

EXECUTIVE SUMMARY

Animal-to-human transplantation: Should Canada proceed?

A public consultation on xenotransplantation



Canadian Public Health Association

© December 2001 by the Canadian Public Health Association

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

ISBN 1-894324-21-8

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
400-1565 Carling Avenue
Ottawa, Ontario, Canada, K1Z 8R1

Canadian Public Health Association

Sylvia Fanjoy, Project Director
Randi Goddard, Project/Conference Officer
Christian Boudreau, Project Assistant

French Translation: Sylvie Lee

The full report is available on the consultation website <http://www.xeno.cpha.ca> or through <http://www.cpha.ca>

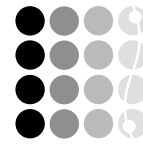
This consultation was funded by Health Canada. The views expressed in this report are those of the Public Advisory Group, and are based on consultations with a broad sector of the Canadian public. They do not necessarily represent the official policy or views of [Health Canada](#) or the Canadian Public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

January 7, 2002

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

Public Consultation on

XENOTRANSPLANTATION



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

EXECUTIVE SUMMARY

There is a critical shortage of organ and tissue donors in Canada and many people die while waiting for a transplant. 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.

Currently in Canada, xenotransplantation studies are being carried out using laboratory animals. These pre-clinical or experimental trials do not involve human patients and are not regulated by Health Canada. A request to conduct clinical trials with human patients could be submitted to Health Canada at any time.

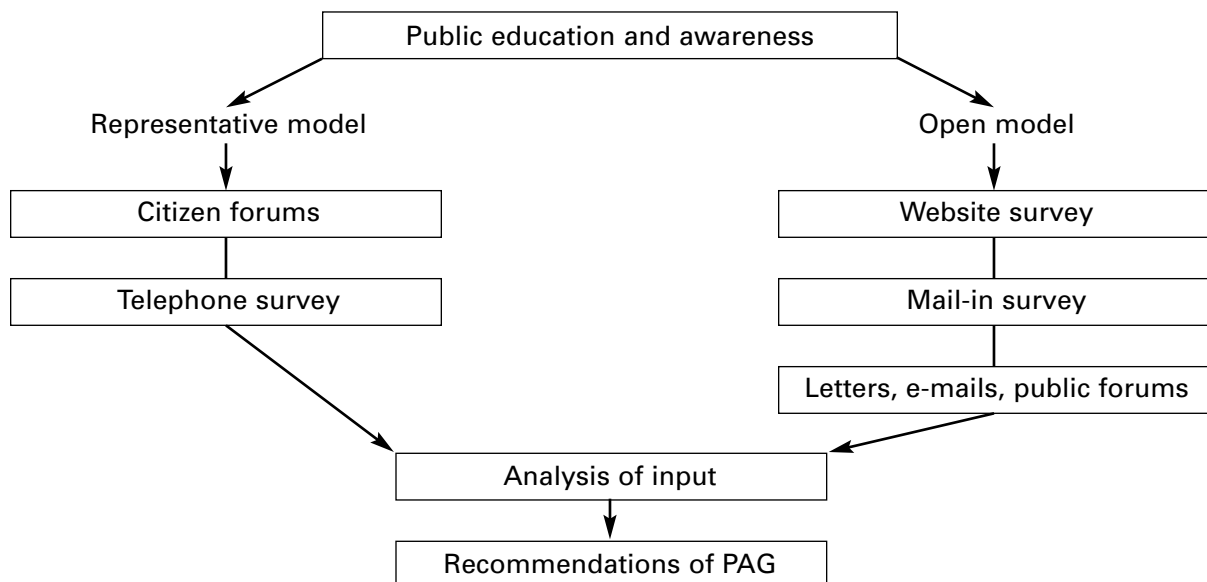
Xenotransplantation raises complex health, ethical, legal, economic, and social issues. Health Canada decided the Canadian public should be involved in answering the overarching question:

“Should Canada proceed with xenotransplantation, and if so, under what conditions?” To that end, Health Canada provided funding to the Canadian Public Health Association to strike a Public Advisory Group (PAG), to conduct an arm’s length public consultation, and to report back to the Minister of Health. Members of the PAG represent a diversity of perspectives, regions and interests.

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

The Public Advisory Group developed two consultation models to determine Canadian views on xenotransplantation (Figure 1). The open model was designed to promote input from any and all Canadians through surveys, letters and e-mails. The representative model drew opinions from specific individuals—panelists at citizen

FIGURE 1
Consultation framework



forums and respondents to a national telephone survey—who could be said to represent Canadian citizens. A public awareness and education campaign was initiated to inform the public of the consultation. Components of the campaign were: two mass mailings, a consultation website and a media and public awareness strategy, all of which were geared to heighten awareness about xenotransplantation issues and the consultation process. Challenging aspects of the consultation were the complexity of xenotransplantation issues, limited public knowledge, time constraints, and budget.

Elements of the consultation framework

Four samples completed a detailed survey. The first three samples (citizen forums, mail-in survey, website survey) were encouraged to read a background paper on xenotransplantation issues before completing the survey.

Sample 1: Citizen forums

Six citizen forums, involving 107 panelists, were held in Saskatoon, Halifax, Vancouver, Toronto, Quebec City 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 the panelists on the overarching question as recorded in proceedings and results of a survey completed by 73 of the panelists.

Sample 2: Mail-in survey

The survey was mailed to approximately 3,700 organizations that cover a broad range of interests such as animal welfare, faith, cultural, human rights, industry, legal, health and safety, consumer, organ recipient, scientific, medical, seniors, youth, hospitals, governments, universities and colleges. 216 surveys were returned and make up this sample. These respondents could be considered “stakeholders.”

Sample 3: Website survey

The survey was posted on the project website, a site that carried a great deal of information on xenotransplantation. “We are seeking Canadian public opinion only” was stated clearly at the start of the survey so as to discourage international participation. The website was promoted through internet search engines, the media, a poster campaign and mailings. 367 website surveys were analyzed. These respondents could be described as members of the public who have an interest in xenotransplantation issues.

Sample 4: Telephone survey

The firm POLLARA drew a random 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. These were the least informed respondents, with 70% saying they were not very or not at all knowledgeable about xenotransplantation.

Responses

The responses to the overarching question are in [Table 1](#). 65% of respondents in the telephone survey said Canada should proceed with xenotransplantation. This representative sample provided information on what Canadians with little knowledge of xenotransplantation would say about Canada proceeding.

The “stakeholder” (mail-in) and website samples were assumed to be more knowledgeable of xenotransplantation issues although this was not measurable. Both samples were encouraged to read the key issues paper as well as information posted on the consultation website. In these samples, 39% of the mail-in surveys and 26% of the website surveys said Canada should proceed.

The citizen forum panelists were representative of the Canadian public (although with higher than average education and income levels) and, at the end of the forums, had a deep understanding of

TABLE 1
Should Canada proceed with xenotransplantation?

Position:	Representative Model					Open Model		
	Telephone survey	CITIZEN FORUMS				Mail-in survey	Website survey	Letters and public forums
		Orienta-tion	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	-

xenotransplantation issues. At the end of the forums, 46% of the panelists said Canada should proceed but all of them qualified their response with conditions such as the need for stringent and transparent legislation and regulations.

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 2). 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. 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 forums clearly demonstrate that “ordinary” citizens can grapple with difficult policy issues and that education and discussion can lead to shifts in position. 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. At the end of the forums, 34% of the panelists said “no,” Canada should not proceed (which they said means never); 19% said “no with qualifications” (which means no, not now, but possibly in the future); and 46% said “yes.” All those who said “yes” qualified their response with conditions. One panelist (1%) had to leave early so his final position was not recorded.

Recommendation

The Public Advisory Group recommends that the citizen forum model be used in future consultations on complex and not widely understood policy issues.

Essential elements of the citizen forum model are:

- 1) education (in this consultation, education included reading materials prior to the forum and discussions with six experts);
- 2) understanding various positions through discussion, interaction and deliberation; and
- 3) continual focus on the overarching question in order to maintain an effective process.

TABLE 2
Positions on the question: Should Canada proceed?
Variations with levels of knowledge, representative samples

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

Critical Issues

When considering whether to proceed with xenotransplantation, Canadians consistently raised issues around health risks, strategies to address the organ shortage, and legislation and regulations.

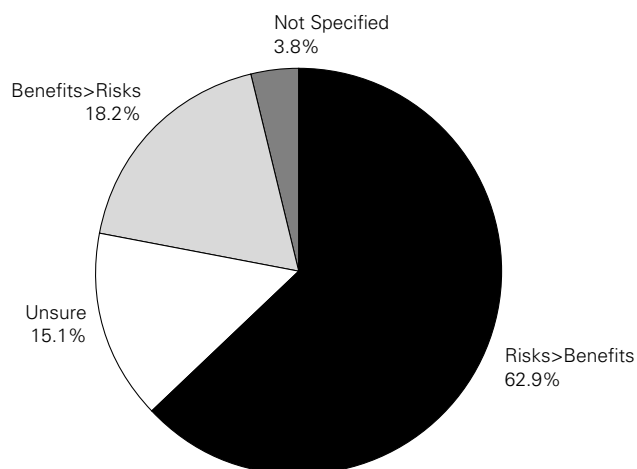
Health risk

Health risk is the paramount concern with xenotransplantation. This was generally expressed as concern about the risk of zoonotic disease (an animal disease transferred to humans) from infection by known and unknown viruses, and the fear that this could lead to a large-scale epidemic. Many informed Canadians said that those who wish to proceed with xenotransplantation should be responsible for establishing the level of risk. Lack of knowledge and inadequate regulations heightened risk concerns. The more informed respondents (citizen forum survey, mail-in survey and website survey) said the risks of xenotransplantation outweigh the benefits (62.9%) (Figure 2). Women were significantly more likely than men to say the risks outweigh the benefits.

FIGURE 2

Do the benefits of xenotransplantation outweigh the risks?

(Citizen forum/mail-in/website surveys)



Strategies to address the organ shortage

Xenotransplantation was consistently rated as the least acceptable strategy to address the organ shortage, with preventative approaches receiving the highest rating, followed by expanding the current donor pool, mechanical substitutes, stem cells, and presumed consent. Citizen forum panelists called for more public information on organ and tissue donation, healthy lifestyles, disease prevention and disease management. Some indicated a need to raise public awareness about underlying social issues. Others suggested offering financial incentives for organ donation, establishing a national organ registry, improving the organ transport system and exploring the feasibility of legislating presumed consent.

Legislation and regulations

Most Canadians who were in favour of proceeding said stringent and transparent legislation and regulations covering all aspects of clinical trials must be in place before xenotransplantation is undertaken. Strict regulation of research practices (both human and animal), public education and designated centres of expertise are measures that could be taken that would most reassure Canadians about xenotransplantation. Citizen forum panelists said a legal framework is needed and should include research protocols, an accountability structure, multidisciplinary ethics committees, a “watchdog” responsible for good clinical practice and a procedure to ensure informed consent.

Other Considerations

Canadians who participated in this consultation consistently raised the following issues:

Funding

Relatively few Canadians support the redirection of health care dollars to xenotransplantation, generally because of scarce funds, high costs, and other priorities. Those who said “yes” to redirecting funds usually cautioned that first there must be more research, the procedure must be proven viable, and it must be well regulated.

Current knowledge

There is a need for increased knowledge, both scientific and public. It was widely agreed that more research is needed on potential health risks associated with xenotransplantation, the viability of the procedure and the consequences of genetic modification. The comfort level of Canadians with xenotransplantation would be greater if the public was supplied with ongoing information. At present, public knowledge of xenotransplantation is unacceptably low.

Animal welfare

While there was modest support for the use of animals in medical research (this support varied significantly across samples), support for animal research in the context of xenotransplantation was lower. Some citizen forum panelists wondered if animals would be humanely treated. A few questioned the ethics of raising animals for “spare parts”. Some said clear rules and regulations on the use of animals in privately and publicly funded research would be needed.

Ethics

Ethical concerns tended to be general in nature, with a few citizen forum panelists asking about the right of humans to meddle with nature or to use animals for their benefit. Some panelists asked how eligibility for a human versus an animal organ would be determined and others said that we must learn to accept death.

International involvement

Canadians clearly want a made-in-Canada approach to xenotransplantation. The majority said Canada should not be influenced, or should be minimally influenced, by decisions taken by foreign governments. Some citizen forum panelists said Canada should take a leadership role internationally by promoting alternatives. Others said it was important to monitor activities worldwide and to share new technology and research.

Recommendation

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.

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. 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 knowledge is insufficient, regulations are inadequate, and other alternatives are more worthy of support.