers. Health Canada recognizes that the people of Canada should contribute to the development of policy before xenotransplantation is attempted in this country.

An important requirement in any public consultation, particularly when dealing with scientific issues, is the ability of participants to carry out an informed discussion. To facilitate the discussion, governments often provide information to the public so that they may become familiar with the issues. In order to gauge the level of public interest in a discussion on xenotransplantation, and to help determine the type of information that may be required for public consultations, Health Canada designed questions on the subject and included them in a public survey.

Survey Method and Results

The questions were administered for Health Canada’s Therapeutic Products Programme (TPP) as part of a survey of 2,526 Canadians 15 years of age and older conducted in March 1999 by the Berger Monitor. The questions were designed by TPP in consultation with Earl Berger, Managing Director of The Berger Monitor, formerly known as the Canada Health Monitor. Health Canada has used this public survey of health issues on a semi-annual basis for the last 11 years to collect information in support of policy development.1 NOTE: DESCRIPTION OF METHODOLOGY PROVIDED AS NOTE AT END OF PAPER.

There were a total of seven questions - two on human organ donation and five on xenotransplantation. The questions and national results are shown in Table 1. The national results are also presented graphically in Figures 1 and 2. The survey categorized respondents by province, age group, income, employment, education, and ethnic or religious background, but results for each of these categories are not presented here.

The survey found that 52% of respondents said they have indicated they are willing to donate their organs for transplantation. An additional 25% said they would be willing to donate an organ upon their death but had not yet indicated it or informed their family.

Three-quarters of respondents indicated that they were aware of (read or heard about) xenotransplantation. Those most likely to be aware were seniors (87%) and university graduates (85%). By comparison, awareness was lower than average among unskilled workers (61%) and high school and university students (62%).
While knowledge of this medical procedure may be commonplace, only 45% of respondents indicated a knowledge of the potential risk of infection to a patient receiving a xenograft - the viable animal organ, tissue, or cells used in the procedure. Still fewer, 18%, were aware that another potential risk of xenotransplantation is that people who come into contact with a patient infected by a xenograft may also become infected and sick.

Based on their current knowledge of potential risks, about half of respondents said they would consider an animal to human transplant for themselves or a member of their family if a human organ were not available. Slightly more than a third (38%) said “Yes” unequivocally and another 16% indicated conditional acceptance. Over a third (39%) said they would refuse a xenograft and 8% were undecided. Women (55%) were more likely to say they would refuse a xenograft than men (37%).

The level of awareness among those of French background, predominantly in Quebec, was significantly lower than people living in Ontario. The reasons for the difference in awareness were not immediately apparent. Surprisingly, there were no significant regional differences in the level of acceptance of a xenograft, with 36% of those in Quebec saying “Yes” and 38% in Ontario.

Table 1

<table>
<thead>
<tr>
<th>Question</th>
<th>%YES Total</th>
<th>%YES Male</th>
<th>%YES Female</th>
</tr>
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<tbody>
<tr>
<td>1. Have you indicated that you are willing to donate an organ or tissue for transplant upon death (for example, on your driver's license, health insurance card, or notifying your next of kin)?</td>
<td>52%</td>
<td>52%</td>
<td>52%</td>
</tr>
<tr>
<td>2. (If answer was NO in #1) Would you be willing to donate an organ or tissue for transplant upon death?</td>
<td>49%</td>
<td>50%</td>
<td>48%</td>
</tr>
<tr>
<td>3. Have you read or heard about medical researchers proposing to use animal organs for transplant into humans, or are you not sure if you’ve heard about this?</td>
<td>75%</td>
<td>76%</td>
<td>74%</td>
</tr>
<tr>
<td>4. Have you heard that one of the risks of animal-to-human transplants is the possibility that an unknown and new disease or diseases might be transmitted from the animal organ to the person receiving the transplant, or are you not sure if you’ve heard about this risk?</td>
<td>45%</td>
<td>47%</td>
<td>42%</td>
</tr>
<tr>
<td>5. (If answer was YES in #4) Have you heard about the possibility that, if the person receiving the transplant is infected by a new disease, there is a risk that people who come into contact with that person might also become infected and sick, or are you not sure if you’ve heard about this risk?</td>
<td>41%</td>
<td>44%</td>
<td>38%</td>
</tr>
<tr>
<td>6. If a human organ were not available, would you consider an animal-to-human transplant for yourself or a member of your family?</td>
<td>54%</td>
<td>63%</td>
<td>45%</td>
</tr>
<tr>
<td>7. In view of the fact that animal-to-human transplants may pose a risk to the general population, what role would you personally want to play in decisions about the acceptability of carrying out this procedure in Canada?</td>
<td>See Figure 2 for results</td>
<td></td>
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</table>
The survey also asked Canadians what role they would want to play in decisions about the acceptability of carrying out xenotransplantation in this country. To date, Health Canada has not received or approved any proposals for clinical trials involving xenografts. A high proportion of respondents (62%) want to be kept informed of decisions, 24% want to be involved in public meetings, and 22% want to be invited to send comments on draft policies or regulations (respondents could choose more than one answer). The results are shown in Figure 2.

**Discussion**

Despite the apparent willingness of a large majority of Canadians to donate organs, as revealed in questions 1 and 2, Canada’s organ donation rate seems to have reached a plateau of 14.4 donors per million population. This is among the lowest of the industrialized countries, with the United States and Spain having rates of 21 and 27 donors per million, respectively, in 1997.
The results of survey questions 3 to 6 indicate that a majority of Canadians have heard about xenotransplantation but most of them are not aware of the infectious disease risks to patients and third parties. It would therefore be necessary to provide the public with information on the risks and benefits of the procedure, as well as the conditions under which xenotransplantation could occur, in order for an informed discussion to take place.

Also significant is the result of question 7 (Fig. 2), which further underlines the need for the government to provide relevant information on a timely basis to the public. It also demonstrates that Canadians want to be kept informed about xenotransplantation and about what the government is doing.

Similar surveys have been conducted in other countries over the last few years to gauge the public’s attitude toward the potential use of xenotransplantation.

In Australia, a 1995 survey done among 1,728 acute care nurses showed that a majority (66%) were opposed to xenotransplantation. A 1996 survey among 277 patients on a waiting list for a kidney, heart, or heart/lung transplant revealed that 50% would accept a xenograft; 10% found it unacceptable; and about 40% were unsure and wanted more information.

A 1998 survey of physicians, nurses, technicians, and students in France found significant differences between groups regarding acceptance of the procedure (33.9% of nurses would consent to a xenograft compared to 54.9% of physicians). The survey also found that providing respondents with information on the theoretical infectious risks of xenotransplantation resulted in higher acceptance rates (groups ranged from 71.4% in nurses to 87.7% in students). This would indicate that providing background information enables a more thoughtful and informed answer and leads to a higher rate of acceptance.

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The National Kidney Foundation (NKF) in the United States conducted a survey in 1997 to assess Americans’ knowledge of and attitudes towards xenotransplantation. The survey was funded through an unrestricted educational grant from Novartis Pharmaceuticals Corporation, a proponent of xenotransplantation. A total of 1,677 general consumers, transplant candidates, transplant recipients, transplant surgeons and physicians, and primary care physicians were surveyed. Over 90% of respondents said they had heard something about xenotransplantation and 71% would consider a xenograft if the organ or tissue was not available from a human. The NKF survey also revealed that transplant recipients are the most supportive of xenotransplantation. The most common concerns about xenotransplantation were disease transmission, organ compatibility, the transplant success rate, and animal welfare.

**Conclusion**

The survey results from Australia, France, the United States, and Canada suggest that about half of the population would consider a xenograft if a human organ or tissue were unavailable. Even though all the questions about potential benefits and risks cannot be answered at this time, there appears to be a willingness among a large portion of the population to try the procedure if it became necessary and other options are not available. However, the issue is complicated by the fact that there are risks to the public at large, not just to the xenograft recipient. Even if there are willing patients out there, the safety to the public, as well as other important issues, would have to be addressed.

The TPP intends to develop appropriate regulatory policy to address the safety, efficacy, ethical, and regulatory issues surrounding the potential use of xenografts in Canada. In November 1997, the TPP sponsored a National Forum on Xenotransplantation in Ottawa. The Forum represented the first national consultation on the scientific, ethical, and regulatory issues surrounding xenotransplantation. One of the key recommendations from the Forum was to inform the public about xenotransplantation and to involve them in the policy development process.

In response to the recommendation, the TPP is currently implementing a public involvement plan to engage Canadians in a dialogue about the potential benefits and risks of xenotransplantation and its role in human medicine. The TPP is also supporting the work of an expert committee in the drafting of a
**Proposed Canadian Standard for Xenotransplantation** (PCSX) that will assist in determining if clinical trials involving xenografts can be performed safely in Canada. A copy of the draft PCSX was recently made public and it and several other documents on the topic of xenotransplantation are available on the TPP website at www.hc-sc.gc.ca/hpb-dgps/therapeut.

**Acknowledgements:** Mr. Earl Berger and the Berger Health Monitor; the TPP Working Team on Public Involvement for Xenotransplantation; and the TPP Survey Working Group.

ENDNOTES

I. The Berger Monitor March 1999 survey was prepared with the assistance of the Hay Health Care Consulting Group, and administered by Environics Research Group using computer-assisted telephone interview procedures (CATI). The samples were generated using a stratified two-stage random sampling technique based on a sample size of 2,000 persons 15 years of age and older. Each of the ten provinces in Canada was allocated a quota proportional to its contribution to the population of Canada, excluding the Territories, and stratified into five community sizes. The provincial quota was distributed among community strata according to their proportion of the province's population. Separate strata are created for the metropolitan areas of Montreal, Toronto and Vancouver. An additional 500 interviews were conducted in Ontario beyond the proportional quota allocated in that province, for a total of ±1,250 Ontario respondents. The TPP questions were administered to the full sample of 2,526 persons.

At the first stage of sampling, households were selected from a stratum. At the second stage of sampling, one eligible respondent was chosen from the selected household using the Troldahl-Carter technique which ensures that the sample accurately represents the age and sex composition of the provincial population. No other person in the household could be substituted as a respondent. Prior to the data analysis, the data were weighted and verified against the latest Statistics Canada census information.


