

Animal-to-human transplantation: Should Canada proceed?

A public consultation on xenotransplantation



Canadian Public Health Association

Animal-to-human transplantation: Should Canada proceed?
[A public consultation on xenotransplantation](#)

© December 2001 by the Canadian Public Health Association

Permission is granted for non-commercial reproduction only, provided there is a clear acknowledgement of the source.

ISBN 1-894324-20-X



Canadian Public Health Association
400-1565 Carling Avenue
Ottawa, Ontario, Canada, K1Z 8R1

CPHA's Mission Statement

The [Canadian Public Health Association \(CPHA\)](#) is a national, independent, not-for-profit, voluntary association representing public health in Canada with links to the international public health community. CPHA's members believe in universal and equitable access to the basic conditions which are necessary to achieve health for all Canadians.

CPHA's mission is to constitute a special national resource in Canada that advocates for the improvement and maintenance of personal and community health according to the public health principles of disease prevention, health promotion and protection, and healthy public policy.

This consultation was funded by [Health Canada](#). The views expressed in this report are those of the Public Advisory Group, and are based on consultations with a broad sector of the Canadian public. They do not necessarily represent the official policy or views of Health Canada or the Canadian Public Health Association.

The English and French reports and executive summaries are available on the consultation website at <http://www.xeno.cpha.ca> or through <http://www.cpha.ca>.

[French](#) translation by Sylvie Lee

January 7, 2002

The Honourable Allan Rock
Minister of Health
Brooke Claxton Building,
Tunney's Pasture
Ottawa, Ontario, K1A 0K9



Canadian Public Health Association
400-1565 Carling Avenue
Ottawa, Ontario
Canada K1Z 8R1
T 613 725 3769
F 613 725 9826
E-mail: xeno@cpha.ca
Internet: www.xeno.cpha.ca

Dear Minister Rock:

It is our pleasure to provide you with the report *Animal-to-human transplantation: Should Canada proceed?* This report documents the results of a comprehensive consultation with Canadians on the complex issue of xenotransplantation.

The [Public Advisory Group](#) commends [Health Canada](#) for initiating this arm's length consultation. We are grateful to the many Canadians who became involved in the initiative by submitting their views on xenotransplantation or by participating in the citizen forums. We also thank our colleagues on the Public Advisory Group for their unflinching commitment to the consultation process and the [Canadian Public Health Association](#) for its outstanding support.

In accordance with its mandate, the Public Advisory Group makes the following recommendations on xenotransplantation based on input from Canadians:

1. **That Canada not proceed with xenotransplantation involving humans at this time as there are critical issues that first need to be resolved.**
2. That alternatives to xenotransplantation, such as prevention, expanding the human donor pool, mechanical substitutes, and stem cell research be further explored.
3. That the Canadian public receive more information about organ and tissue donation, healthy lifestyles, disease prevention, and disease management.
4. That pre-clinical research continue in order to gain further knowledge about the potential health risks and viability of xenotransplantation.
5. That stringent and transparent legislation and regulations be developed to cover all aspects of xenotransplantation clinical trials.
6. That the public continue to be informed and involved in discussions about the future of xenotransplantation.
7. That the citizen forum model be strongly considered for future consultations on complex and not widely understood policy issues.

We trust this report and the above recommendations will help guide the future development of government policy on xenotransplantation in Canada.

Sincerely,

Dr. Heather Ross
Co-chair
Public Advisory Group
on Xenotransplantation

Mr. Robert Van Tongerlo
Co-chair
Public Advisory Group
on Xenotransplantation

Animal-to-human transplantation: Should Canada proceed?

A public consultation on xenotransplantation



Canadian Public Health Association

December 2001

Public Advisory Group

Dr. Heather Ross (co-chair)

Mr. Robert Van Tongerloo (co-chair)

The Reverend Canon Eric Beresford

Rabbi Dr. Reuven Bulka

Dr. Keith Campbell

Dr. Dmytro Cipywnyk

Dr. Edna Einsiedel

Dr. Ian Gemmill

Mr. Nicholas Hurley

Dr. Thérèse Leroux

Ms. Laurie Potovsky-Beachell

Dr. John Shortreed

Canadian Public Health Association

Sylvia Fanjoy, Project Director

Randi Goddard, Project/Conference Officer

Christian Boudreau, Project Assistant

Acknowledgments

The Canadian Public Health Association would like to thank members of the Public Advisory Group for their hard work and direction, and the citizen forum panelists and experts for giving so generously of their time.

Table of contents

Summary	v	Accepting restrictions for a family member.....	17
1. Introduction	1	Acceptability of measures to keep patients alive	17
2. Methodology	2	3.5 Strategies to Address the Organ Shortage	18
2.1 Health Canada, the Canadian Public Health Association and the Public Advisory Group	2	Final positions of citizen forum panelists.....	18
2.2 Key Issues	3	Relative support for strategies	18
2.3 Survey Instrument.....	3	3.6 Health Risk	19
2.4 Publicity	3	Final positions of citizen forum panelists.....	19
2.5 Consultation Framework.....	4	Principal concern	20
Representative model.....	5	Potential benefits	20
Open model.....	7	Risks versus benefits	20
3. Results and Discussion		Potential risks associated with genetic modification of animals	21
3.1 Highlights	10	3.7 Legislation and Regulations	21
Key findings.....	10	Final positions of citizen forum panelists.....	21
Strategies to address shortages.....	10	Conditions affecting acceptability	22
Health risk.....	10	Level of influence.....	23
Legislation and regulations	10	Establishing the level of risk.....	24
Funding.....	11	3.8 Funding	24
Animal welfare.....	11	Final positions of citizens forum panelists	24
Current knowledge	11	Redirection of health care dollars	24
Ethics.....	11	3.9 Animal Welfare	24
International involvement.....	11	Final positions of citizen forum panelists.....	24
3.2 Samples	11	Animal welfare as a principal concern	25
Citizen forums	11	Use of animals in medical research.....	25
Telephone survey.....	11	Use of animals for xenotransplantation	25
Mail-in survey.....	11	Source animal	26
Website survey.....	12	3.10 Current Knowledge	26
Explanation of positions	12	Final positions of citizen forum panelists.....	26
Other data.....	12	Public information	26
Accuracy of data	12	3.11 Ethics	27
3.3 Demographic Characteristics of Samples	12	Final positions of citizen forum panelists.....	27
Comparative figures	12	Ethical issues as a concern	27
Citizen forums	13	3.12 International Involvement	27
Mail-in survey.....	13	Final positions of citizen forum panelists.....	27
Website survey.....	13	International influence.....	27
Telephone survey.....	14	3.13 Discussion	28
3.4 Key Findings	14	Limitations.....	28
Informed versus uninformed Canadians:		Engaging the public.....	28
Should Canada proceed?	14	Recognizing bias.....	28
Surveys.....	15	Importance of information and discussion	29
Personal decision on having a xenotransplant	16	Most informative source of information.....	29
		4.0 Conclusion	30

Appendixes

1. Public Advisory Group.....	31
2. Time lines.....	32
3. Terms of reference-PAG.....	33
4. Conflict of interest statement-PAG.....	34
5. Citizen forum panelists.....	35
6. Citizen forum experts.....	37
7. Presentations by experts.....	40
8. Regulatory framework.....	41
9. Final positions—Citizen forums.....	42
10. Evolution of opinions.....	43
11. Other data.....	44
12. Important factors in shaping views- Telephone survey.....	45

Figures

1. Health Canada’s regulatory process.....	1
2. Consultation framework.....	5
3. Public consultation on xenotransplantation website front page.....	7
4. Comparing education levels of survey respondents to Canadian population.....	12
5. Family income.....	13
6. Comparing representation of survey respondents to Canadian population.....	13
7. Relative support for strategies to meet the need for organs.....	19
8. Do the benefits of xenotransplantation outweigh the risks?.....	21

Tables

1. Website hits.....	8
2. Telephone survey: Should Canada proceed?.....	14
3. Citizens forums – Orientation session: Should Canada proceed?.....	14
4. Citizens forums – After day 1: Should Canada proceed?.....	15
5. Citizens forums – After day 2: Should Canada proceed?.....	15
6. Should Canada proceed?: by gender.....	15
7. Should Canada proceed? by education level.....	15
8. Citizen forums – Survey: Should Canada proceed?.....	15
9. Positions on the question: Should Canada proceed?.....	16
10. Agreement to having a xenotransplant.....	17
11. Agreement to certain requirements if an immediate family member were offered a xenotransplant.....	17
12. Support for various forms of transplant.....	18
13. Relative support for strategies to meet the need for organs.....	19
14. Health risk as a principal and secondary concern.....	20
15. Principal benefits of xenotransplantation.....	20
16. Do the risks outweigh the benefits or benefits outweigh the risks?.....	21
17. Conditions affecting acceptability.....	23
18. Level of influence in the decision to proceed.....	23
19. Who has the greater responsibility to establish the level of risk?.....	24
20. Redirection of health care dollars.....	24
21. How do you feel about the use of animals in medical research?.....	25
22. How do you feel about the use of animals as a source of living cells, organs and tissue to prolong human life?.....	26
23. Extent to which Canada should be influenced by foreign governments.....	28
24. Positions on the question: Should Canada proceed? - Variations with levels of knowledge, representative samples.....	29

Summary

There is a critical shortage of organ and tissue donors in Canada and many people die while waiting for a transplant. Xenotransplantation could potentially provide an unlimited supply of cells, tissues and organs for humans. (Xenotransplantation is the transfer of living cells, tissues or organs from one species to another for medical purposes. In this consultation, xenotransplantation refers to animal-to-human transplantation.) There is worldwide interest in xenotransplantation and an application to conduct clinical trials (involving humans) could be submitted to Health Canada at any time.

As xenotransplantation raises complex health, ethical, legal, economic, and social issues, Health Canada concluded that the Canadian public should be involved in answering the overarching question, “Should Canada proceed with xenotransplantation and if so, under what conditions?” To that end, Health Canada provided funding to the Canadian Public Health Association (CPHA) to strike a Public Advisory Group (PAG) to conduct an arm’s length consultation, and to report back to the Minister of Health. Members of the PAG represent a diversity of perspectives, regions, and interests ([Appendix 1](#)).

The Public Advisory Group commends Health Canada for this innovative initiative.

Challenging aspects of the consultation were the complexity of xenotransplantation issues, limited public knowledge, time constraints, and budget. Given these challenges, different consultation models were considered and utilized. The most innovative and useful model comprised a series of six citizen forums, each involving 15-23 citizens who met over 2 1/2 consecutive days to take an informed position on the overarching question. Other models were more traditional and included a telephone survey of 1,500 Canadians, a survey mailed to stakeholder organizations, a survey posted on a specially designed website, and informal feedback from the public through letters and e-mails.

The most effective model for consulting the public on this complex and controversial topic was the citizen forum. The PAG therefore recommends that this model be used in future consultations on complex and not well understood policy issues. Essential elements of the model are:

- 1) education (in this consultation, education included reading materials prior to the forum and discussions with experts in transplantation, ethics, animal welfare, infectious disease, law, and a transplant recipient);
- 2) understanding various positions through discussion, interaction and deliberation; and
- 3) continual focus on the overarching question to maintain an effective process.

Should Canada proceed with xenotransplantation, and if so, under what conditions?

The Public Advisory Group recommends that Canada should not proceed with xenotransplantation involving humans at this time as there are critical issues that first need to be resolved.

The majority of informed Canadians who participated in the consultation felt that xenotransplantation involving humans, including clinical trials, should not proceed at this time. For the most informed respondents, 34% did not want xenotransplantation to proceed under any conditions; 19% said no, it is too soon, ask us later; and 46% said yes, but only if a number of concerns are resolved before clinical trials proceed.

The top three issues of concern to Canadians, regardless of their position on proceeding with xenotransplantation, are health risks, viable alternatives, and regulations and legislation.

- Of paramount concern is the potential health risk to humans, particularly infections by known viruses (such as PERVs) and unknown infectious agents that could be transmitted to the human population from source animals.
- Canadians emphasized the need to explore alternative options (such as mechanical devices, stem cells and prevention) and to improve the human organ donation process. The recent government initiative, Canadian Council for Donation and Transplantation, will hopefully lead to improvements in organ donation rates.
- Canadians said that stringent and transparent legislation and regulations must be in place before proceeding with clinical trials. These would include strict regulation of research practices (both human and animal), the use of specially designated centres, and control of potential health risks.

Most Canadians who participated in this consultation did not support the redirection of health care dollars to support xenotransplantation. They recognized that considerable research is needed. Many also expressed concern about ethical, moral, and animal welfare issues.

In summary, the majority of informed Canadians do not support xenotransplantation involving humans at this time. The main reasons pertain to potential health risks, the need to explore alternatives to xenotransplantation, and the inadequacy of current regulations and legislation governing xenotransplantation.

*Public Advisory Group
Public Consultation on Xenotransplantation*

1. Introduction

The demand for healthy cells, tissues and organs for medical purposes far exceeds the available supply and many people on transplant waiting lists die before organs or tissues become available. In response to this shortage, scientists are considering using animals, such as pigs, as donors of living cells, tissues and organs for humans—a procedure known as xenotransplantation.

Any disease that is treated by human-to-human transplantation could potentially be treated by xenotransplantation. Organ xenotransplants could include whole hearts, lungs, livers, kidneys or pancreases. Tissue xenotransplants could include skin grafts for burn victims, corneal transplants for the visually impaired or bone transplants for limb reconstruction. Cellular xenotransplants may be a way to treat people with diabetes or Parkinson's disease.

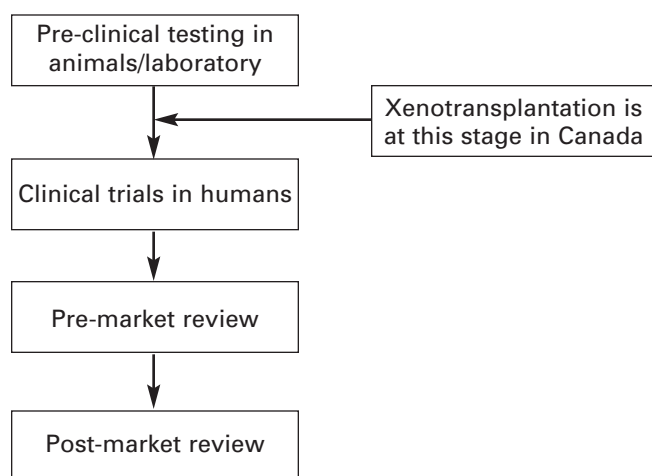
Scientists have experimented with xenotransplantation for almost a century without much success. The main scientific challenges to xenotransplantation are immune rejection and infection. Over the past decade, advances in anti-rejection drugs and progress in the field of biology have resulted in a renewed interest in xenotransplantation. The most recent scientific development in xenotransplantation is the breeding of transgenic pigs, pigs that have been bred with human genes to lower the risk of their organs being rejected by human recipients.

Xenotransplantation is not a recognized medical procedure in Canada nor in other industrialized countries. Some countries have allowed limited and controlled clinical trials, in which medical scientists try out procedures on informed volunteers. Some people believe that there are too many unknowns to proceed with xenotransplantation and that it is better to wait until more information is available through pre-clinical studies that do not involve humans. Others argue that only through careful clinical trials with small numbers of patients will the necessary

scientific data become available to evaluate the procedure.

Currently in Canada, xenotransplantation studies are being carried out using laboratory animals (Figure 1). These pre-clinical or experimental trials do not involve human patients and are not regulated by Health Canada. Xenotransplants are considered therapeutic products and can only be used in clinical trials if authorized by Health Canada. A request to conduct clinical trials could be submitted to Health Canada at any time ([Appendix 8](#)).

FIGURE 1
Health Canada's regulatory process



Xenotransplantation raises a number of issues that call for informed public discussion. Xenotransplantation potentially poses serious risks to public health and has many scientific uncertainties. There are also ethical and legal issues that need to be considered.

In August 2000, the Minister of Health announced that the Canadian Public Health Association (CPHA) would consult with the Canadian public on the health, ethical, legal, economic and social issues related to xenotransplantation and would report to the Minister of Health on the results of those consultations. In September 2000, CPHA struck a Public Advisory Group with the mandate

to develop recommendations on xenotransplantation based on input from Canadians.

The consultation was carried out between March and July 2001. Data from the consultation was analysed in August and September 2001. The Public Advisory Group met in September 2001 to consider the data and to make its recommendations on xenotransplantation.

2. Methodology

2.1 Health Canada, the Canadian Public Health Association and the Public Advisory Group

In August 2000, Health Minister Allan Rock announced that the Canadian Public Health Association, a non-governmental organization, would be funded to consult with Canadians on the health, ethical, legal, economic and social issues related to xenotransplantation. This consultation would be carried out at arm's length from Health Canada. Minister Rock said "the views of Canadians will help to guide the future development of government policy on xenotransplantation in Canada."

The first task of the Canadian Public Health Association (CPHA) was to strike a Public Advisory Group (PAG) with the mandate to develop recommendations on xenotransplantation based on input from Canadians. To this end, CPHA invited participants of previous Health Canada initiatives on xenotransplantation to submit nominations for membership on the PAG. CPHA selected members from these nominations and endeavoured to strike an advisory group balanced in expertise, perspectives, geographical regions and gender ([Appendix 1](#)). A citizen (lay) representative was later added to the PAG.

The PAG worked in partnership with CPHA in defining and developing processes for public awareness, education and dialogue. PAG members agreed to serve in accordance with the Terms of Reference ([Appendix 3](#)). The PAG also agreed to develop a conflict of interest policy ([Appendix 4](#)), nominate a chair (co-chairs were elected), and establish a decision-making process (largely consensual with differences noted in meeting minutes).

The Public Advisory Group met on four occasions and held conference calls between meetings. Two Health Canada officials and two members of Health Canada's Expert Advisory Committee on Xenograft Regulation attended meetings as observers.

2.2 Key Issues

From October 2000 to March 2001, the key issues around xenotransplantation were fleshed out through research and discussion. A background paper on the key issues (*Animal-to-human transplantation: Should Canada proceed?*) was produced in March after being reviewed by a scientific expert panel, stakeholders and a focus group. The paper was modified based on the reviews so that it accurately and fairly presented the issues. This paper was a major resource for the citizen forum panelists, “stakeholder” organizations and website visitors.

Key issues discussed in the paper were:

- Is xenotransplantation needed?
- Is xenotransplantation viable?
- How far should we go to save a human life?
- Is the risk to the public acceptable?
- Are there legal issues that should be considered?
- What animal issues need to be considered?
- What costs need to be considered?
- If Canada proceeds with xenotransplantation, what regulations would need to be in place to manage it?

2.3 Survey instrument

The survey instrument was developed by the Public Advisory Group during its January meeting. The survey was designed to probe opinions on:

- The shortage of organs, tissues and cells for human transplantation
- The degree of knowledge of xenotransplantation
- The acceptability of human and animal transplants
- The benefits and risks of xenotransplantation
- The use of animals in medical research
- The conditions that would facilitate approval of xenotransplantation
- The decision makers in the event of proceeding
- The level of agreement to a xenotransplant by oneself or family members
- The redirection of health care dollars to xenotransplantation
- The decision to proceed with xenotransplantation

Four samples were surveyed: 1) citizen forum panelists, 2) stakeholder groups and individuals, 3) website visitors, and 4) telephone poll participants. The survey instrument was pre-tested in a focus group and in telephone interviews. The telephone survey was shorter than the one developed for the other three samples because of budget restrictions and acceptable interview length; the telephone survey required 60 responses whereas the other surveys recorded 87 responses (questions are presented in the “Results” section). A unique question in the telephone survey asked what influence a number of factors had on the individual’s overall position on xenotransplantation ([Appendix 12](#)).

2.4 Publicity

Publicity was an important component of the consultation. Publicity raised awareness of the initiative and informed the public about how to become involved. Publicity messages conveyed to the public were:

It’s important.

- The demand for organs far outstrips supply and Canada needs to decide if xenotransplantation is a viable alternative.
- Xenotransplantation is a complex and sensitive issue that begs for public involvement.
- A request to conduct clinical trials could be submitted to Health Canada at any time.
- Participate. Tell us what you think.
- This is not a public relations exercise but a fair and open process being carried out at arm’s length of the government.
- This consultation has the power to influence government decision-making.
- Here’s how you can become involved.

There is no right answer.

- We encourage input from all Canadians.
- Recommendations to Health Canada will be based on feedback from Canadians.
- This is an open discussion.

The consultation was successful in attracting extensive national and regional media coverage. A media release was issued nationally in March 2000,

at the beginning of the consultation process, and locally, prior to each citizen forum. A consultant arranged media interviews for the PAG co-chairs, who were the consultation spokespersons.

The Cable Public Affairs Channel (CPAC) filmed the public portion of the first citizen forum (4 1/2 hours) and aired segments nationally for several months. CBC Health Matters (national) did a 20-minute program on xenotransplantation including information about the consultation. RDI Quebec en direct, the French equivalent of Newsworld, did a one-hour, call-in TV show with citizen forum experts. CTV covered the Toronto forum on its national news. Canadian Press picked up the story on four occasions between December 2000 and May 2001.

In most instances, media coverage included the website address and information about the citizen forums.

Media coverage was informally tracked. Known coverage is summarized below.

Television coverage: Fairchild TV (Chinese language television), Canadian Public Affairs Channel (CPAC), CTV Saskatoon, Global Saskatoon, Global Maritimes Today, CJCH-TV Maritimes, BCTV, CBC Health Matters, RDI Quebec en direct, CBC North Beat.

Radio coverage: CJWW Open line Show (Saskatoon); CBC Radio drive-home show (Saskatoon); CBC Radio, "Maritime Noon" (Halifax); CJCH, "The Hotline" (Halifax); CBC Radio, "Afternoon Show" (Halifax); CKNW, Peter Warren Show (Vancouver); CKNW, Rutherford Show (nationally syndicated, open-line radio show); "The World Today" (Vancouver); CHUM Radio (Toronto); CBC Metro Morning (Toronto); Radio Canada, "Nouvelles" (Toronto); CFRB, "The Motts" (Toronto); CKLW, "Windsor Now with Melanie Deveau" (Windsor); The Chorus Radio Network, "Shirley Connects Show" (Hamilton); CBC Yellowknife; Nouvelles Télé-Radio (NTR); CBC Quebec AM; Radio Canada, Quebec Express (Quebec City); CJCD Radio (Yellowknife).

Print coverage: National Post (4 articles), Globe and Mail, Canadian Press (4 articles), The Calgary Herald (3 articles), The Ottawa Citizen (2 articles), The Ottawa Sun, The Toronto Sun (2 articles), The Edmonton Sun, The Vancouver Sun, Winnipeg Free Press, The Saskatoon Star Phoenix (3 articles), The Toronto Star, The Sault Star, The Halifax Chronicle Herald (3 articles), London Free Press (3 articles), The Halifax Daily News, The Kingston Whig-Standard, The Edmonton Journal, La Presse (2 articles), Le Devoir (2 articles), Le Soleil (2 articles), Le Journal de Québec, The Whitehorse Star, The Yellowknifer (2 articles).

Internet coverage: WebMD Canada, The StarPhoenix.com, cbc.ca (Saskatchewan), Canoe.ca, Canada.com, Canadian Medical Journal, thestar.com (Toronto), Citizensontheweb.com (Political Action News Ontario).

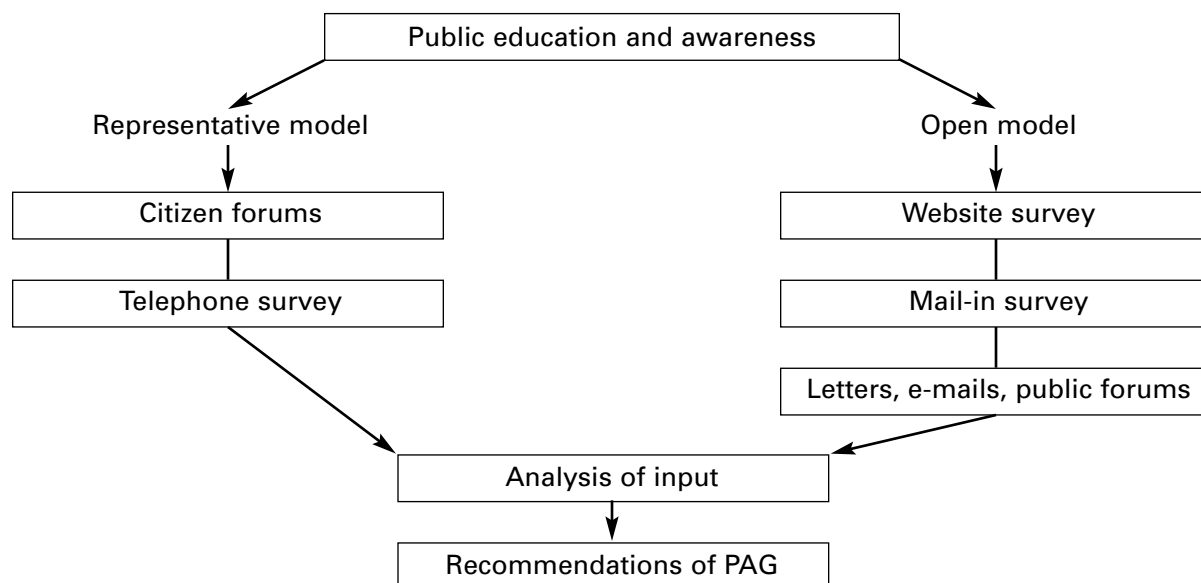
Other publicity

For each citizen forum, an advertisement was placed in the local newspaper promoting the public sessions and the website (an ad was not placed in a Vancouver newspaper because there were budget concerns at that time). 250 posters were distributed in each forum location to encourage public participation. An e-mail campaign notified local hospitals, health centres, doctors, patient groups, universities, public libraries, faith organizations and animal welfare groups. Information was carried on public service announcements and Internet bulletin boards.

2.5 Consultation Framework

A variety of consultation methods were considered. The consultation framework that was implemented incorporated both representative and open models (Figure 2). Under the representative model, a national telephone survey provided data that could be generalized to the Canadian population; the citizen forums examined the outcome of a process of learning and deliberation. The open model gave all Canadians an opportunity to participate.

FIGURE 2
Consultation framework



Representative Model

Citizen Forums

Telephone surveys and stakeholder consultations are traditional models to gather public opinion. When the issue under consideration is complex and not widely understood, the more innovative “deliberative” model is most effective. The deliberative model in the consultation was the citizen forum and was based on similar work carried out at the University of Calgary.

Citizen forums were held in six regions of the country: Saskatoon (March 2001), Halifax (April 2001), Vancouver (May 2001), Toronto (May 2001), Quebec City (June 2001), and Yellowknife (July 2001). At each forum, 15 to 23 citizens learned about and discussed issues related to xenotransplantation before giving their opinions as to whether Canada should proceed. All forums were professionally facilitated and proceedings were captured by professional recorders. Experts gave presentations and were available to answer questions. At least two PAG members (including one co-chair), a Health Canada official and a representative of Health Canada’s Expert Advisory Committee on Xenograft Regulation attended each forum as observers.

Prior to each forum, an invitation to participate was mailed to 2,500 randomly selected households. The invitation stated that current knowledge of xenotransplantation was not required in order to participate; panelists would receive reading materials before the forum; there would be an orientation dinner; experts representing a variety of viewpoints on xenotransplantation would give presentations on the first day and answer questions; on the second day, panelists would discuss issues and recommend if Canada should proceed with xenotransplantation and if so, under what conditions. Potential panelists were advised that they must not have had previous or current involvement with xenotransplantation research and must be willing to spend approximately eight hours prior to the forum reading background materials provided by the organizers. Panelists had travel costs reimbursed and were given one dinner, two lunches, a \$100 honorarium, and an opportunity to have their say on xenotransplantation. Potential panelists were encouraged to visit the consultation website or call CPHA if they had any questions. A postage-paid return envelope and a response questionnaire were included in the mailing.

From the responses received, a selection committee considered demographic information (gender, age, mother tongue, urban/rural location, occupation) as well as written comments and chose 20 panelists for each forum. In Yellowknife, four additional panelists participated; they were selected by aboriginal organizations but represented themselves, not their organizations.

Prior to each forum, panelists were sent an information binder containing:

- general information about the consultation and the logistics of the citizen forum
- profile of expert presenters and fellow panelists (Appendixes 5 and 6)
- the key issues paper (plus its summary), *Animal-to-human transplantation: Should Canada proceed?*
- the survey
- a flow chart explaining the regulatory process (Appendix 8)
- background documents available on the website: *ABCs of Xeno, Ethical and Social Issues Raised by Xenotransplantation, and Scientific Issues Raised by Xenotransplantation*

Forums were structured as follows*:

Friday evening

6:00pm—9:00 pm Orientation session

- introductions
- dinner
- viewing of the documentary “Spare Parts” which examines xenotransplantation, its history, the state of research, risks, and perspectives[§]
- at three of the six forums, panelists were asked for their preliminary response to the question: Should Canada proceed with xenotransplantation?; responses were submitted anonymously and recorded in order to detect changes in opinion during the course of the forum

Saturday

* In Yellowknife, the forum was held during the work week as it was anticipated many people would be out-of-town on weekends

§ October 19, 2000 episode of the CBC television show “The Nature of Things”.

9:00am—2:30pm Public session

- presentations by experts in transplantation, infectious disease, law, ethics, animal welfare, and a transplant recipient
- questions from the panelists
- luncheon for experts and panelists
- questions from the public (1:00pm-2:30pm)

2:30pm—5:00pm Closed session

- informal discussion between panelists and experts led by the facilitator

Sunday

11:00am—3:30pm Closed session

- at the start of the session, panelists were each asked the question: Should Canada proceed with xenotransplantation?; responses were recorded on flip charts and captured in the proceedings
- panelists broke into groups to flesh out positions on xenotransplantation
- positions were presented to the plenary on flip charts and further clarified
- each panelist indicated her/his final position on xenotransplantation, which was recorded

Post forum

- final positions, as recorded in the flip chart notes, were mailed to panelists

Experts

An important component in educating panelists was the participation of experts in the forums. During the Saturday morning session, experts gave brief presentations and panelists asked them questions. During lunch and in the afternoon, panelists and experts discussed issues in a more relaxed setting. Experts were generally secured locally instead of having one group of experts travel to all forums. There was positive feedback on selecting local experts instead of “bringing them in”.

Expertise was sought in the areas of transplantation, infectious disease, law, ethics, animal welfare, and transplant recipient. Experts were asked to present existing knowledge to help people understand the issues, to give a range of perspectives, and not to be speculative. In the end,

most experts covered similar issues but occasionally there was a difference of perspective or emphasis (Appendix 7).

The PAG identified an initial database of experts. When those identified were unable to participate, they often recommended others as they were well aware of the pool of local talent and expertise.

Experts did not receive an honorarium. They gave excellent presentations and were enthusiastic and patient throughout.

Facilitator

One bilingual facilitator travelled to all forums. The facilitator was successful in getting the panelists to work effectively together, respect different perspectives, and focus on the “overarching question”: Should Canada proceed with xenotransplantation and if so, under what conditions?

Telephone survey

The tool used to gather public opinion was a national telephone survey of randomly selected adult Canadians. This could be described as a

broad, representative sample and it was used as a benchmark to which other samples were compared. The public opinion and research firm POLLARA was contracted to carry out the fieldwork. Using the CATI System, computers dialed telephone numbers drawn from a reliable population database. 1,519 Canadians aged 18 and older were interviewed. This sample was large enough that, if generalized to the overall Canadian population, results would be accurate to within (plus or minus) 2.5 percentage points. The telephone survey was conducted in March 2001.

Open Model

Website

A website was developed to inform the public of xenotransplantation issues and to provide a vehicle for public input to the consultations, using the website survey. The website (<http://www.xeno.cpha.ca>) went online in November 2000. When the first citizen forum was held in March 2001, the site offered the information in Figure 3:

ABCs of xeno: A brief overview of issues around

FIGURE 3

Public consultation on xenotransplantation website front page



xenotransplantation including its history, current interest, use of animal parts, risk of rejection, choosing the species, risk of disease, and sources of information.

In the news: Brief summaries of news stories related to xenotransplantation presented in chronological order.

Viewpoints: Highlights of available information from various perspectives, including a survey of attitudes in seven countries as well as ethical, legal, scientific, and religious viewpoints.

Legislation and regulations: Excerpts from the Council of Europe on legal, regulatory and scientific developments on xenotransplantation in 27 countries including Canada.

About the project: A brief explanation of the project objectives and the role of the Canadian Public Health Association, the Public Advisory Group and Health Canada.

Mailings: Easy-to-download copies of publications sent to stakeholders in December.

What's happening: Overview of the consultation and how to get involved. Visitors were encouraged to subscribe to the listserv.

Public Forums: Information on the citizen forums such as locations, times, panelists, experts, and public sessions.

The Big Issues: The key issues paper *Animal-to-human transplantation: Should Canada proceed?* and summary.

Have your say: Website survey that could be completed and submitted on-line. The survey was linked to the key issues paper.

Media room: National and regional media releases with links to the background paper.

As indicated in Table 1, the website had many visitors.

TABLE 1
Website hits

Month:	# of hits
March	5,619
April	8,237
May	13,377
June	7,919
July	7,224

The website survey was posted at the end of March. "We are seeking Canadian public opinion only" was stated clearly at the start of the survey in order to discourage international participation. The survey could be completed and submitted on-line. It was promoted in mailings, through the media and at public sessions of the citizen forums. In early July, a message was sent to the website listserv with the reminder that the deadline for submitting the survey was the end of the month. In the end, 367 website surveys were submitted on-line.

Mail-in survey

It was assumed that certain groups and individuals would have an inherent interest in xenotransplantation. Broadly speaking, so-called stakeholders could be concerned with xenotransplantation issues from varying perspectives: animal rights and welfare, the environment, ethics, religion, government, consumer, culture, health and safety, health professional, human rights, industry, legal, potential recipient, regulatory, scientific, academic, senior or youth. Potential stakeholders were identified in The Canadian Sourcebook, the Canadian Almanac & Directory and CPHA's database. Participants at Health Canada's meetings on xenotransplantation were included in the consultation database as well as anyone who indicated an interest in stating their views. By March 2001, there were approximately 3,700 stakeholders in the database.

Stakeholders were sent an information package in December 2000 and again in March 2001. National and Quebec organizations were sent bilingual materials.

The December 2000 mailing introduced the consultation, the website and the Public Advisory Group, and included a summary of the issues (ABCs of Xeno) along with a fax-back information sheet.

The March 2001 mailing provided information on the citizen forums. The key issues paper (*Animal-to-human transplantation: Should Canada proceed?*) was enclosed along with the stakeholder survey and a postage-paid return envelope.

In early July, an e-mail was sent to 1,250 stakeholder organizations and individuals to remind them that the deadline for submitting the survey was the end of the month. Health, faith, cultural, legal and environmental organizations were targeted in this e-mail blitz. Organizations in Quebec, Prince Edward Island, New Brunswick and Newfoundland were given more attention as participation had been low in these provinces. In the end, 216 stakeholder surveys were completed and returned.

Letters, e-mails, public sessions

The consultation model allowed for informal expression of public opinion (compared to using the survey) through letters and e-mails. The public was invited to submit written views by mailing letters to the Canadian Public Health Association or by sending electronic messages to the consultation e-mail address, xeno@cpha.ca.

In many cases, the tone of these messages was vehement, such as “I am absolutely FOR looking at the matter in a cautious, measured, scientific and informed way” and xenotransplantation “is about making money for those with a vested interest in this research - at the expense of desperate people”.

During the public portion of the citizen forums, members of the public were invited to voice their opinions or ask questions of the experts. All views stated at the public sessions were recorded in audio and written format.

Data related to public opinion expressed through letters, e-mails and the citizen forums is included in the results section of the report.

3. Results and discussion

3.1 Highlights

Key Findings

When generally uninformed Canadians were asked if Canada should proceed with xenotransplantation, the majority said yes. However, as they became more informed, a shift occurred and the majority of informed Canadians said no, Canada should not proceed.

- Panelists at citizen forums became the most informed Canadians who were surveyed. At the end of the citizen forums, the majority of the panelists said Canada should not proceed with xenotransplantation at this time. 34% said no, 19% said no with qualifications, and 46% said yes with qualifications.
- Faced with a choice of yes or no, the majority who responded to the citizen forum, mail-in and website surveys said Canada should not proceed.
- Women were less likely to endorse xenotransplantation than men, while those in the highest income bracket were more likely to favour proceeding with xenotransplantation than those in the lowest.
- Most citizen forum panelists who said yes to proceeding with xenotransplantation said that stringent and transparent legislation and regulations covering all aspects of clinical trials must first be in place.
- Polling an uninformed public is not the most useful method to gauge responses to a complex policy question because opinions can change once information flows. Instead, a representative public should first become informed of pertinent issues through education, discussion and interaction and then be polled for their opinions.
- As a whole, Canadians were most resistant to the idea of accepting animal-to-human organ transplants for short-term quality of life and

most accepting of animal-to-human cellular transplants for long-term quality of life.

- If a family member was offered a xenotransplant, the majority of those polled would agree to restrictions such as lifelong blood monitoring or being quarantined for a period of time if necessary.
- Across samples, human-to-human transplants of any kind were viewed as highly acceptable and animal-to-human transplants were viewed much less enthusiastically.

Strategies to address shortages

Xenotransplantation was consistently rated as the least acceptable strategy to address the shortage of organs, cells and tissues, with preventative approaches being the most acceptable, followed by expanding the current donor pool, mechanical substitutes, stem cells, and presumed consent.

Health risk

Potential health risk was the paramount concern with xenotransplantation. This was generally expressed as concern about the risk of zoonotic disease from infection by known and unknown viruses and the fear that this could lead to large-scale epidemics.

- Informed Canadians tended to conclude that the risks of xenotransplantation were greater than the benefits because of health risks and scientific uncertainty surrounding these risks.
- Support for genetic modification of animals was generally low to moderate. For those commenting on why genetic modification was not acceptable, the greatest concern was that it was too risky.

Legislation and regulations

Strict regulation of research practices (both human and animal), public education and designated centres of expertise would do the most to reassure Canadians about xenotransplantation. Least reassuring would be measures designed to monitor close contacts of xenotransplant recipients.

Across samples, it was felt that multi-disciplinary panels and expert scientific panels should have a great deal of influence in the decision about proceeding with xenotransplantation; corporate interests and decisions made by foreign governments should have the least influence.

Funding

Relatively few Canadians support the redirection of health care dollars to xenotransplantation.

Animal welfare

While there is modest support for the use of animals in medical research (this support varies significantly across samples), support for animal research in the context of xenotransplantation is lower.

- If xenotransplantation were deemed an acceptable procedure, pigs would be the source animal of choice.

Current knowledge

There was overall agreement that scientific knowledge of xenotransplantation is lacking and that the public wants to be kept informed.

Ethics

Most ethical concerns were general in nature.

International involvement

Canadians clearly want a made-in-Canada approach to xenotransplantation.

3.2 Samples

Data was collected primarily from four samples.

Representative samples

- Citizen forums
- Telephone survey

Open samples

- Mail-in survey
- Website survey

Citizen forum proceedings and survey

Six citizen forums, involving 107 panelists were held across the country (in Saskatoon, Halifax, Vancouver, Toronto, Quebec and Yellowknife) over a four-month period. Potential panelists were invited to participate through a random sampling process and final selection was largely based on demographics. These panelists were given written materials on xenotransplantation before the forum. Over 2 1/2 days they heard and questioned experts (in transplantation, infectious disease, law, ethics, animal welfare, and a transplant recipient). They also discussed the issues with fellow panelists. Two sets of data emerged from these forums: positions of 106* panelists recorded in proceedings and a survey completed by 73 panelists.

Telephone survey

The firm POLLARA randomly drew this sample from a national database of Canadians aged 18 and older and completed 1,519 telephone interviews. The number of respondents was weighted to statistically represent the five geographical areas of Canada: Atlantic, Quebec, Ontario, Prairies and the Territories, Alberta and British Columbia. This was the least informed sample with 70% saying they were not very or not at all knowledgeable about xenotransplantation.

Mail-in survey

The survey was mailed to approximately 3,700 organizations covering a broad range of interests such as animal welfare, faith, cultural, human

* A Toronto panelist left before the final positions were recorded.

rights, industry, legal, health and safety, consumer, organ recipient, scientific, medical, seniors, youth, hospitals, governments, universities and colleges. From those sources, 216 surveys were returned and make up this sample. These respondents could be considered “stakeholders.” It is assumed these respondents have an interest in xenotransplantation issues.

Website survey

The survey was posted on the project website, a site that carried a great deal of information on xenotransplantation. 367 website surveys were analyzed (398 were received, of which 18 were blank, another 6 were duplicates and 7 were sufficiently incomplete as to not warrant inclusion). “We are seeking Canadian public opinion only” was stated clearly at the start of the survey so as to discourage international participation.

Explanation of positions

In answer to the question “Should Canada proceed with xenotransplantation?”, citizen forum positions were categorized as follows:

Position	Definition
No	No, never
Qualified no	No, not now, but possibly in the future
Qualified yes	Yes, with conditions
Yes	Yes, without conditions

Respondents to the surveys were not given the option to choose a qualified position; therefore results are presented as “yes”, “no” or “unsure”.

Other data

Additional input from the public through letters and public sessions (held during the citizen forums) is summarized in Appendix 11 and presented in this report under Key Findings and Animal Welfare.

Accuracy of data

The citizen forum, mail-in and website surveys were analyzed by Neil Chambers, Ph.D. of The Action Group in Ottawa. The data was not weighted by sample but rather equal weight was accorded to individual respondents. Dr. Chambers

stated that “the convergence of findings shows a remarkable consistency of opinion regarding the issues relating to xenotransplantation, even if that opinion is consistently divided. Not only were the issues raised of a very similar nature, but the relative number of individuals in each sample supporting the various positions was also largely consistent.” Due to rounding, totals do not always equal 100%.

The telephone interviews and subsequent analysis were conducted by Ian L. Knowles, Ph.D. of POLLARA in Ottawa. This sample was large enough that, if generalized to the overall Canadian population, results would be accurate to within (plus or minus) 2.5 percentage points.

3.3 Demographic Characteristics of Samples

Of the 661 respondents to the citizen forum/mail-in/website surveys, 38% were male, 55.2% female and 6.8% did not specify gender. 87.4% of respondents completed the survey in English and 12.6% in French. Levels of education and income were higher than in the general population (Figures 4 and 5). On the whole, regional representation was commensurate with the population distribution across Canada, with the exception of Quebec where response rates were low (Figure 6).

FIGURE 4
Comparing education levels of survey respondents to Canadian population (Citizen forum/mail-in/website surveys)

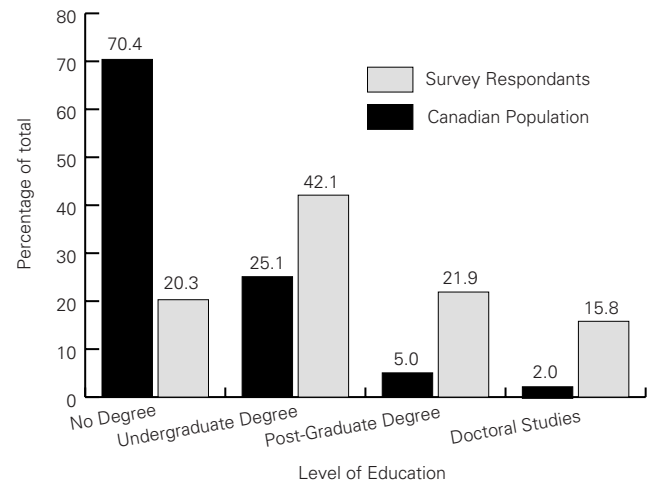


FIGURE 5
Family income
(Citizen forum/mail-in/website surveys)

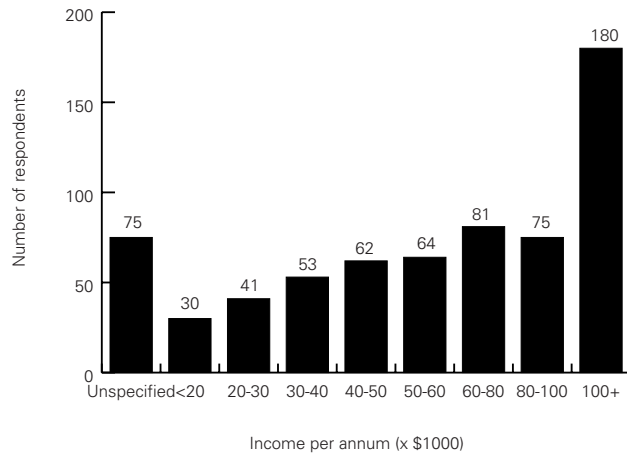
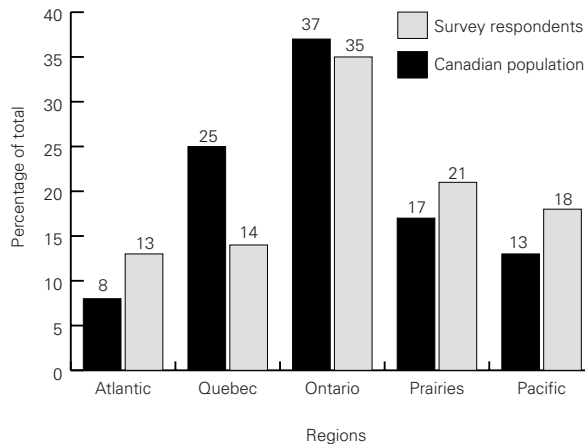


FIGURE 6
Comparing regional representation of survey respondents to Canadian population
(Citizen forum/mail-in/website surveys)



Citizen forum proceedings and survey

Of the 107 panelists who attended the citizen forums, 57 were female and 50 were male. Citizen forums were held in six different regions of Canada (Pacific, North, Prairies, Ontario, Quebec, and Atlantic) and local panelists were selected for each. At the end of each forum, panelists were asked to complete the general survey. 90% of the 73 panelists who responded provided information on the four variables, gender, age, education and family income. 51.4% of these were female, 40.5% male, and 8.2% did not specify gender. While the age and gender distributions were balanced, a

large number of participants had a university degree or college diploma and family incomes over \$80,000, suggesting this is not an entirely representative sample. 8.1% had a high school education or less, while 69% had a university degree or college diploma and of those, 24.4% had a post-graduate degree. Similarly, only 17.6% had a family income under \$40,000, while 52.7% had a family income over \$60,000.

Mail-in survey

Approximately 88% of the 216 “stakeholders” provided information on gender, age and level of education, while 83% also indicated family income level. 50% of respondents were female, 36.6% male, one couple filled out the survey jointly, and 13% did not specify gender. Few respondents were 25 years of age or younger (2%). Nearly one half (46.6%) indicated they had a post-graduate degree and/or completed doctoral-level studies. Over one half (58.1%) noted a family income of over \$80,000. For those indicating their province of origin (89%), distribution was commensurate with the Canadian population except Quebec, which was under-represented.

Website survey

In this sample, approximately 97% provided information on gender, age, education and province of residence, while just under 90% also indicated family income. 58.8% were female, 37.7% male, and 3.5% did not specify gender. 9.8% were under 25, 44.7% of respondents were in the age group 26-40, 19.3% were between 41-50, 18% between 51-65, and 5.2% were age 65 and over. There was a predominance of university-educated respondents, although relative to the mail-in surveys, there were fewer post-graduates. All provinces and territories, with the exception of Nunavut, were represented. Broadly speaking, representation was consistent with the size of the population in each region, with the possible exception of a somewhat higher response rate for Ontario and British Columbia and a slightly lower response rate for Quebec. With the exception of the high number of respondents with a family income over \$100,000, other income groups were generally evenly distributed. This sample was relatively broad-based and representative in all categories except perhaps level of education and income.

Telephone survey

In the telephone survey, 50% of the participants were female and 50% were male. The five regions of Canada were statistically represented. Levels of education and income were more in keeping with the general population than in the citizen forum/mail-in/website surveys. 36% had a high school education or less, 19% had some college or university, 30% had a university degree or college diploma, and 8% had a post-graduate degree. 37% had a family income under \$40,000 while 31% had a family income over \$60,000.

3.4 Key Findings

When the Public Advisory Group developed the consultation framework, it did not know what effect information and discussion would have on a decision to proceed with xenotransplantation. The framework that was selected tested this, and found that there was a dramatic shift in positions with increased information.

Informed versus uninformed Canadians: Should Canada proceed?

Overarching question: Should Canada proceed with xenotransplantation and, if so, under what conditions?

When generally uninformed, randomly-selected Canadians were asked if Canada should proceed with xenotransplantation, the majority said yes. However, as they became better informed, a shift occurred and the majority of informed Canadians said no, Canada should not proceed.

Uninformed

In the telephone survey of 1,500 randomly selected Canadians (the least informed sample), the majority said that Canada should proceed with xenotransplantation (Table 2).

TABLE 2

Telephone survey: Should Canada proceed?

Position:	
Yes	65%
No	24%
Unsure/no response	11%

Moving from uninformed to informed

After three citizen forums were completed, the Public Advisory Group decided to investigate whether a shift in thinking occurred over the course of the deliberations. Therefore, panelists at the final three citizen forums (Toronto, Quebec City and Yellowknife) were asked the overarching question at orientation sessions that preceded the forums. Although panelists were sent background information on xenotransplantation to read before the forums started, their knowledge level was relatively low when compared to their knowledge of xenotransplantation at the end of the forum (Table 3).

TABLE 3

Citizens forums (3 only)-orientation session: Should Canada proceed?

Position:	
Yes	5%
Yes (qualified)	50%
No	20%
No (qualified)	7%
Unsure/no response	18%

Panelists at all six citizen forums were asked if Canada should proceed with xenotransplantation on two other occasions during the forums:

- At the end of Day 1, after a full day of discussions with experts
- At the end of the forum, after an additional day interacting and discussing issues with each other, and, with the help of a facilitator, keeping the focus on the overarching question.

After Day 1, panelists were asked to give a brief summary of their position on the overarching question. Their responses are summarized in Table 4.

TABLE 4**Citizens forums (6)-after day 1:
Should Canada proceed?****Position:*

Yes	4%
Yes (qualified)	44%
No	28%
No (qualified)	19%
Unsure/no response	5%

During Day 2, positions on the overarching question were developed and at the end of the day, panelists indicated which position they held. Panelists often agonized over the wording of their positions and the reasons why the position was held or put qualifications around their position (Appendix 9).

The final positions are summarized in Table 5.

TABLE 5**Citizens forums (6)-after day 2:
Should Canada proceed?§***Position:*

Yes (all qualified)	46%
No	34%
No (qualified)	19%
Left early	1%

There was no clear will on the part of panelists to proceed on xenotransplantation, at least not right away. They indicated that too much is unknown, the potential risk is too great and there are other viable alternatives. Of the 46% who said “yes” to proceeding, all of them qualified their response. Some of these qualifications would be difficult to achieve, such as establishing the level of risk or implementing complex regulations.

* Positions after Day 1 for the three citizen forums in Table 3 were: Yes 2%; Qualified yes 46%; No 25%; Qualified no 22%; Unsure/no response 5%

§ Positions after Day 2 for the three citizen forums in Table 3 were: Qualified yes 49%; No 40%; Qualified no 9%; Unsure/no response 2%

Surveys

All four surveys (citizen forum/mail-in/website/telephone surveys) asked the question:

Question:

Should Canada proceed with xenotransplantation?
(check ✓)

- Yes
 No

Faced with a choice of yes or no, the majority who responded to the citizen forum/mail-in/website surveys said Canada should not proceed. Women were far less likely to endorse xenotransplantation than men, while those with the highest education level were more likely to favour proceeding with xenotransplantation than those with the lowest (Tables 6 and 7).

TABLE 6**Should Canada proceed? by gender
(Citizen forum/mail-in/website surveys)**

<i>Position:</i>	<i>Female %</i>	<i>Male %</i>	<i>Unspecified %</i>
Yes	23.2	46.5	41.0
No	75.6	53.1	53.8
Unsure	0.4	0.4	5.1

TABLE 7**Should Canada proceed? by education level
(Citizen forum/mail-in/website surveys)**

<i>Position:</i>	<i>No degree %</i>	<i>Under- graduate %</i>	<i>Post graduate %</i>	<i>Doctorate %</i>
Yes	26.4	35	26.7	43.2
No	72.7	64.2	72.6	55.8
Unsure	0.8	0.8	0.7	1.1

The 73 citizen forum panelists who completed the survey after the session responded as shown in Table 8.

TABLE 8**Citizen forums (73 panelists)-survey:
Should Canada proceed?***Position:*

Yes	42%
No	55%
Unsure	3%

The majority of those in the self-selected samples (mail-in and website surveys, letters and comments at public forums) were more opposed to proceeding with xenotransplantation.

Table 9 gives the position of all samples on the overarching question.

In the citizen forum/mail-in/website surveys, those not in favour of proceeding were asked to comment on their primary concern. In the citizen forum survey, the largest number believed the risk was too great (41%), while 38% said there were too many unknowns and that more information, research and pre-clinical testing were needed before moving forward. 16% mentioned other alternatives were more attractive than xenotransplantation, while 6% said other health care issues were a greater priority. In the mail-in survey, 29% said too much is unknown and we need to do more research before considering this; 18% found the idea too risky; 13% said that organ shortfalls could be met through other more viable alternatives; 12% said there are other more pressing priorities; 12% mentioned animal rights; 9% ethics; and 6% costs.

Personal decision on having a xenotransplant

All four surveys asked the question:

Question:

Would you agree to have a transplant of cells, tissues or organs from an animal for the following reasons? (yes, no, unsure)

- To improve your quality of life in the short term
- To improve your quality of life in the long term
- To provide a temporary bridge to another treatment
- As a last resort to keep you alive

Comments

The results were consistent in the citizen forum/mail-in/website surveys, with the majority of respondents unwilling to accept animal-to-human transplants. Canadians would be most resistant to the idea of accepting animal-to-human organ transplants for short-term quality of life and most accepting of animal-to-human cellular transplants for long-term quality of life (Table 10).

The largest group of respondents commented that we must (or they have already) come to terms with dying rather than trying to prolong life through procedures such as xenotransplantation.

TABLE 9
Positions on the question: Should Canada proceed?

Position:	Representative Model					Open Model		
	Telephone survey	CITIZEN FORUMS				Mail-in survey	Website survey	Letters and public forums
	%	Orientalion	After day 1	After day 2	Survey	%	%	%
Yes	65	5	4	-	42	39	26	16
Yes (qualified)	N/A	50	44	46	N/A	N/A	N/A	-
No	24	20	28	34	55	58	69	84
No (qualified)	N/A	7	19	19	N/A	N/A	N/A	-
Unsure /No response	11	18	5	1	3	3	5	-

TABLE 10
Agreement to having a xenotransplant

Would you agree to have a transplant of cells, tissues or organs from an animal for the following reasons?

	Cell			Tissue			Organ			Cell/Tissue/Organ
	Cit. Forum %	Mail in %	Website %	Cit. Forum %	Mail-in %	Website %	Cit. Forum %	Mail-in %	Website %	Telephone*
For short term quality of life:										
Yes	40	29.6	22.8	37	25.6	20.9	18	18	15.2	43
No	42	62.6	64.4	48	63.3	66.1	68	73.3	73	49
Unsure	18	7.8	12.8	16	11.1	13	14	8.7	11.8	8
For long term quality of life:										
Yes	53	41.1	34.1	47	40.1	33.7	32	33.3	27.7	66
No	32	49.8	54.3	38	51.7	55.3	52	57	63.7	26
Unsure	15	9.2	11.6	16	8.2	10.9	16	9.7	8.5	8
As a bridging measure:										
Yes	47	40.6	32.2	41	38.5	30.6	31	30.4	21.8	65
No	37	49.3	54.1	42	49.5	54.5	48	57	65.2	27
Unsure	16	10.1	13.7	17	11.5	14.8	21	12.6	13	8
As a last resort:										
Yes	39	33.2	38.4	34	30.6	26.2	27	27	23.4	55
No	46	59	60.7	51	60.7	61.3	59	65.7	66.9	37
Unsure	15	7.8	11	16	6.7	12.5	14	7.4	9.7	8

* In the telephone survey, responses to cells, tissues and organs were not obtained separately

Accepting restrictions for a family member

All four surveys asked the question:

Question:

If a member of your immediate family (partner, child, parent, sibling) were offered a xenotransplant, would you agree to certain requirements such as lifelong monitoring of your blood and the possibility of you being quarantined for a period of time? Please explain.

Despite the fact that respondents to the citizen forum/mail-in/website surveys expressed considerable reservation towards xenotransplantation, the majority in all four samples would agree to restrictions if a family member were to be offered a xenotransplant (Table 11). Among comments as to why they would accept restrictions (or why not), the most frequent was that it would be an acceptable price to pay for saving a family member, although almost as frequent were comments that the cost of complying would be just too high.

TABLE 11
Agreement to certain requirements if an immediate family member were offered a xenotransplant

Position:	Forum %	Mail-in %	Website %	Telephone %
Yes	64	50.9	36.2	71
No	25	33.3	34.3	16
Unsure/ no response	11	15.7	29.4	14

Acceptability of measures to keep patients alive

All four surveys asked the question:

Question:

How do you feel about using the following measures to keep patients alive with a reasonable quality of life? (1 “very unacceptable” ⇒ 10 “very acceptable”)

- Transplanting human cells to other humans
- Transplanting human tissue to other humans
- Transplanting human organs to other humans
- Transplanting animal cells to humans
- Transplanting animal tissue to humans
- Transplanting animal organs to humans

Across all samples a very similar pattern emerged with human-to-human transplants of any kind viewed as highly acceptable and animal-to-human transplants viewed much less favourably (Table 12).

TABLE 12
Support for various forms of transplant
(Mean rating on a scale of 1 to 10, 10 being “very acceptable”)

Type:	Forum	Mail-in	Website	Telephone
Human-to-Human				
Cell	9.3	9.2	8.8	8.4
Tissue	9.4	9.2	8.9	8.7
Organ	9.2	9.1	8.9	9.0
Animal-to-Human				
Cell	5.6	4.7	3.8	5.5
Tissue	5.3	4.6	3.7	5.5
Organ	4.2	4.1	3.5	5.3

3.5 Strategies to address organ shortage

Final positions of citizen forum panelists

In their final presentations, 80% of the citizen forum panelists raised the issue of alternative options to xenotransplantation, generally calling for increased efforts in public education, prevention and research to address the shortage of human organs, tissues and cells. While acknowledging the ever-increasing need, panelists often said that the shortage should first be addressed by educating the public about organ and tissue donation, healthy lifestyles, disease prevention, and disease management.

Some recommended that Health Canada hire an ad agency to get the prevention messages out to schools and the general public through television, infomercials, mail-outs and billboards. Others spoke of the need to address underlying social issues such as fetal alcohol syndrome, effects of pollution and second-hand smoke, air quality at work and home, and proper diet and exercise. Another recommendation was to give incentives to medical professionals to provide patients with sufficient information, guidance and monitoring for diseases such as diabetes.

Many panelists spoke of the need to increase research in alternatives such as stem cells and mechanical devices, and in disease prevention and treatment. They spoke of possibly offering financial incentives for organ donation, establishing a national organ registry, improving the organ transport system, and exploring the feasibility of legislating presumed consent.

Relative support for strategies

All four surveys asked about the need for organs:

Questions:

(Citizen forum/mail-in/website surveys) Do you have any comments on the need for organs in Canada? (Telephone survey) Would you say that at most times there is an adequate supply of human organs and tissues available to be used in transplants, or is there normally a shortage of tissues and organs for transplants?

The shortage of organs was generally acknowledged. In the citizen forum survey, 88% said the need for organs should be addressed. Of those who commented in the mail-in survey, 51% emphasized that the need for organs is real and pressing. In the website survey, 25% emphasized the need for organs is real and pressing; others chose to indicate what strategy they felt would best meet this need. In the telephone survey, 87% said that there is normally a shortage of organs and tissues for transplant.

The citizen forum/mail-in/website surveys asked the question:

Question:

What possible strategies in addressing the need for organs do you favour? Please rate any or all of the following using the scale: 1 “very unacceptable” ⇔ 10 “very acceptable”

- xenotransplantation
- stem cells (cells that can develop into any type of tissue)
- expanding the current donor pool
- reducing the need for organs through preventative approaches
- mechanical substitute (cont'd)

- presumed consent (assume people agree to donate their organs, cells and tissues upon death unless otherwise indicated)
- other (specify)

Xenotransplantation was consistently rated as the least acceptable strategy to address the organ shortage, with preventative approaches receiving the highest rating followed by (in order of preference) expanding the current donor pool, mechanical substitutes, stem cells, and presumed consent (Figure 7 and Table 13).

FIGURE 7
Relative support for strategies to meet the need for organs
(Citizen forum/mail-in/website surveys)
(Mean rating on a scale of 1 to 10, 10 being “very acceptable”)

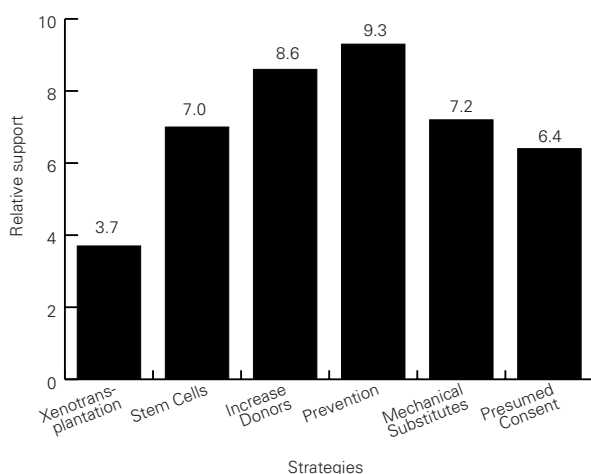


TABLE 13
Relative support for strategies to meet the need for organs - by sample
(Mean rating on a scale of 1 to 10, 10 being “very acceptable”)

Strategy:	Forum	Mail-in	Website
Prevention	9.6	9.1	9.3
Increase donors	9.4	8.6	8.4
Mechanical Substitutes	8.1	7.2	7.2
Stem cells	8.1	7.0	6.7
Presumed consent	6.7	5.9	6.6
Xenotransplantation	3.9	3.9	3.4

3.6 Health Risk

Final positions of citizen forum panelists

In their final presentations, 82% of citizen forum panelists specifically mentioned health risk as a concern with statements such as “the mitigation of risk is our paramount concern” and “the risks may not be worth it if xenotransplantation benefits a few but puts larger populations at risk”.

Health risk was a concern raised by panelists who had differing views on proceeding with xenotransplantation. For example, a comment by some panelists holding a “qualified yes” position was “ensure minimal risk and proceed only after pre-clinical solutions are found to eliminate problems with hyperacute rejection, PERVs, cloning”; while some who held a “qualified no” position stated “there are more risks than advantages”; and others who said “no” felt “there are too many unknown elements and the risks are too high.”

Panelists raised concerns about known and unknown viruses. They spoke of the potential risk to the individual and society, with comments such as “the collective good of society must take precedence over the individual good” and “evaluate the pros and cons (individual and societal) of immunological risk and xenozoonosis risk.”

Lack of knowledge and adequate regulations heightened risk concerns. Panelists spoke of the need for “further scientific study,” that “safeguards [should be] in place to protect against xenozoonotic infection,” that we must “learn more about other cross-species viruses and pathogens,” that “clinical trials should not proceed until we have a better understanding of infectious risks and efficacy of treatment,” and that we need to put “regulations in place to minimize infection risk.”

There were also concerns about potential risks around genetically modifying animals, with comments such as needing to “understand the long-term implications of altering human and animal genetics” and “manipulation of genes—

how do we know what the end results will be, what mistakes could occur?”. Environmental concerns about the disposal of animal excretions was an issue for a few.

Principal concern

The citizen forum/mail-in/website surveys asked the question:

Question:

What potential problems with xenotransplantation worry you the most, if any? Why?

Health risk was the overwhelming concern (Table 14). This was generally expressed as concern about the risk of disease through zoonosis, retroviruses and infection and the fear that this could lead to large-scale epidemics. While this question was not asked in the telephone survey, those polled were asked “How important is your view about risks of xenotransplantation in determining your overall views about xenotransplantation?”. 70% said it was very or somewhat important.

TABLE 14

Health risk as a principal and secondary concern

<i>Health risk:</i>	<i>Forum</i> %	<i>Mail-in</i> %	<i>Website</i> %
Principal concern	76	52	44
Secondary concern	18	19	32

Potential benefits

The citizen forum/mail-in/website surveys asked the question:

Question:

What potential benefit(s) with xenotransplantation appeals to you the most, if any? Why?

39% of those who responded said there was no benefit, 33% said the main benefit was that it would meet the need for organs, 17% said it would save lives, and 6% that it would increase the patient’s quality of life. Women were significantly more likely than men to mention “no benefit” as their first choice. Table 15 provides the breakdown by sample.

TABLE 15

Principal benefits of xenotransplantation

<i>Position:</i>	<i>Forum</i> %	<i>Mail-in</i> %	<i>Website</i> %
No benefits	24	35	45
Meets need for organs	36	35	31
Saves lives	22	17	15
Increases patient quality of life	10	6	6
Other	8	7	3

Risks versus benefits

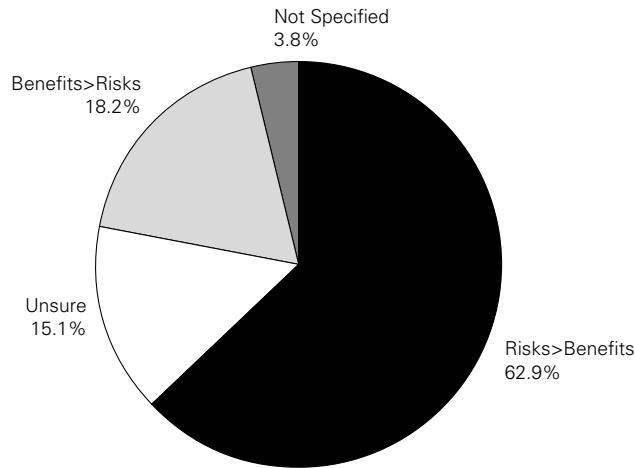
All four surveys asked the question:

Question:

On balance, do you believe the risks of xenotransplantation outweigh the benefits or do you believe the benefits of xenotransplantation outweigh the risks?

Respondents to the citizen forum/mail-in/website surveys clearly indicated that the risks outweigh the benefits (62.9%), with only 18.2% indicating that the benefits outweigh the risks (Figure 8 and Table 16). Women were significantly more likely to say the risks outweigh the benefits than men. Among those who considered the benefits outweigh the risks and made a comment, the largest percentage qualified their answer with statements such as: “once we know more about zoonoses”; “if sufficient expertise is developed”; “if the process is well regulated”. Even those who felt that the benefits outweigh the risks considered health risk to be the major worry.

FIGURE 8
Do the benefits of xenotransplantation outweigh the risks?
(Citizen forum/mail-in/website surveys)



Of those who said the risks outweigh the benefits and chose to elaborate:

- Citizen forum survey: 54% said the risk was too great, 36% said the level of scientific knowledge was insufficient;
- Mail-in survey: 48% commented on the health risks, 30% said there were too many unknowns;
- Website survey: 44% mentioned health risks, 32% were concerned with animal rights, 5% said it was unethical, 5% said it was against nature.

The telephone survey revealed very different results with 45% saying that the benefits outweighed the risks (Table 16).

TABLE 16
Do the risks outweigh the benefits or benefits outweigh the risks? - by sample

	Forum %	Mail-in %	Website %	Telephone %
Risks > benefits	62	60	65	29
Benefits > risks	21	20	18	45
Unsure	18	17	13	25
Not specified	-	3	4	-

Potential risks associated with genetic modification of animals

The citizen forum/mail-in/website surveys asked the question:

Question:
 How do you feel about modifying the genetic make-up of animals to facilitate their use in xenotransplantation procedures? (1 “very unacceptable” ⇔ 10 “very acceptable”).

Support for genetic modification of animals was generally low to moderate, ranging from an average rating of 3.41 in the website survey to 4.46 in the citizen forum survey. Overall, 63% were against genetic modification of animals. For those commenting on why genetic modification was not acceptable, the greatest concern in each of the samples was that it was too risky.

For those who accepted genetic modification, 20% commented that they were concerned about the risks (39% in the citizen forum survey, 10% in the mail-in survey, and 19% in the website survey).

3.7 Legislation and Regulations

Final positions of citizen forum panelists

Legislation and regulation issues were raised by 96% of the citizen forum panelists in their final presentations.

Panelists who said ‘no’

Some panelists who said ‘no’ to proceeding with xenotransplantation doubted if adequate and enforceable regulations could ever be put in place. They were concerned that consent might be obtained under duress, and that researchers could be influenced by companies that would finance their work. They pointed to the lack of regulations around pre-clinical trials and to Canada’s poor track record in regulating the water and blood supply. Some said that a policy and legal framework should be established to regulate pre-clinical trials and to prevent animal-to-human xenotransplantation.

Panelists who said ‘no’ with qualifications

Some of the panelists who gave a “qualified no” response to proceeding with xenotransplantation said a legal framework should be put in place. This framework should include: research protocols; an accountability structure;

multidisciplinary ethics committees; a “watchdog” responsible for good clinical practice; and a procedure to ensure informed consent. Three panelists said they were in favour of re-evaluating their position on xenotransplantation once the required and socially acceptable guarantees were in place.

Panelists who said ‘yes’ with qualifications

Most panelists who said ‘yes’ to proceeding said that stringent and transparent legislation and regulations covering all aspects of the clinical trials must be in place before xenotransplantation is undertaken in Canada. Some said that the public must be closely involved in the development of legislation. Others said that public safety was the “number one” concern.

According to some of these panelists, legislation should address:

- establishment of a broadly-based governance structure; some suggested this should be an arm’s length committee to monitor and report back to the public; members should represent the scientific, medical, religious, ethical and legal communities
- containment of major hazards
- research protocols
- conformity to existing public health legislation to safeguard public security
- production of transgenic animals
- mechanism for accountability
- infectious risk control
- registry of xenotransplant recipients and donor animals
- monitoring the safety of products produced elsewhere
- enforceable regulations governing clinical trials
- importing and exporting tissues, cells and organs
- compensation and liability
- standards and protocols for dealing with patients and their families including surveillance and monitoring
- humane and ethical use and care of test subjects, both animal and human
- contractual consent including a “no opt out” option
- eligibility to receive human versus animal organs, tissues and cells

Conditions affecting acceptability

All four surveys asked the question:

Question:

If the Government of Canada decides to proceed with xenotransplantation, how would having each of the following in place affect your comfort level with xenotransplantation? (0 “much less comfortable” ⇒ 5 “would have no impact” ⇒ 10 “much more comfortable” with xenotransplantation)

- Lifelong monitoring of the patient
- Monitoring of close contacts (family members)
- Mandatory autopsy upon death of patient
- Quarantine laws if there is an epidemic outbreak
- Widespread availability of public information concerning xenotransplantation
- Establishing an international registry of patients
- Fair procedures to determine who gets human or animal cells, tissues or organs
- Establishing regulations on acceptable human research practices
- Establishing regulations for the humane care and treatment of animals
- Xenotransplants carried out only at specially designated centres of expertise

Other conditions (specify)

Table 17 shows the conditions affecting acceptability. The three most highly rated conditions in the citizen forum/mail-in/website surveys were research regulation, animal regulations and public information. In the telephone survey, they were public information, designated centres and animal welfare regulations.

Most of those who did not rate any strategy (21% in the mail-in survey and 22.8% in the website survey) and who commented, indicated they were so opposed to xenotransplantation that none of the measures would make a substantial difference.

TABLE 17**Conditions affecting acceptability****(Mean rating on a scale of 1 to 10, 10 being “much more comfortable”)**

Strategy	Forum	Mail-in	Website	Telephone
Lifelong monitoring	8.2	7.4	6.0	6.4
Monitoring of close contacts	7.7	6.4	4.9	5.9
Mandatory autopsy	8.1	7.0	5.6	6.7
Quarantine laws	8.0	6.6	5.7	7.5
Public information	8.3	7.5	6.3	8.5
International registry	7.8	6.8	5.5	7.1
Fair procedures	7.8	7.5	6.0	7.4
Research regulations	8.7	8.3	6.8	8.2
Animal welfare regulations	8.5	8.0	6.7	8.4
Designated centres	8.2	7.8	5.9	8.4

Level of influence

All surveys asked the question:

Question:

How much influence should each of the following have in the decision about proceeding with xenotransplantation? (1 “no influence” ⇔ 10 “a great deal of influence”)

- Federal government
- Provincial governments
- Positions taken by foreign governments (e.g. USA, UK)
- International bodies (e.g. World Health Organization)
- The general public
- Expert scientific panels
- Expert multidisciplinary panels (e.g. scientists, medical professionals, ethicists, legal experts, consumers, theologians)
- Professional health associations
- Religious institutions

(cont'd)

- Corporate interests (e.g. pharmaceutical industry)
 - Organizations representing transplant recipients
 - Organizations representing animal interests
- Other (specify)

Respondents said that multi-disciplinary panels and expert scientific panels should have the greatest influence in the decision to proceed with xenotransplantation; corporate interests should have the least influence; and decisions made by foreign governments should have limited influence (Table 18).

TABLE 18**Level of influence in the decision to proceed****(Mean rating on a scale of 1 to 10, 10 being “a great deal of influence”)**

Body /sector of society	Forum	Mail-in	Website	Telephone
Federal government	7.5	7.7	6.3	6.6
Provincial governments	6.0	6.0	4.8	6.1
Foreign governments (e.g. US, UK)	5.0	4.8	3.6	4.6
International bodies	7.7	6.9	6.1	6.7
General public	8.3	7.2	7.1	7.1
Expert scientific panels	8.0	7.8	6.8	8.4
Expert multidisciplinary panels	9.3	8.5	7.8	8.2
Professional health associations	7.9	6.7	6.1	8.1
Religious institutions	5.2	4.8	3.7	4.0
Corporate interests	3.5	2.3	1.8	4.1
Organizations representing transplant recipients	6.4	5.9	5.2	7.2
Organizations representing animal interests	5.9	6.1	6.4	6.1

Establishing the level of risk

The citizen forum/mail-in/website surveys asked the question:

Question

Who has the greater responsibility to establish the level of risk associated with xenotransplantation?

- Those who wish to proceed (their argument being that the unknown risks are minimal and can be managed)
- Those who wish not to proceed (their argument being that the unknown risks are substantial and unmanageable)
- Not sure

Many of the respondents to the citizen forum/mail-in/website surveys said that those who wish to proceed with xenotransplantation should be responsible for establishing the level of risk (Table 19).

TABLE 19

Who has the greater responsibility to establish the level of risk?

Position	Forum %	Mail-in %	Website %
Those who wish to proceed	46	48	48
Those who don't wish to proceed	35	32	32
Unsure	17	19	20

3.8 Funding

Final positions of citizen forum panelists

In their final presentations, 66% of panelists at citizen forums raised the issue of xenotransplantation funding. For those against proceeding with xenotransplantation, comments were about scarce health care dollars, that the costs would be high, and that there are other priorities. For those who gave qualified support to proceeding, there were comments that money should not be diverted from existing programs and that the research should be publicly funded.

Redirection of health care dollars

All four surveys asked the question:

Question:

Would you favour a redirection of health care dollars to xenotransplantation should it become an acceptable alternative? Why or why not?

Across all four samples, the majority of respondents would not support the redirection of health care funds to xenotransplantation (Table 20). For the citizen forum/mail-in/website surveys, the principal reasons were that there are better strategies to address the organ shortage (usually prevention, education and increasing the donor pool) and that there are other priorities within the health care system. Those who said 'yes' to redirecting health care dollars usually cautioned that there must be more research, that xenotransplantation must be proven viable, and that it must be well regulated.

In the telephone survey, of those who said 'no' to redirection, 32% said other procedures should have funding priority and 18% said outside money would be needed as funds should not be taken from health care. Of those who favoured redirection of health care dollars, 27% indicated the procedure could save lives and offer hope.

TABLE 20

Redirection of health care dollars

Position	Forum %	Mail-in %	Website %	Telephone %
Opposed	60	51	54	50
Support	30	35	22	35
Unsure/No response	10	13	25	14

3.9 Animal Welfare

Final positions of citizen forum panelists

Over half of the citizen forum panelists (59%) addressed animal welfare in their final presentations. There was concern that regulations pertaining to the humane treatment of animals would not be respected if xenotransplantation was adopted. A few questioned the ethics of "raising animals specifically for spare parts." Others said clear rules and regulations on the use of animals

in privately and publicly-funded research were needed. A few suggested a public watchdog be appointed while others said Health Canada should provide funding to ensure that animals are humanely treated.

Animal welfare as a principal concern

The citizen forum/mail-in/website surveys asked the question:

Question:

What problem(s) with xenotransplantation worries you the most, if any?

Overall, 20.5% indicated animal welfare was a principle concern. This concern varied significantly among samples. It did not register as a principal concern in the citizen forum survey; 15.8% in the mail-in survey indicated it was a principal concern; and 28% in the website survey indicated animal welfare was a principal concern.

Most of those who provided feedback through letters were concerned with the welfare of animals, as were members of the public who attended the open session of the citizen forums; 84% of these respondents were clearly opposed to xenotransplantation and of these, 30.3% stated that they disapproved of using animals for this procedure ([Appendix 11](#)).

Use of animals in medical research

All surveys asked the question (with the telephone survey asking for open-ended opinions):

Question:

How do you feel about the use of animals in medical research? (1 “very unacceptable” ⇒ 10 “very acceptable”)

Why?

Support for animal research in the citizen forum/mail-in/website surveys as a whole was only modest (mean rating 5.45), ranging from a high of 7.31 in the citizen forums survey to a low of 4.77 among the website respondents. The top four reasons given as to why animal research was unacceptable were: it is cruel; humans have no right; all life is equal; and it is unethical. The four

major comments made by those who consider animal research to be acceptable were that such research should be humane (25%); that it is necessary (10%); that there are no current alternatives (10%); and that using animals for research is no different than using them for food (10%).

TABLE 21

How do you feel about the use of animals in medical research?

<i>Position</i>	<i>Forum</i>	<i>Mail-in</i>	<i>Website</i>	<i>Telephone</i>
	<i>%</i>	<i>%</i>	<i>%</i>	<i>%</i>
Acceptable	68	52	38	66
Unacceptable	8	30	48	17
Unsure/Neutral	23	18	15	17

Use of animals for xenotransplantation

All surveys asked the question (with the telephone survey asking for open-ended opinions):

Question:

How do you feel about the use of animals as a source of living cells, tissues and/or organs to prolong human life? (1 “very unacceptable” ⇒ 10 “very acceptable”)

Why?

In the citizen forum/mail-in/website surveys, support for animal research in the context of xenotransplantation was lower than for animal research in general (mean rating 4.30), ranging from a high of 6.11 among the citizen forum panelists to a low of 3.53 for website respondents. In all groups, standard deviations were high (over 3) suggesting a consistently polarized view. For those who found it unacceptable, the reasons were largely that it is cruel, unethical, and that humans have no right. In the telephone survey, support for animal research in the context of xenotransplantation was significantly lower than support for animal research in general.

TABLE 22**How do you feel about the use of animals as a source of living cells, organs and tissue to prolong human life?**

Position	Forum %	Mail-in %	Website %	Telephone %
Acceptable	57	35	24	48
Unacceptable	29	47	66	22
Unsure/Neutral	14	18	10	30

Source animal

If xenotransplantation were to proceed, pigs would be the source animals of choice.

The citizen forum/mail-in/website surveys asked the questions:

Questions:

If xenotransplantation is acceptable, which animal should be considered as a source of living cells, tissues or organs to prolong human life? (check ✓) Pigs, primates, dogs, cats, rabbits, rodents, other (specify).

If xenotransplantation is acceptable, which animal would it be acceptable to genetically alter in order to facilitate its use in xenotransplantation procedures? (check ✓) Pigs, primates, dogs, cats, rabbits, rodents, other (specify).

In the citizen forum/mail-in/website surveys, the majority of those who indicated a species in response to the above questions favoured pigs. However, a significant percentage did not indicate any preferred species.

The telephone survey asked the first of the above two questions. 94% answered the question and indicated that pigs (70%) and primates (64%) would be the most acceptable donors.

3.10 Current knowledge

There was overall agreement that scientific knowledge of xenotransplantation is lacking and that the public wants to be kept informed.

Final positions of citizen forum panelists

In their final presentations, 81% of panelists commented on the current state of knowledge of xenotransplantation. There was wide agreement on the need for more research. Areas of greatest concern were the need to know more about health risks, the consequences of genetic modification, and the viability of xenotransplantation. Several panelists commented on the lack of transparency, stating that the public is “left in the dark,” not even aware of the concept of xenotransplantation.

Of those who said ‘no’ to proceeding, comments tended to focus on the need to conduct pre-clinical trials for a longer period; the unknown and doubtful viability of xenotransplantation; and our present inability to find solutions to known animal and human infections. Those who wished to proceed generally indicated that first we need to have a better sense of the potential for success.

Specific recommendations of those who gave a ‘qualified no’ response to proceeding included: continue research on PERVs and its effect; create a pathogen-free transplant donor; conduct more research into the detection of unknown pathogens; and focus on cellular transplants in pre-clinical trials.

Public information

All four surveys asked the question:

Question:

If the Government of Canada decides to proceed with xenotransplantation, how would having each of the following in place affect your comfort level with xenotransplantation?

One of the choices listed was “widespread availability of public education concerning xenotransplantation”.

In [Table 17](#), “Conditions affecting acceptability,” of the ten conditions given that could affect comfort level with xenotransplantation, public education rated relatively high, with mean ratings of 8.3, 7.5, 6.3 and 8.5 for the citizen forum, mail-in, website, and telephone surveys respectively.

3.11 Ethics

Final positions of the citizen forum panelists

In their final presentations, 56% of the panelists commented on ethical issues. Most comments were general in nature such as “ethical concerns must be taken into consideration” or “we feel concerned about the moral and spiritual issues around xenotransplantation.” Specific issues were raised such as: Isn’t xenotransplantation unnatural and contrary to major religions? What right do we have to meddle with nature? Is it ethical to use animals for our own benefit? Who would get a human organ transplant versus an animal one? Concerns were raised about the invasiveness of the procedure, the ethics of surveillance, and the potential stigmatization of the xenotransplant recipient. For those against proceeding, a common theme was that we must learn to accept death.

Ethical issues as a concern

The citizen forum/mail-in/website surveys asked the question:

Question:

What potential problem(s) with xenotransplantation worries you the most, if any? Why?

In the citizen forum survey, 7.5% said a primary concern was the ethics of tampering with nature by crossing the species, while 26% indicated that their secondary concern was that xenotransplantation was against nature.

In the mail-in survey, nearly 7% noted unspecified ethical issues as a primary concern and 5.6% were concerned about tampering with nature. Nearly 15% of those with a secondary concern mentioned xenotransplantation as being against nature and just over 11% mentioned unspecified ethical issues.

In the website survey, 4% identified largely unspecified ethical issues as a primary concern and 5% were concerned that it was against nature. Of those with a secondary concern, nearly 9% said

it was against nature while 3% were concerned with unspecified ethical issues.

In the telephone survey, 50% of those surveyed indicated that it is “very important” (9 and 10 on a scale of 1-10) to respect nature’s boundaries.

3.12 International involvement

Final positions of citizen forum panelists

In their final presentations, 60% of panelists commented on Canada’s involvement internationally regarding xenotransplantation. Some who were opposed to proceeding with xenotransplantation said that Canada should take a leadership role internationally by:

- promoting alternatives through education and prevention
- taking a cautious approach
- establishing international conventions with regards to information sharing, participation and regulations
- developing international standards for research
- monitoring research as it progresses in other countries.

Comments of those in favour of proceeding with xenotransplantation included:

- the importance of monitoring worldwide progress
- share new technology and research
- participate in related international activities
- proceed cautiously through consultation and cooperation with international partners
- the need for an international information bank.

International influence

The citizen forum/mail-in/website surveys asked the question:

Question:

To what extent should Canada be influenced by decisions taken by foreign governments (e.g. USA, UK) on xenotransplantation? Why?

Canadians clearly want a made-in-Canada approach to xenotransplantation. Across the samples, 48% said there should be no foreign

influence or that Canada should learn from other governments and international research but make its own decision. Only 17% said Canada should be closely involved with the international process and be influenced accordingly.

Responses to the question of foreign influence are shown in Table 23.

TABLE 23
Extent to which Canada should be influenced by foreign governments

<i>Position</i>	<i>Forum</i> %	<i>Mail-in</i> %	<i>Website</i> %
Not be influenced	52	39	54
Minimal influence	17	9	7
Moderate influence	19	30	25
Considerable influence	13	22	12

3.13 Discussion

Limitations

At the outset, Health Canada indicated that a request to conduct clinical trials could be submitted at any time. The Public Advisory Group consequently decided that since time-is-of-the-essence, the report would be submitted to the Minister of Health by the end of 2001. This deadline imposed relentless timelines.

The Public Advisory Group developed two consultation models to determine Canadians' views on xenotransplantation. The open model was designed to promote input from any and all Canadians, through letters, e-mails and website surveys, whereas the representative model drew opinions from specific individuals who could be said to represent Canadian citizens. A public awareness and education campaign was initiated to inform the public of the consultation.

While there was a desire to consult broadly with Canadians, budget and time constraints limited the extent to which Canadians could be informed about xenotransplantation and the consultation. The information mailings were sent to a limited audience: targeted stakeholders and individuals indicating an interest in the issue. Only Canadians with internet

access could visit the website and take advantage of the posted information, survey and links to other related sites. Since most media and public awareness activities focused on the six citizen forums, Canadians in provinces where forums were not held were probably less aware of the consultation.

Engaging the public

The object of this consultation was to ask informed Canadians if Canada should proceed with xenotransplantation. Since polling indicated that 70% of Canadians were not very or not at all knowledgeable about xenotransplantation, educating the public was a major endeavour.

A simple internet poll requiring a "yes", "no", "not sure" response to the question "Should animal organs be transplanted into humans?" received 3,528 votes in a short period of time*. However, when efforts were made to engage the public in a more meaningful way, participation rates were very low. A great deal of effort was made to produce materials suitable for a broad readership and to promote the website and the public forums. Yet responses through surveys, letters and e-mails and participation at the public sessions were consistently low due to an overall low level of awareness of xenotransplantation and related issues.

Recognizing bias

A random selection process was used to develop a pool of interested citizens from which a panel could be selected for the forums. The selection committee took care to create regional panels that were as balanced as possible in terms of gender, age, ethnicity, occupation and location of residence (rural/urban). However, in some locations, there were not sufficient applicants to achieve an ideal balance. As well, Canadians with higher than average levels of education and income tended to apply to be panelists.

Given the nature of the forums, it is recognized that the expert speakers could have inadvertently or intentionally indicated their position on xenotransplantation in their presentations. For the

* Canoe C-Health poll, April 2, 2001, <http://www.canoe.ca/Health/previouspolls.html>; 53% voted "Yes", 34% voted "No", 13% voted "Not sure"

most part, it was thought that experts gave balanced, factual presentations and did not exhibit obvious biases.

The results of the self-selected samples are likely more biased since the respondents were not randomly chosen and, as in the case of the internet survey, the responses from individuals with vested interests could have been disproportionate (greater) compared to responses from those with no particular agenda.

Importance of information and discussion

A comparison of the two representative samples (citizen forums and the national telephone survey) clearly shows the impact of information and discussion on positions taken (Table 24). At the start of the forums, positions of panelists were similar to those surveyed by telephone. As panelists became better informed, the level of uncertainty dropped and there was a dramatic shift towards not proceeding across all citizen forums.

The forums clearly demonstrate that “ordinary” citizens can grapple with difficult policy issues and that information and discussion can lead to shifts in position. At the end of the forums, panelists were able to articulate the conditions under which

Canada could proceed or document the reasons why it should not go ahead. The only “unsure” response related to a panelist who had to leave early so his final position could not be recorded.

Most informative source of information

The public consultation on xenotransplantation has demonstrated the value of and need for public education and discussion when society is confronted with complex and not widely understood policy issues.

Given the opportunity to make an informed decision about the future of xenotransplantation in Canada, 106 Canadians from six regions volunteered to become involved in the consultation and demonstrated a laudable commitment to the decision-making process. They embraced the responsibility of their task and made their thoughtful judgements on xenotransplantation in the spirit of representing fellow Canadians.

The Public Advisory Group believes that the most informative data received during the consultation was from the six citizen forums. These forums indicate that Canadians would probably be more cautious about xenotransplantation if they were more knowledgeable of the issues.

TABLE 24

**Positions on the question: Should Canada proceed?
Variations with levels of knowledge, representative samples**

<i>Position:</i>	<i>Telephone Survey</i> %	<i>Citizen panelists at orientation</i> %	<i>Citizen panelists after day 2</i> %
Yes (includes qualified yes)	65	55	46
No (includes qualified no)	24	27	53
Unsure / No response	11	18	1

4.0 Conclusion

Canadians are well aware that the need for organs, cells and tissues for transplant is real and pressing. However, the majority of informed Canadians conclude that we should not proceed with xenotransplantation at this time. We first need to put greater effort into exploring other alternatives such as prevention, expanding the human donor pool, finding mechanical substitutes, and supporting stem cell research. The public needs to be educated about organ and tissue donation, healthy lifestyles, disease prevention, and disease management.

This does not mean that most informed Canadians are absolutely opposed to xenotransplantation. However, they favour a precautionary approach. At the present time, the health risks are uncertain, the level of scientific knowledge is insufficient, and regulations are inadequate. Canadians say that those who wish to proceed with xenotransplantation need to determine the level of risk and demonstrate how the benefits of the procedure would outweigh those risks.

Research concerning unknown pathogens, the effect of retroviruses, and ways to combat transplant rejection should go forward. Stringent and transparent legislation and regulations covering all aspects of clinical trials should be developed. Finally, efforts should continue to further the knowledge and public discussion of xenotransplantation.

Appendix 1: Public Advisory Group

Co-chair

Dr. Heather Ross is the director of the Cardiac Transplant Program and assistant professor and staff cardiologist at the University Health Network, Toronto General Hospital Site. She is also pursuing her Master's degree in Bioethics at the University of Toronto. Dr. Ross is the co-chair of the Canadian Cardiovascular Society's 2001: Consensus Conference on Transplantation.

Co-chair

Mr. Robert Van Tongerlo is executive director of the Canadian Federation of Humane Societies which is a national organization working to improve conditions for all animals across Canada. Headquartered in Ottawa, the Federation represents over 100 member societies across the country.

Members

Reverend Canon Eric Beresford is a consultant for ethics and interfaith relations for the Anglican Church of Canada and a member of the Biotechnology Working Group of the Canadian Council of Churches. Canon Beresford has worked as a bioethicist at the Institut de Recherche, Clinique de Montréal, and on the ethics committee of several hospitals. He resides in Toronto.

Rabbi Dr. Reuven Bulka is host of the TV series "In Good Faith," and the weekly radio call-in program "Sunday Night with Rabbi Bulka". He has contributed scholarly and popular articles to various journals and has written or edited 31 books. Rabbi Bulka lives in Ottawa and is the chairman of the Organ Donation Committee of the Kidney Foundation for Eastern Ontario.

Dr. Keith Campbell is past president of the Manitoba Veterinary Medical Association, Manitoba representative to the Canadian Veterinary Medical Association, and a member of the Canadian Veterinary Medical Association Animal Welfare Committee. Dr Campbell practises small animal medicine and surgery in Winnipeg.

Dr. Dmytro Cipywnyk represents the Canadian Ethnocultural Council, a coalition of national ethnocultural umbrella organizations. Dr. Cipywnyk was associate clinical professor of psychiatry at the University of Saskatchewan and medical director of Saskatchewan's Alcohol and Drug Abuse Commission. He is a Member of the Order of Canada.

Dr. Edna Einsiedel is a professor of the Graduate Program in Communications Studies at the University of Calgary. The focus of her research is involving the public in technology assessments and technology decision-making. In 1999, Dr. Einsiedel and her graduate students conducted the first consensus conference in Canada on the issue of food biotechnology.

Dr. Ian Gemmill is the Medical Officer of Health for the Kingston, Frontenac and Lennox & Addington Health Unit in Ontario. He is a member of the National Advisory Committee on Immunization, the Provincial Advisory Committee on Communicable Diseases, and the Board of Directors of the Canadian Public Health Association. Dr. Gemmill is an associate professor in the departments of Family Medicine and Community Health and Epidemiology, Queen's University.

Mr. Nicholas Hurley is the chair of the Board of Directors of the Canadian Association for Community Care, which promotes the development of a range of community health care services in Canada. Mr. Hurley is a member of Health Canada's Expert Advisory Committee on Blood Regulation. He resides in Newfoundland.

Dr. Thérèse Leroux is a professor of law at the Centre de recherche en droit public of the University of Montreal's Faculty of Law and has a Ph.D in medical biochemistry. She is a member of the National Council on Ethics in Human Research, president of Québec-Transplant's ethics committee and past-president of the Canadian Bioethics Society.

Ms. Laurie Potovsky-Beachell is a member of the Board of Directors of the Prairie Women's Health Centre of Excellence, founding member of the Women and Health Reform Working Group, and past chair of the Health and Safety Committee, Consumers' Association of Canada (Manitoba). Ms. Potovsky-Beachell was director-at-large of the Manitoba Women's Institute and co-wrote the organization's presentation to the 1990s Royal Commission on New Reproductive Technologies. She lives in Rosser, Manitoba.

Dr. John Shortreed is the executive director of the Network for Environmental Risk Assessment and Management and professor emeritus, Civil Engineering, University of Waterloo. Dr. Shortreed was the Canadian representative to ISO/IEC Working Group on Risk Management Definitions and the director of the Institute for Risk Research.

Appendix 2

Time lines

November 1997: Health Canada's Therapeutic Products Programme (TPP) sponsored a National Forum on Xenotransplantation in Ottawa. This Forum represented the first national consultation on the scientific, ethical and regulatory issues surrounding xenotransplantation. Participants included professional associations, transplant recipients, scientists, health professionals and specialists in the areas of transplantation, disease transmission, ethics, law, animal rights and veterinary medicine. The Forum's summary report included several important recommendations, such as the need to inform the public about xenotransplantation, to involve the public in the policy development process and to develop safety standards that could be used to regulate xenografts if they are approved for use in Canada.

July 1999: The TPP released, for public comment, the draft *Proposed Standard for Xenotransplantation*, which identifies important issues that should be addressed for the safe and effective implementation of xenotransplantation. This document was written by an expert working group established by TPP, comprised of experts in the areas of transplantation, infectious disease, veterinarian medicine and ethics.

April 2000: The TPP sponsored a planning workshop to obtain public input on a Public Involvement Plan for Xenotransplantation, a plan which included the formation of a Public Advisory Group. A broad range of people interested in and affected by xenotransplantation participated.

August 2000: Minister Allan Rock announced that Health Canada was funding the Canadian Public Health Association to form a Public Advisory Group and consult with Canadians on the issue of xenotransplantation.

October 2000: First meeting of the Public Advisory Group.

November 2000: Xeno website (<http://www.xeno.cpha.ca>) launched to provide information about the consultation and xenotransplantation.

December 2000: Information mailing sent to some 3,700 stakeholder organizations. It introduced the consultation and website, and included the information sheet, *ABCs of Xeno*, and a fax-back form.

December 2000: National media release sent to 350 media outlets to introduce the consultation and the website.

January 2001: Second meeting of the Public Advisory Group.

March 2001: Information mailing sent to some 3,700 stakeholder organizations. It included the key issues paper, *Animal-to-human transplantation: Should Canada proceed?* and the stakeholder survey.

March 2001: Key issues paper, *Animal-to-human transplantation: Should Canada proceed?* and survey posted on the website.

March 2001: National telephone survey conducted.

March 2001: Third meeting of the Public Advisory Group.

March 2001: National media release distributed announcing the consultation, website, citizen forums, key issues paper.

March-July 2001: Citizen forums held in Saskatoon, Halifax, Vancouver, Toronto, Quebec City and Yellowknife.

March - July 2001: Regional media releases distributed promoting the forums, panelists and experts.

March - July 2001: Regional public relations campaigns conducted to promote the local citizen forums.

July 2001: Consultation deadline July 31.

September 2001: Fourth meeting of the Public Advisory Group.

December 2001: Consultation reports (English and French) published

Appendix 3

Terms of Reference - PAG

Mandate

The Public Advisory Group is responsible for developing recommendations on xenotransplantation based on input from Canadians.

Functions

- Work in partnership with the Canadian Public Health Association in defining and developing the processes for public awareness, education and dialogue.
- Recommend to the Canadian Public Health Association a process for consultation record taking and analysis of public input.
- Confirm a range of issues that should be considered from a public perspective including issues raised by the public.
- Provide policy advice and recommendations to the Minister of Health, and governments generally, on issues pertaining to xenotransplantation.

Background

The Therapeutic Products Programme, Health Products and Food Branch, of Health Canada, is responsible for the safety and efficacy of therapeutic products, including xenotransplants (living cells, tissues and organs transplanted from animals into humans). The very breadth of the issues raised by xenotransplantation requires informed public dialogue with Canadians and consideration of their views and concerns in the development of appropriate policy by Health Canada. The Canadian Public Health Association is being funded by Health Canada to implement this broad consultation process.

Composition

Mandatory Membership Criteria

- Canadian (or landed immigrant)
- Demonstrated ability to be open to various perspectives on xenotransplantation
- Without financial or legal conflict of interest
- Able to commit to the term of office and activities

General Membership Criteria

- Overall balance of perspectives (see below)
- Merit based
- Desire for regional, linguistic and gender balance
- Include content and process expertise
- Willing to serve in a voluntary capacity
- Limited to 8 to 12 members

Perspectives

- Animal welfare
- Cultural diversity
- Faith or spiritual
- Health care professional
- Citizen representative
- Public health and safety
- Recipient

Observer Status

The following are designated observers of the Public Advisory Group:

- A member of the Therapeutic Products Programme Expert Advisory Committee on Xenograft Regulation (which provides expert advice to Health Canada on scientific and medical issues related to xenotransplantation)
- A representative of Health Canada
- A representative of the Canadian Public Health Association

Type of Committee

The Public Advisory Group is an ad hoc committee that will sunset following the synthesis of public input, evaluation of the process, and submission of the report to Health Canada.

Term of Office

The term of office will be from September 2000 to March 2002, subject to possible reappointment.

Activities

It is anticipated that the Public Advisory Group will meet face-to-face on four occasions during the term of office, will review documents and take part in telephone, fax or email communications.

Appendix 4

Conflict of Interest Statement - PAG

Preamble: The mandate of the Public Advisory Group (PAG) on Xenotransplantation is to develop recommendations on xenotransplantation based on input from Canadians. PAG members bring a variety of perspectives and skills to this task.

The PAG would be in a position of real or perceived conflict of interest if actions of individual members damage the work or integrity of the PAG.

Conflict of interest will be managed by ensuring that:

- there is a balance of perspectives in the decision-making process
- collective decisions of the PAG are presented
- the work of the PAG is transparent

Appendix 5

Citizen Forum Panelists

Saskatoon and area

Nichole Andre, civil engineer
 Dita N. Calayan, full-time mother
 Stacey Cameron, student
 Veronica Dagenais, retired
 Mervin Dahl, risk and insurance analyst
 Lori Dufort, teacher
 Norm Fagnou, member of the National Parole Board
 Darryl Fehr, commissioning coordinator
 Maureen Gammell, university administration
 Louis J. Lauzière, retired criminologist
 Terry McFaull, massage therapist and goldsmith
 Alfred W. Neufeldt, woodworker and farmer
 Lynne Panasiuk, mental health therapist
 Heather Panchuk, lab technologist in transfusion medicine
 Tim Rachev, staff at a centre for young offenders
 Michele Rajput, stay-at-home mother, Ph.D. in epidemiology
 Tarlochan S. Sidhu, university professor
 Donna Thomas, partner in a small business

Halifax/Dartmouth and area

Pierrette Bazinet, retired
 Heather Brooks, writer
 Kim Brown, stay-at-home mother
 Dorothy Carson, retired
 Ian Duncan, data processor
 Danny Dyke, full-time university student
 Rosemary Haley, retired senior compensation and benefits consultant
 Diane Hearn, registered nurse
 B. Sharon Johnston, self-employed
 Malcolm A. MacKay, retired
 Annette McPhee, support worker for adults who have mental challenges
 Robert Moore, pressman
 John Prescesky, pattern maker
 Blair Richards, CEO
 Paul Anthony Rodgers, Nova Scotia Film Development Corporation
 Elizabeth Stoddard, health care worker
 Eleanor Wright, medical laboratory technologist
 James R. Wright, retired scientist

Vancouver and area

Jonathan William Bean, student
 Bohdan Bodnar, company vice president, human resources
 Kirsten Chapman, administrator
 Shae Cooke-Aronetz, marketing representative and instructor
 A university graduate student (chose to remain anonymous)
 Angela Fok, sales and marketing
 Rose Marie Fournier, retired health care educator
 Jas Khattra, research technician in genetics
 Dieter J. Meiners, retired

David Naylor, accountant
 Jennifer Pascoe, community nurse
 Fred Scheuermann, retired
 Sandy Singers, residential care attendant
 John D. Turnbull, retired
 Susan Vishloff, homemaker
 Godwin Wijesinghe, retired

Toronto and area

Danilo M. Baluyot, logistics manager
 James E. Carter, e-commerce consultant/business analyst
 Raymond N. Cauchi, retired aircraft engineer
 Joan Desmarais, housewife and former medical receptionist
 Michael Doiron, computer systems consultant
 Christine Farrugia, small animal veterinarian
 Sharon Gaydos, secondary school teacher (family studies & science)
 Alex Harvey, business executive
 Walter Hein, self-employed
 Sunil Kashyap, industrial maintenance mechanic
 Ted Kung, office supervisor in the public sector
 Bonnie Lavigne, office administrator
 Majo Li Ying, administrative assistant
 Patricia Matthews, retired secondary school teacher
 Doreen Reed, caregiver and retired secretary
 Steven G. Tomosvary, retired civil engineer

Quebec City and area

Pauline Bélanger, homemaker
 Suzanne Blanchet (no occupation given)
 Alain Cloutier (asked that occupation remain confidential)
 Jacques Côté, forestry engineer
 Susan Doyle, representative
 Émile Émond, retired director of a health care establishment
 Steeve Gagné, computer analyst and project officer
 Julie Goulet, financial advisor
 Colette Guénette, retired
 Denyse Lafontaine, public and mental health nurse
 Jacques Lévesque, meter reader for Hydro-Quebec
 Éleine Nolet, paralegal
 Robert Rioux, retired Quebec civil servant in the field of communications
 Rachel Tremblay, public servant
 Ovila Veilleux, pensioner
 Lorraine Vermette, acupuncturist

Yellowknife and area

Nancy Anderson, public servant
 Liz Bailey-Hopf, representative of Native Women's Association of the NWT
 Paul Berthelet, semi-retired management consultant
 Loc Bui, self-employed
 Alan Cash, public servant
 Rebekah Clarke, project assistant with the Northwest Territories Dept. of Transportation
 Meaghan Fisher, student and part-time cashier
 Karen Fulmore, nurse with the Aboriginal Nurses Association of the NWT
 Bertha Harman, nurse with the Aboriginal Nurses

Association of the NWT
Bill Hoggarth, public servant
Edward Hornby, public servant (district manager)
Bryan C. Imray, retired physics teacher and school
administrator
Marianne Kardash, senior project officer
Fred Keetch, retired
Werner Klinger, airport electrician
Jocelyne LeBlanc Boulet, teacher and website provider
Rick Maddeaux, public servant
Jennifer Marchant, property management
Alphonsine McNeely, member of the Native Women's
Association of the NWT
Jemma M. Rivera, psychology student, public servant
Barb Round, nurse recruiter
Tammy Saunders, data processing and customer
service
Rebecca Veinott, lawyer

Appendix 6

Citizen Forum Experts

Saskatoon Citizen Forum

Animal Welfare

Dr. Ernest Olfert is director of the Animal Resources Centre at the University of Saskatchewan and is responsible for administration of the university's program for ensuring the well-being and welfare of animals used for research, teaching and testing. He is also an associate professor with the Department of Veterinary Pathology.

Ethics

Fr. Mark Miller works half-time as a bioethicist for St. Paul's Hospital, Saskatoon. He is currently teaching a course in religious studies at St. Thomas More College and assisting in the ethics course for medical students at the University of Saskatchewan. He has presented numerous workshops on a variety of moral issues for Catholic teachers, other educators and health care personnel.

Infectious Disease

Dr. Lorne Babiuk is director of the Veterinary Infectious Disease Organization in Saskatoon, an organization recognized for its role in the use of biotechnology to develop veterinary vaccines. His special areas of research are in molecular virology, vaccinology, immunology and viral pathogenesis. Recent interests include novel vaccine development and helping to set science policy in Canada.

Legal

Professor Brent Windwick is executive director of the Health Law Institute at the University of Alberta. Since joining the Institute, he has taught in numerous university faculties or departments, including law, medicine, pharmacy, dentistry, rehabilitation medicine and public health sciences. He has also participated in a variety of health law and health policy reform activities.

Transplant Recipient

Mr. Bernard Bitz received a double lung transplant in July 2000 after a 17-month wait. He is a member of the North Saskatchewan Chapter of the Canadian Cystic Fibrosis Foundation and currently serves as that Chapter's representative to the Saskatchewan Coalition for Organ Donor Awareness. Mr. Bitz is a lawyer and resides in Saskatoon.

Transplantation

Dr. Ahmed Shoker is head of the division of Nephrology at Royal University Hospital in Saskatoon. He is also director of the Saskatchewan Transplant Program and a professor of medicine. His professional practice in nephrology and kidney transplantation involves clinical duties and research. Within the last year, his department performed 39 kidney transplants.

Halifax Citizen Forum

Animal Welfare

Ms. Beth MacKenzie-Kent has been active in animal welfare for 20 years. She is president of the Nova Scotia Humane Society and has been a board member of the Society for the Prevention of Cruelty to Animals, the Shelter for Helpless Animals in Distress, and the Canadian Wolf Research Centre.

Ethics

Dr. Carolyn Ells is a lecturer in the Department of Bioethics at Dalhousie University. She coordinates activities under the Cooperative Venture in Health Care Ethics which is a partnership program between the university's Department of Bioethics and Health Law Institute, the Nova Scotia Hospital and two health centres. Her research interests include organizational ethics, ethics and health policy, and the intersection of personal and social decision-making.

Infectious Disease

Dr. Spencer Lee is professor of the Department of Microbiology and Immunology and the Division of Infectious Diseases, Department of Medicine, Dalhousie University. He is the director of the virology/immunology diagnostic laboratory at Queen Elizabeth II Health Sciences Centre and co-director of the National Centre for Enteroviruses at the Canadian Health Science Centre for Human and Animal Health, Health Canada.

Legal

Professor Elaine Gibson is associate director of the Health Law Institute and associate professor of law at Dalhousie Law Faculty. She chairs the Psychiatric Facilities Review Board for Nova Scotia, which reviews the civil commitment and capacity to consent to treatment of psychiatric patients. She recently completed a report for Health Canada on the legal, ethical, economic, and rehabilitative aspects of government provision of HIV drugs.

Transplant Recipient

Ms. Jackie Jayasinghe received a kidney transplant from her brother in September 1995. She was diagnosed with chronic renal failure in 1982, when she was entering the Bachelor of Nursing program at Dalhousie University. In August 2000 she won four medals in the first Canadian Transplant Games. She is working towards her Master's in Nursing and her thesis focuses on experiences of female renal transplant recipients.

Transplantation

Dr. James Wright is a pediatric/perinatal pathologist at the Izaak Walton Killam Health Centre and a professor of pathology at Dalhousie University's Faculty of Medicine. A current research focus is the genetic engineering of

insulin-producing cells for xenotransplantation. He was a member of Health Canada's Expert Working Group on Safety Standards for Xenotransplantation that drafted the Proposed Standard for Xenotransplantation.

Vancouver Citizen Forum

Animal Welfare

Dr. Jim Love is the director of the Animal Care Centre at the University of British Columbia, which is closely allied with the Animal Welfare Programme at UBC. He has been involved in many Canadian Council on Animal Care assessment visits across the country.

Ethics

Dr. Paddy Rodney is assistant professor with the University of Victoria's School of Nursing. She is also a faculty associate with the UBC Centre for Applied Ethics, a research associate with Providence Health Care Ethics Services, and a member of the Canadian Nurses' Association Advisory Committee on Ethics.

Infectious Disease

Dr. William Bowie is a professor of Medicine at the University of British Columbia in the Division of Infectious Diseases. Much of his work has been related to public health aspects of infections including those arising from, or spread by, animals, travel or sexual activity.

Legal

Ms. Gail Poole is a lawyer who teaches health law at the University of Victoria in the Faculty of Law and the Department of Health Information Sciences. She has been a teacher and consultant in health care ethics in Victoria, Chicago and throughout Alberta.

Transplant Recipient

Mr. Peter Quinn received a new heart in 1998 because of severe heart problems. He had been on leave from his position as a controller with the Income Tax Department since 1992. Today he volunteers with the B.C. Transplant Society, speaking on behalf of transplantation and the organ donor registry system.

Transplantation

Dr. Karim Qayumi is a professor of surgery and director of research for the Divisions of Thoracic and Cardiovascular Surgery, UBC. He is director of the UBC Centre of Excellence for Surgical Education, program director of the BC Transplant Society's Transplant Biology Unit, senior scientist for the Medical Research Council of Canada, and editor-in-chief of the Journal of Investigative Surgery.

Toronto Citizen Forum

Animal Welfare

Ms. Liz White is a director at the Animal Alliance of Canada, an organization committed to the protection of all animals and to the promotion of a harmonious

relationship among people, animals and the environment.

Ethics

Dr. Kerry Bowman is a clinical ethicist at Mount Sinai Hospital in Toronto and the University of Toronto's Joint Centre for Bioethics. He is an assistant professor in Family and Community Medicine at the University of Toronto. Dr. Bowman lectures on ethics in health care, mediation, end-of-life care and cultural diversity.

Infectious Disease

Dr. Atul Humar is an infectious disease physician at the Toronto General Hospital, University Health Network. His area of specialty is infection in organ transplant recipients. He is also affiliated with the Multi-Organ Transplant Program at the University Health Network.

Legal

Ms. Megan Evans is a lawyer in the health law group at the law firm of Cassels Brock & Blackwell LLP. She advises hospitals and other health care-related corporations, associations and foundations on a broad range of legal and policy issues. She has a strong interest in legal issues pertaining to medical ethics.

Transplant Recipient

Ms. Sandra Holdsworth received a liver transplant in February 1997. She is the national membership secretary and Ontario vice-president for the Canadian Transplant Association. As a member of CTA's Dragonboat Team, she won a bronze medal at the World Games in Budapest in 1999 as well as one silver and four gold medals at the Canadian Games in Quebec in 2000.

Transplantation

Dr. Gary Levy is the director of the Multi-Organ Transplant Program at the University of Toronto and the Toronto General Hospital, and the director of the University's Division of Gastroenterology. Dr. Levy recently participated in an international multi-centre pre-clinical study of transgenic porcine kidneys in xenotransplantation.

Quebec City Citizen Forum

Animal Welfare

Dr. Renée Bergeron is an associate professor in the department of Animal Sciences at Laval University. Her research activities focus primarily on the welfare of farm animals, particularly the porcine species. She sits on the local committee for the protection of animals at Laval University.

Ethics

Dr. Jocelyne St-Arnaud is an associate professor at the University of Montreal. She teaches ethics and bioethics in the Faculty of Nursing Sciences. Dr. St-Arnaud sits on a number of ethics committees and leads research in various ethical issues.

Infectious Disease

Dr. Suzanne Claveau is head of the microbiology and infectious disease service at the Centre Hospitalier Universitaire de Québec. She is an associate professor at Laval University and her interests include HIV infection, nephrology, kidney transplantation, hematology-oncology and radiotherapy.

Legal

Dr. Pierre Deschamps is an assistant professor with the Faculty of Law, McGill University. He is a member of the ethics research committee of the Cardiology Institute of Montreal and of the Faculty of Medicine at McGill. He was named to the Order of Canada in 1999.

Transplant Recipient

Unable to attend.

Transplantation

Dr. Réal Noël heads the nephrology service of the kidney transplant unit at the Centre Hospitalier Universitaire de Québec. He is also a professor of medicine at Laval University.

Transplant Recipient

Ms. Joan Schollar received a liver transplant in November 1994. At the time, she was suffering from primary biliary cirrhosis. Joan is married with two children and one grandchild. She has lived in Yellowknife for 25 years.

Transplantation

Dr. Patricia Campbell is assistant professor in the Division of Nephrology and Immunology, University of Alberta. Dr. Campbell is a transplant nephrologist, medical consultant to the HLA laboratory and director of the Nephrology Training Program.

Yellowknife Citizen Forum*Animal Welfare*

Ms. Andrea Lemphers was the founding president of the Humane Society Yukon, serving in that capacity for 12 years. In 1998, Humane Society Yukon opened the first permanent animal shelter north of the 60th parallel. Last year, Ms. Lemphers organized the first seminar in the Canadian north on the link between animal abuse and human violence.

Ethics

Captain Karen Hoeft has served as an officer in The Salvation Army for the past 11 years in Yellowknife. She is chairperson of the Ethics Committee of the Stanton Regional Health Board. Captain Hoeft is a potential kidney donor as two of her sisters have a genetic kidney disease and her mother is a kidney transplant recipient.

Infectious Disease

Dr. Dan Gregson is associate professor in the departments of Pathology and Laboratory Medicine and Medicine, University of Calgary. He is also a medical microbiologist at Calgary Laboratory Services. He previously served on the Advisory Committee on Communicable Disease with the Ontario Ministry of Health.

Legal

Professor Brent Windwick is executive director of the Health Law Institute at the University of Alberta. Since joining the Institute, he has taught in numerous university faculties or departments, including law, medicine, pharmacy, dentistry, rehabilitation medicine and public health sciences. He has also participated in a variety of health law and health policy reform activities.

Appendix 7

Presentations by Experts

Issues generally covered by expert presenters at the citizen forums.

Transplant

- The need for organs is immense and demand far exceeds supply
- Must raise awareness of this situation
- Potential benefits of xenotransplantation: greater supply of organs for transplant; transplantation could be offered to a wider range of people; better ability to plan; potential cost saving
- Barriers: organ rejection; different biochemical processes in different species; difficult to know if xenotransplants are viable; genetic modification
- Alternatives to xenotransplantation: increase organ donor pool; pursue stem cell research; develop national organ sharing network; improve existing procedures, e.g. dialysis; preventive health measures
- Feasibility of xenotransplantation: move forward with research; scientific discovery involves taking risks

Infectious Disease

- Risks involve individuals and society as a whole
- There are examples of cross-species transmission of serious infection to humans
- Infection could be direct or an unpredictable recombination event (genetic fragments combine to result in some other event)
- Immuno-suppression increases the risk of infections
- Of greatest concern: unknown viruses
- Reducing risk: use non-primates; raise segregated, pathogen-free animals; have infection surveillance and control programs in place; monitor to detect new agents that may emerge
- Risks versus benefits must be carefully weighed

Legal

- There are no statutes designed to address xenotransplantation
- Current laws pose serious barriers to the pursuit of xenotransplantation
- Regulation is inevitable; current law is a poor “fit”; law reform will likely be required
- Consent issue is the cornerstone of all medical treatment and there are strict criteria for consent in Canadian law
- There are issues of withdrawal of consent and societal consent
- Xenotransplantation would involve impositions on individual rights; challenge to the Charter of Rights and Freedoms is predictable
- A legal framework for non-medical issues would be difficult to achieve, e.g. long-term monitoring of the recipient and close contacts

Ethics

- Core ethical principles need to be considered such as:
 - Autonomy, i.e. a person’s right to hold views and make decisions; there is a conflict between public safety and personal choice that needs to be resolved
 - Beneficence, i.e. being of benefit to others; benefits versus risk
 - Nonmaleficence, i.e. the obligation to avoid inflicting harm on others
 - Justice, i.e. fair and equal treatment for all; equality of access to xenotransplantation
 - Informed consent; individual versus societal consent
 - Animal rights; the acceptability of the use of animals as a source of organs; genetic manipulation
 - Public participation creates a positive moral climate for health care delivery

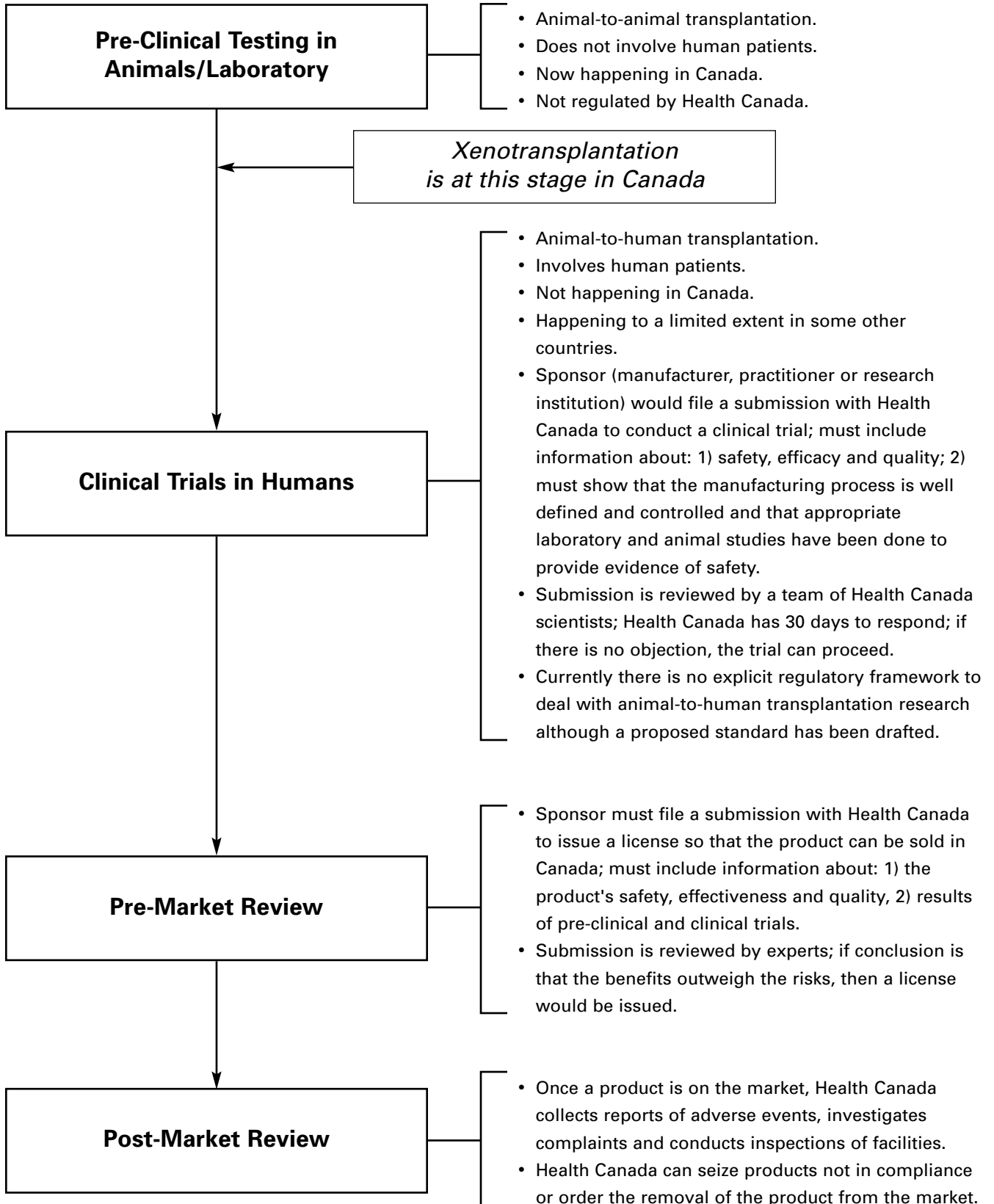
Animal Welfare

- There are animal health and welfare issues associated with xenotransplantation
- Council on Animal Care (CCAC) sets the standard for the care and use of animals in research, teaching and testing in Canada
- Publicly funded institutions must be part of the CCAC but private and commercial companies have the option to subscribe; could be a concern if the development and production of transgenic animals becomes a private industry in Canada
- The public must be confident that animals receive the fullest protection possible
- Programmes must be adequately funded
- Two welfare/ethical concerns: potential for serious complications/undesirable consequences as a result of new genes; waste involved in creating transgenic animals
- Two animal welfare experts voiced opposition to xenotransplantation clinical trials and a third stated “just because we can do it does not mean we should do it”

Transplant Recipient

- If no risks existed, and if the chance of getting a human transplant was bleak, it might be tempting to accept an organ from a pig
- Xenotransplantation would be acceptable as a last resort solution for a dying person
- Patients may need someone to protect them from their own desperation
- If a xenotransplant was the only hope for survival, “I would take that chance”
- “Never say never”
- Now, it is up to society to decide

Appendix 8 Regulatory Framework



Appendix 9

Final positions—Citizen forums

City	Position	# Panelists holding that position
Saskatoon	No, never...	3
	No, not now...	3
	Very cautious yes, only if...	5
	Yes, when...	7
Halifax	No, under no conditions	4
	Not now...Ask again later	6
	Yes, with these conditions	8
Vancouver	Absolute no	8
	No, but...(a)	4
	No, but...(b)	2
	Conditional yes to cell and tissue research. No to organ research	2
Toronto	No	5
	No, but if it goes ahead the following should be addressed	1
	Yes, but not until at least 5 years, and with the following limitations and conditions	4
	Yes, proceed with these conditions	5
	Left early	1
Quebec City	Definite no	8
	No, because...	1
	No, not now but reserving the right to re-evaluate when the proper conditions are met	3
	Yes, provided that...	4
Yellowknife	No	9
	Cautious yes	7
	Yes, with these recommendations	7

Appendix 10

Evolution of opinions - citizen forum panelists

Location	Position	Orientation Session #	After Day 1 #	After Day 2 #
Saskatoon	Unsure/no response	n/a	2	-
	No	n/a	3	3
	Qualified no	n/a	1	3
	Qualified yes	n/a	11	12
	Yes	n/a	1	-
Halifax	Unsure/no response	n/a	-	-
	No	n/a	6	4
	Qualified no	n/a	5	6
	Qualified yes	n/a	5	8
	Yes	n/a	2	-
Vancouver	Unsure/no response	n/a	-	-
	No	n/a	7	8
	Qualified no	n/a	3	6
	Qualified yes	n/a	6	2
	Yes	n/a	-	-
Toronto	Unsure/no response	2	-	1
	No	3	3	5
	Qualified no	-	5	1
	Qualified yes	10	7	9
	Yes	1	1	-
Quebec City	Unsure/no response	3	1	-
	No	6	5	8
	Qualified no	3	5	4
	Qualified yes	4	5	4
	Yes	-	-	-
Yellowknife	Unsure/no response	5	2	-
	No	2	6	9
	Qualified no	1	2	-
	Qualified yes	13	13	14
	Yes	2	-	-
Summary	Positions	%	%	%
	Unsure/no response	18	5	1
	No	20	28	34
	Qualified no	7	19	19
	Qualified yes	50	44	46
	Yes	5	4	-

Appendix 11

Other Data

122 members of the general public expressed their opinions on xenotransplantation through letters, e-mails and at the public session of the citizen forums. 83.6% were clearly opposed to Canada proceeding with xenotransplantation, 4.1% expressed qualified approval, and 12.3% were clearly in support.

Of the 102 clearly opposed, 30.3% were against using animals for this procedure; 18.6% mentioned ethical concerns; 13.7% supported alternatives to xenotransplantation; 6.9% thought the risks were too great; 5.9% thought funding should be directed elsewhere; 4.9% were worried about the cost-benefit ratio; 4.9% expressed distrust in the system and fears of conflicts of interest; 2.9% had doubts about the quality of life after xenotransplantation; 2% had environmental concerns; 1% commented on xenotransplantation research; 1% specifically mentioned lack of regulations and legislation; and 7.8% did not specify the reasons for their opposition.

Of the 5 people who gave qualified approval, 2 thought the risks were too great; 1 had ethical concerns; 1 was worried about the cost; and 1 was against using animals for this purpose.

Of the 15 people who expressed clear support, 46.7% said they believed the benefits were worth the cost and 20% did not specify the reason for their support. The balance (5 persons) each mentioned an issue of concern: ethics; pursuing alternatives; lack of regulations and legislation; need for research; quality of life.

Appendix 12

Important factors in shaping views – telephone survey

The final question in the telephone survey rated the importance of personal views on different aspects of xenotransplantation. Respondents rated “views about the importance of saving human lives” (87%) and “views about the individual’s right to choose a health care option” (85%) as most important in determining their overall views about xenotransplantation.

Question:

How important are each of the following in determining your overall views about xenotransplantation (1 “not at all important” ⇒ 10 “very important”).

- Your views about animal welfare
- Your views about the risks of xenotransplantation
- Your views about the individual’s right to choose a health care option
- Your views about health care costs
- Your views about respecting nature’s boundaries
- Your views about the importance of saving human lives

Relative Importance of personal views
(in percentages)

