The project "Impact of Citizen Participation on Decision-Making in a Knowledge Intensive Policy Field" (CIT-PART), Contract Number: SSH-CT-2008-225327, is funded by the European Commission within the 7th Framework Programme for Research – Socioeconomic Sciences and Humanities. We would like to thank the Commission for its contribution. The project runs from 2009 to 2011. For more details see: www.cit-part.at
# Contents

1 Introduction 7

2 The Canadian Political System 8

3 Biotechnology and Biomedical Innovation as Arena for Policy Development 12

4 Xenotransplantation: a Site for Policy Development and Participatory Technology Assessment 14
   4.1 Health Canada and the Therapeutic Products Programme (TPP) ............................... 14
   4.2 The National Forum ........................................................................................................ 16
   4.3 Health Canada Surveillance Workshop ............................................................................ 22
   4.4 Public Engagement Planning Workshop ........................................................................... 23
   4.5 The Arms-length Public Consultations through the Canadian Public Health Association (CPHA) and Public Advisory Group .................................................................................. 24
   4.6 Outcomes .......................................................................................................................... 31

5 The Meanings of Impact on XTP Policy 32
   5.1 Impacts in the literature .................................................................................................... 32
   5.2 Learning as institutional impact ....................................................................................... 33
   5.3 Description of Canadian public consultation .................................................................... 35
   5.4 Outcomes .......................................................................................................................... 35
   5.5 Analysis: Institutional learning as impact ......................................................................... 38

6 Conclusion 43

7 References 45

8 Abbreviations 49

9 XTP Canadian Policy Chronology 50

10 List of Interviewees 52
   10.1 Policy Analysis & Regulation ....................................................................................... 52
   10.2 Citizen Groups: Patient advocacy, animal rights/welfare, XTP science .......................... 52
1 Introduction

New technologies that are considered critical to a country have historically been adopted on the basis of scientific or technical adjudication. This simple linear diffusion and adoption process has been increasingly difficult as new technologies considered strategic or critical to innovation paths have evolved in more public arenas, typically situated at the intersection of technical and social forces. Concepts of risk and how to manage their constructions and perceptions, competing social values, changing networks of social mobilization have all contributed to changing the dynamics of technological governance.

Such is the story of xenotransplantation (hereafter XTP) in different national contexts. Here we recount the evolution of this technology’s storyline in Canada, particularly as its development has been navigated through the lens of public involvement. We start with a brief description of the general political context, then trace the more specific context of the evolution of biotechnology and biomedical policy, then move to this report’s central foci: an accounting of how XTP policy developed through the engagement of different publics and an explanation of how the engagement of citizens and other stakeholders led to a policy outcome that may have been unexpected. We end with theorizing on the multiple meanings of “policy impacts” and suggest institutional learning as one important dimension.
2 The Canadian Political System

Canada’s constitution was passed in 1867 so the country’s political system is relatively “young”. It was not till 1931, however, when the British Parliament legally recognized the autonomy of its commonwealth countries. Canada is a constitutional monarchy as a member of the British Commonwealth, a ‘loose federation of independent states, with the (British) Queen still head of state but with extremely limited (mostly ceremonial) powers. However, it was not till 1982 that agreement was reached on a process for amending the constitution, meaning constitutional decisions would no longer have to be approved by the British parliament.

As is the case with most democracies, there are three branches of government: the executive, legislative and judicial. The executive branch is dominant in its relationship with the legislature, with most laws introduced and steered through parliament by the executive. The Canadian legislature features two chambers: the House of Commons (elected) and the Senate (unelected and appointed by the Governor-General on recommendations from the Prime Minister). The Canadian government is formed by the party which possesses a majority share of the seats in the House of Commons, with the House the more powerful chamber in the legislature. In the Senate, seats are assigned on a regional basis, with each of four major regions receiving 24 seats and the remainder being assigned to smaller regions.

Its political system functions within a framework of parliamentary democracy. Canada’s electoral system reflects the UK’s system which has been based on the ‘first-past-the-post’ system of voting as opposed to being based on proportional representation. While this might disadvantage protection of minority rights, the adoption of a Charter of Rights has helped to redress this problem.

Until the 1990’s, two parties – the Conservative and the Liberal – dominated parliament. Since the 1990’s, Canadian politics began to function more like a multi-party system. Four political parties have been in the House of Commons for the last decade and a half. The dominant or majority party has typically been either the Liberal or Conservative party for a long time but in recent years, a minority government under the Conservatives has been in power. In the most recent election, the Conservatives have now gained majority position and the official opposition has been won by the New Democratic party, which had occupied the third place for a long time, and now displacing the Liberals.

In essence, Canada’s political system has some similarity with the British system, with a lower house of elected representatives and an upper chamber of appointed senators (appointed by the Prime Minister).
The courts are an important third branch of government, a branch that has assumed greater importance with passage of the Canadian Charter of Rights in 1981. This branch is supposed to provide interpretations to legislative decisions. The Supreme Court of Canada is the final court of appeal. The repatriation of the Canadian constitution and the adoption of a Charter of Rights in 1982 have made the courts more influential than they had been in the past. The courts have played major roles in interpreting rights as defined by this (relatively new) charter (the Canadian version of the US’ bill of rights). Increasingly, the courts have been used not just in a passive way (i.e., interpreting legislative pronouncements) but in a slightly more activist fashion, with court decisions also receiving greater public attention and discussion. Relevant decisions include biotechnology patent issues including agricultural biotechnology patent questions and the Harvard oncomouse issue.

There are ten provincial governments and three territories. The provincial governments are based along the same principles as the federal government system. The provincial governments are largely responsible for healthcare, education, two critical sectors, and a few other areas. The provincial governments enjoy sufficient power and responsibilities such that there is often tension between federal and provincial governments over such issues as healthcare funding and control of natural resources. One significant characteristic of Canadian politics is the importance of regionalism, a term that encompasses an acknowledgment of different interests and resources based on region.¹

While Canada has a strong central government, provincial powers provide a counterbalance (with provinces considered co-sovereign) and federal-provincial relations are occasionally contentious. Quebec often wants to preserve and strengthen its distinctive character and has done so through its language rights and immigration policies; western provinces typically want greater control over their natural resources, especially energy; Ontario is protective of its manufacturing base while the Atlantic regions try to strengthen their economic position within the country.

The civil service functions through departments, agencies, commissions, crown corporations and other federal organizations of which there are approximately 200 bodies with over 265,000 employees. It is large and plays a significant role in the provision of advice and expertise to the government and implementing government priorities. The civil service is officially bilingual.

Canadian political culture is a reflection of the confluence of North American and European political cultures, with its emphasis on constitutional law, and its geographical and social profiles. Its political culture and structures reflect British common law traditions as well as French civil law traditions (in Quebec). At the same time, the country’s particularities have led to an evolving identity that marks it as more than a product of this confluence. The

country’s social profile includes a mosaic of its aboriginal communities, its European-origin populations, and its more recent multi-cultural communities. The country’s aboriginal communities enjoy a measure of autonomy provided for by aboriginal self-government systems. The country’s immigration system has also made for a more diverse multi-cultural mix of diverse ethnic groups and all these dimensions tend to exercise some influence on consultation practices in terms of ensuring regional, linguistic, and aboriginal representation.

Canada has a pluralist interest group system which has been partially reflected in the consideration of various interests when policy-makers seek input into the policy process. At the same time that different interest groups might be represented in specific policy decision-making processes, this co-exists (sometimes uneasily) with particular goals that might be undertaken. For example, when the agriculture ministry developed its renewal policy called Growing Forward, many interest groups participated in such a process. At the same time, the strong emphasis on economic development and innovation as led to dominance of certain groups – in this case, agricultural groups -- to wield greater influence than others.

It is interesting to look at the symbolism behind and enactment of the stated goals of Canadian government, which is “peace, order, and good government”. This is often contrasted with the U.S.’ goals and values of “life, liberty, and the pursuit of happiness”. Canadian emphasis on traditions of loyalty, tolerance, and compromise, and greater trust in/deference to and reliance on government are expressions of its symbolic vision and identity construction. The contrast has often been made with neighbors to the south whose political identity has been forged through revolutions and confrontational change and Canadian representations of “tolerance, inclusion, and ‘official multiculturalism’ and not through the erasure of cultural difference.”

The tradition of liberalism is relatively recent in Canada with the creation of the Charter of Rights and Freedoms in 1981, a move that some consider a reflection of the U.S. political tradition’s bill of rights. This is balanced with other traditions such as universal health care, gun control, sexual identity rights that at the same time set it apart from the U.S. This balancing act of maintaining its culture and interests against the weight of its much larger (in term of population and economy) neighbor and largest trading partner remains a defining part of Canada’s social-political landscape and sense of self.

Canada has a tradition of political participation that is grounded in a growing civil society and a government bureaucracy that has attempted to be more open to participation by both stakeholder groups and the larger public. Its traditions and practices of consultation are often marked by two streams: multi-stakeholder consultations (where representation of different interests is carried out) and consultation of the “general public”. This bureaucracy remains strongly reliant on scientific and technical expertise but more recently, has tried to balance

---

such technical input with considerations of social values. The relationship between multi-
stakeholder groups and government elites has been characterized as “a series of mutually
beneficial exchanges of valued currencies of several kinds, including information, political
support, companionship, advice, and services.”

Traditions of public consultation are primarily associated with the commission of inquiry
model. The use of Royal Commissions as an instrument for policy reviews and policy change
include explicit mandates for providing representation “by providing access for individuals
and groups to a forum of debate and policy-making”. In addition to this tradition of public
consultation in Canada less resource-intensive forms (e.g. surveys, polls, stakeholder
meetings) have been utilized by government bodies throughout the years, particularly by
Health Canada (the Canadian ministry of health) which uses stakeholder consultations on a
regular basis during policy development. However, consultations tend to take the form of
advice rather than input with statutory implications. As one consultation organizer told us,
participants are not making decisions, they are giving advice. It needs to be clear at the
outset, however, exactly how that advice will be used (AL).

Direct democracy is not an important element in Canadian politics and there have been no
binding referenda in Canada. One notable exceptional national referendum was held in 1992
over what was known as the Charlottetown accord which would have allowed Quebec to be
a signatory to the constitution which had been repatriated from the British government a
decade earlier. Quebec was a non-signatory then. The Accord was defeated.

There is a relatively strong civil society in Canada. Many organizations are recognized as
important actors in advisory capacities and in the policy development and implementation
processes. Depending on the policy question, relevant civil society organizations can be
consulted within the multi-stakeholder consultation process or are invited to participate in
either or both policy development and implementation. The relationships between such
groups and government tend to be less conflictual and can be more collaborative than what
occurs in the U.S.

Science-society relations had been characterized in the past by the elevation of scientific
and technical expertise. However, this situation has increasingly been replaced with the
move away from a strictly “sound science” approach to one more open to recognition and
accommodation of social values.

---

3 Biotechnology and Biomedical Innovation as Arena for Policy Development

Canada’s biotechnology innovation efforts have been predominantly in two areas: agricultural and medical. While research and development efforts have been relatively contentious in the GM agriculture area, they had been relatively uncontentious in the biomedical area.

Since the early 1980’s, Canada developed a set of incentives to promote the development of the new biotechnology. While the emphasis in the beginning was on agricultural and environmental biotechnology, in the late 1980’s, the focus shifted to human health products and services.\(^5\)

Canadian biotechnology policy has been described as developing through three phases\(^6\): the first, in the early to late 1980’s, was described as explicitly promotive and driven by emphasis on supporting the Canadian economy by maximizing potential of new technologies. The second phase was characterized as focusing on the development of a science-based regulatory framework, covering the late 1980’s to the mid- to late ‘90s. Beginning in the late 1990’s to the present, the authors contend that an acknowledgment of the need for a biotechnology framework that addressed social and ethical dimensions became evident. An important marker at this time was the change in biotechnology advisory committees from the National Biotechnology Advisory Committee (NBAC) to the Canadian Biotechnology Advisory Committee. NBAC recommended a number of initiatives including tax incentives, revised intellectual property laws, facilitation of technology transfer between industry and universities, and greater networking with the international community. Greater coordination of biotechnology policies with Canada’s trading partners was also promoted.

The renewal of Canada’s national biotechnology strategy occurred in 1998, this time with the creation of the Canadian Biotechnology Advisory Committee whose mandate was “to provide comprehensive, independent expert advice on policy issues related to ethical, social regulatory, economic, scientific, environmental and health aspects of biotechnology, and to raise public awareness and engage Canadians in an informed discussion on biotechnology”.\(^7\)

However, the efforts to balance social-ethical considerations with the need to nurture economic goals through innovation areas such as biotechnology remains a struggle. While this was particularly true in agricultural biotechnology, it soon became evident as well in the


biomedical arena. An example of policy development in this area demonstrating a different struggle – this time between competing social values – was the effort to develop legislation around new reproductive technologies. When the Canadian Act respecting Assisted Human Reproduction and Related Research (AHR Act) came into effect in 2004, it was the culmination of some 15 years of policy development in this highly contentious area. It was at the same time an illustration of the challenges involved in the efforts of policy makers to keep policy and regulations up to date with scientific developments and the difficulties of balancing these advances with social-ethical considerations. It was also during the same third period referred to earlier when xenotransplantation emerged for policy consideration.

---

4 Xenotransplantation: a Site for Policy Development and Participatory Technology Assessment

4.1 Health Canada and the Therapeutic Products Programme (TPP)

Health Canada is the federal department responsible for ensuring Canadians maintain and improve their health.

“Our mission is to help people of Canada maintain and improve their health. In partnership with provincial and territorial governments, Health Canada provides national leadership to develop health policy, enforce health regulations, promote disease prevention and enhance healthy living for all Canadians. Health Canada ensures that health services are available and accessible to First Nations and Inuit communities. It also works closely with other federal departments, agencies and health stakeholders to reduce health and safety risks to Canadians”.  

Health Canada is the highest ministerial body overseeing the development of XTP in Canada. Under the direction of then Minister of Health, Allan Rock Health Canada and the Therapeutic Products Programme (TPP) were charged with developing appropriate policies on XTP. They were also responsible for informing and educating the Canadian public about the potential risks and benefits of XTP. Under the direction of the Minister of Health and the health ministry, TPP’s general mandate was two-fold:

- to ensure that new therapeutic products reach the health care system in a timely manner, and
- to regulate the sponsors of new therapeutic products.

An important political legacy that drove Health Canada’s public engagement activities on XTP was the significant public controversy in the mid 1990’s on the contamination of the blood supply. The Canadian Red Cross and the government were implicated in a regulatory failure where donated blood was not properly screened for a substantial period of the 1980s, and many patients receiving transfusions contracted HIV. Health Canada, as the ministry responsible for overseeing the safety of the blood supply, was the central target of criticism and the object of eroded public confidence and regulatory bodies were “looking to make sure they were a bit more pro-active in transplantation than they had been in blood” (AL). Another individual who worked within Health Canada during the same period noted that the organization was “super-sensitive” (KB) to the blood scandal: “there was huge political

---

9 Health Canada Website: “About Health Canada” (http://hc-sc.gc.ca/english/about/about.html)
10 TPP was separated (sometime before March 31, 2000) into the Therapeutic Products Directorate and the Biologic and Genetic Therapies Directorate, Health Products and Food Branch.
nervousness at that time regarding the introduction of scientific and technical advances, and great concern that any regulatory actions be taken with the greatest of caution” (KB). This motivated a shift in organizational culture towards a precautionary approach as a means to respond to mistrust in government as well as “the internal desire to be more open and transparent.” (KH).

XTP came to the forefront as an urgent issue as Health Canada became aware that some research groups were planning to submit applications to conduct limited clinical trials:

“...there was a sense that time was of the essence and these submissions would be imminent. And according to our regulations, a clinical trial submission had [by] default a 30 day review [period]. So it can only be rejected under certain criteria to not proceed, and so the implications of, of the government making a decision to not proceed with the clinical trial had significant implications for all parties concerned.” (KH)

A representative of the Health Products and Food Branch told us that the anticipation of these submissions “sparked a lot of discussion among our reviewers and also with our legal advisors as to what... did the Food and Drugs Act encompass” (KH). At that time, Health Canada did not have the appropriate expertise to address genetically modified animals and the potential for disease transmission to humans, and saw the need to recruit outside experts and to engage with the international policy community to ensure Canadians were protected (KB). These were rapidly evolving areas of science, and “contentious publicly and politically” (KB). An expert interdisciplinary panel was convened to discuss the foundation for a regulatory framework. This National Forum on XTP (discussed further below) in turn recommended that a public consultation process be implemented. These conditions set the stage for Canadian regulators to begin investigating options for public consultation on how to address the scientifically and ethically complex therapeutic technology of xenotransplantation. At the same time, Canadian regulators kept in close contact with their U.S. counterparts and also actively participated in international policy workshops sponsored variously by the WHO and the OECD.

On the legislative end, a parliamentary Standing Committee on Health, Organ and Tissue Donation and Transplantation was convened to address the issue of Canada’s organ and tissue donation rate, one of the lowest among western industrialized countries (Health Canada, 1999). To address this issue, the federal Minister of Health, Allan Rock, requested that the Standing Committee on Health broadly consult and provide advice on the appropriate role for the federal government in the development of national safety, outcome and process standards for organ and tissue donations, as well as in promoting public and professional awareness and knowledge regarding organ and tissue donation, procurement and transplantation.
The environment of caution and concern for public trust at that time also provided an opportunity for policy developers to innovate. One of the first moves of the individual charged with a key role in policy development was to create an internal network of linkages between groups because “it was truly a horizontal issue... xenotransplantation had implications for various areas of the organization” (KH). She also identified as essential a) a discussion of underlying values to drive the public involvement strategy, especially in light of the culture of a science-based organization where value judgments may be dismissed, and b) that the consultation be held at arm’s length from Health Canada, as “there wasn’t a high climate of trust, public trust in the government at that time. Because of the nature of the issue, the ethical and science issues... we didn’t want the public to perceive the process as being biased by involvement of Health Canada” (KH). It was decided that the consultation would be organized and run by the Canadian Public Health Association (CPHA), a non-government professional association, with a contribution of resources from Health Canada.

In the following sections, we describe the different key meetings or workshops which represented the major consultation steps undertaken by Health Canada and its partners towards the development of a regulatory framework for XTP. The first step was to convene an expert interdisciplinary committee, the National Forum on XTP which was co-chaired by an ethicist and a scientist. This was a recognition that the issue was not just scientific but also social-ethical. This meeting set the stage for two further consultation tracks: a public and stakeholder track and an expert consultation track running in parallel. The latter was designed to develop a regulatory framework at the same time that publics and stakeholders were also going to be consulted. Most likely for practical reasons emanating from the need to address what was seen to be imminent applications for clinical trials, the two consult tracks could not occur sequentially.

### 4.2 The National Forum

Health Canada and TPP began considering XTP issues in greater depth by sponsoring the Canadian National Forum on Xenotransplantation held in Ottawa November 6-8, 1997. This process within the bureaucracy began with Health Canada bringing together regulators, scientists, legal and ethics experts, and stakeholder communities which included animal welfare representatives. Its purpose was to “present information and initiate discussion on the risks, benefits and ethics of XT; to identify key regulatory issues; and define areas where research and new information is required (Health Canada, 1997). The co-chairing by an ethicist and a scientist was a recognition of the balancing act required for XTP issues. In addition to this gathering of experts, the forum report: National Forum on Xenotransplantation Clinical and Regulatory Issues indicated that the national forum was to be the first step in the public consultation process. During this forum, experts and stakeholders of the working committee recommended that a sub-committee be developed to start developing a draft framework for Canadian xenotransplantation standards. The sub-
committee that was subsequently created was comprised of experts representing various backgrounds including: clinical, ethical, scientific and regulatory specializations.

Discussions focused on whether XTP was intrinsically acceptable. Other areas of concern included conditions for informed consent and the risks to public health. The latter was reflected in the division among Forum members on the question of whether clinical trials ought to proceed. There was general agreement on the need for informed public debate and discussion as a necessary condition for proceeding on this front (Health Canada, 1997).

As a result of the attention raised during the National forum on XTP, the participants decided that future public consultations with the Canadian public would be necessary in order to educate the public and encourage discussion of all issues surrounding xenotransplantation. At this early point in time (1997), the Canadian Government’s perspective was that the public must be involved in all stages of discussion on these issues and have their perspectives incorporated into decision-making, as articulated by public pronouncements by the Minister of Health.

The primary recommendation from this forum was the creation of a National Advisory Board on XTP by Health Canada (which subsequently became known as the Public Advisory Board). It was decided that the board should include public representatives, patients, and experts. The primary reason for the board’s creation would be to interface with the Canadian public. The Canadian public was to be encouraged to submit their opinions about the report from this forum by mail, fax, or e-mail.

Interestingly, although one might expect the animal rights sector to be an obstructive vocal opposition to XTP, animal rights groups in Canada tend to have a more ‘moderate’ stance in comparison to their southern or transatlantic counterparts. This has been attributed to the structure of the Canadian Council on Animal Care (CCAC), a national organization responsible for setting and maintaining standards for the care and use of animals in science. This Council works in partnership with educators, veterinarians and delegates from industry and the animal welfare movement. For example, the Canadian Federation of Humane Societies (CFHS) and the Society for the Prevention of Cruelty to Animals (SPCA) have been partners with the CCAC since its inception (1968). Representatives of these groups write that the CCAC and the CFHS “have worked closely and constructively together over the past 40 years to ensure effective community representation at all levels of the Canadian

---

system for the ethical review and surveillance of animal used for scientific purposes.” The CCAC and CFHS have included community representation to ensure members of the public are involved in the decision-making process for the care and use of animals in science.

An animal rights organization, the Animal Alliance, does not share this welfare perspective of the CCAC, calling it “just a shelter and doing only a very tiny amount of advocacy on the part of animals” (LW). However, this organization has had little prominence in the public arena, neither employing the shock and shaming tactics prominent among animal rights activists in the UK nor using legal strategies that have also been important tools among UK and US activists to bring public bodies to account. Despite the frustrations felt by animal rights groups in Canada, participants in the public participation process maintained that animal rights organizations had a strong voice. Health Canada noted the presence of animal rights groups in the national forum as indicative of its broad representation (AL, LL). At the same time, Canadian animal rights organizations see the freedom-of-information legislation in the United States as providing easier access “to information to find out what’s going on in research laboratories whereas it’s virtually impossible to find anything out in Canada” (LW). Informally known as “sunshine laws”, these are designed to protect the right to data or information held by the state. The U.S. legislation in this area has been seen to be much stronger than similar Access-to-information legislation in Canada.

4.2.1 An Initial Public Opinion Survey

One of the outcomes of the National Forum in 1997 was a recommendation for a public opinion survey to assist in planning public engagement considerations. This survey was conducted in March 1999 to assess the attitudes of Canadians concerning XTP and to see how knowledgeable people were with respect to this topic. Health Canada had previously used this public survey approach for 11 years to amass information as background for policy development. The survey questions were designed by health ministry officials in consultation with Earl Berger, Managing Director of The Berger Monitor, a survey unit used by the ministry for policy questions. The survey sample (N=2,526) was composed of Canadians 15 years of age and older. Key findings of this survey were as follows:

- A slight majority of Canadians (52%) said they had indicated willingness to donate an organ or tissue for transplant on their death (e.g., on their driver’s license or health insurance card)
- Three quarters said they had heard of or read about medical researchers proposing to use animal organs for transplant into humans.

---

12 Gauthier, C. and Griffin, G. (2007). Public participation in informed decision-making on animal use in Canada. AATEX 14, Special Issue, 197-201 Proc. 6th World Congress on Alternatives & Animal Use in the Life Sciences August 21-25, Tokyo, Japan
• When asked whether they had heard that one of the risks of such transplants was the possibility that an unknown or new disease might be transmitted to the person receiving the transplant, fewer than half (47%) responded in the affirmative.
• Among those who had heard of this transmission risk, only four in ten had also heard that this infection risk might also apply to those in contact with the patient.
• If a human organ were not available, slightly over half (54%) said they would consider an animal organ for themselves; men were more likely than women to say yes.¹⁴

When disaggregated by gender, the survey results suggested that men and women had similar views on willingness to donate an organ, their awareness of medical research on the use of animal organs for transplant to humans and awareness of potential risks. However, significantly more men than women were willing to consider transplant of an animal organ for themselves (63% versus 45%).

These results suggested an important role for public education in the area of risks.

4.2.2 The Public Involvement Plan

In 2000, Health Canada released the XTP report: Proposal for a Public Involvement Plan for Xenotransplantation to outline the Government’s intentions to include public views in the xenotransplantation debate:

A fundamental rationale for public involvement was to produce high quality policy and promote a transparent and open decision-making process. As well, given the scientific uncertainties concerning unknown, unrecognized or emerging risks on xenotransplantation, a policy development approach that took account of public views on the issue was seen to be requisite. The nature of the research and possible technological developments in XTP was seen as warranting a broad decision-making base.

It was also recognized early on that issues raised by xenotransplantation could occur at several levels of society: the individual level (patient in need of care), community (patient groups), Canadian society in general, and the international community. It was “the very breadth and profoundness of the issues raised” that was recognized as “necessitating informed public debate to promote credible policy development”.¹⁵

What question was being posed and what issues were Canadians being asked about? The over-arching question posed to the Canadian public was whether Health Canada should proceed with xenotransplantation and, if so, under what circumstances?

Given that XTP was recognized as raising a number of health, ethical, legal, economic and social issues that called for informed public discussion, how was the health ministry going to achieve this? Figure 1 below indicates the outlined plan by Health Canada to include public input in the development of xenotransplantation policy. It is clear from this diagram that the Canadian public was one of several consultation players in this process. Stakeholders, other institutional partners and international players were also considered important to be involved in the policy discussions.
Consequently, the public involvement plan that was drawn up was anticipated to direct the policy process and was expected to result in “higher quality outcomes”. In addition to increasing Canadians’ level of understanding about XTP, Health Canada envisaged including members of the public in the development, implementation, and impact evaluation of xenotransplantation policies. Figure 2 outlines the six phase plan:


16 (http://www.hcsc.gc.ca/hpb-dgps/therapeut/zfiles/english/btox/reports/awsreport_e.pdf)
Figure 2: Health Canada’s Public Involvement Plan – Project Phases

| Phase 1: Information and initial outreach |
| Phase 2: Planning workshop: Public involvement on XTP |
| Phase 3: Public education, awareness and dialogue |
| Phase 4: Regional consultation |
| Phase 5: Synthesis of public input for policy development |
| Phase 6: Continuation of public involvement |

Source: Report - Proposal for a Public Involvement Plan for Xenotransplantation [2000]\(^\text{17}\)

The report goes on to indicate that the public involvement plan would strive to respect the following principles:

- a visible/transparent process,
- credibility (includes honesty and willingness to discuss hard issues),
- equal opportunity for all to participate,
- each participant will be considered as contributing valuable input,
- willingness of Health Canada to seriously consider all the input from the public involvement process.

### 4.3 Health Canada Surveillance Workshop

As part of what we have called its expert consultations track, on March 31 2000, a surveillance workshop was held in Ottawa as a starting point for discussion among 26 international infectious disease experts and 2 observers on xenotransplantation. This workshop represented the international consultation that was indicated in Health Canada’s Public Involvement and Policy Development Plan (see Figure 1). It was intended as an expert consensus conference workshop and is mentioned in this report because of its importance as a starting point for “future deliberations” on xenotransplantation surveillance - including public debate in Canada. The committee members came from various countries, organizations, and companies to discuss XTP from a Canadian and international perspective.

Participants included representatives from: Council of Europe (COE), U.S. Centers for Disease Control and Prevention (CDC), United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA), Novartis Pharma, Canadian Food Inspection Agency (CFIA), and the Organization for Economic Co-operation and Development (OECD).

A key outcome of this workshop was the completion of the draft regulations for XTP. It was not to be finalized until the public consultation outcomes would be reported.

\(^{17}\) [http://www.hc-sc.gc.ca/hpbдgps/therapeut/зfiles/english/btox/reports/awsreport_e.pdf](http://www.hc-sc.gc.ca/hpbдgps/therapeut/зfiles/english/btox/reports/awsreport_e.pdf)
4.4 Public Engagement Planning Workshop

Health Canada and TPP held a planning workshop April 10-11, 2000 in Ottawa, Canada to consolidate information regarding XTP from a scientific and policy standpoint.

Moderator, John Benesh, described the three types of workshop participants as:

1. those who will be actively involved in discussions,
2. those who are resource people or subject matter experts, and
3. other interested observers.\textsuperscript{18}

Panelists were divided into three break-out groups, each group having to discuss a distinct set of questions which were listed earlier by panelists in the workshop. The ministry relied heavily on workshop participants to provide input on how to move the consultation process forward towards efficient public participation. Participants included animal rights and welfare stakeholders, representatives from the CPHA, provincial public health representatives, representatives from religious groups, ethnocultural groups, patient organizations, consumer representatives, experts on research ethics, health economics, veterinary health, transplant researchers and practitioners, industry representatives, and representatives from the regulatory community.

A report of this workshop remains in the public domain (see http://www.hc-sc.gc.ca/hpb-mpbs/brgtherap/activit/consultation/xenotransplant/awsreport-rapportvif-eng.php) and portions of the representation of the question-and-answer between participants and Health Canada regulators are revealing.

Participants asked the regulators how scientific findings and public involvement results would come together. Julia Hill, Director of the Bureau of Policy and Coordination of TPP responded:

“If there’s unanimity around the notion that xenografts should go forward, and that the process as we’ve (TPP) described it is perfect, I don’t suppose we’ll really see much impact, because there won’t be any kind of polemic or discussion around it. If, on the other hand, the results of the public consultation show that the public is very opposed, or wants to set particular parameters around how xenotransplantation happens, then you will probably see that impact in the way the regulatory framework is structured.” It would be unreasonable to expect every viewpoint to be reflected in the regulations, “because there are going to be contradictions, so it’s a difficult line to balance”.

A comment from one of the participants was made in response to the presentation given by one of the regulators. This participant observed that the presentation seemed to imply that there would be XTP clinical trials. The question then raised was if consultation moves forward, would clinical trials also move forward?

In response, Robert Peterson, the Associate Director General of TPP indicated that Health Canada was expecting to receive submissions for clinical trials. He indicated that Health Canada (technically) could not refuse applications for clinical trials. However, he added that there may be scientific and safety reasons for not approving a submission. “The public debate is also important to have and if a clinical trial submission is received, it might be the science and/or the public that may influence that the trial be delayed, would not occur, or could describe how (under what conditions) it would take place”. Another question asked was whether safety and effectiveness would be among the issues for public consultation.

“Because xenotransplantation is cutting-edge science with tremendous risks, all public input is important. Health Canada is seeking information about values in addition to the scientific barometers of safety and effectiveness.” (emphasis added).

These exchanges were revealing in three respects: first was the explicit acknowledgment that the traditional metric of science was to be complimented by public or social values. Second was the public recognition that uncertainty remained on the scientific questions which could provide a rationale for not approving a clinical trial. Finally, there was the acknowledgment that the public consultation could also delay or prevent clinical trials from proceeding.

Health Canada was encouraged to proceed with two means of incorporating public input. The first included complementing “stakeholder consultations” with “communities of discussion”. The second involved a town-hall approach.

4.5 The Arms-length Public Consultations through the Canadian Public Health Association (CPHA) and Public Advisory Group

The Canadian Public Health Association (CPHA) is a national, independent, not-for-profit, voluntary association representing public health in Canada. On August 10, 2000, Minister of Health Canada, Alan Rock, announced publicly that it was funding the CPHA to form a Public Advisory Group (PAG) to conduct xenotransplantation consultations across Canada. “The key role of the Public Advisory Group will be to develop recommendations on xenotransplantation, based on input from Canadians” and was expected to be completed by
2001.\(^{19}\) PAG’s consultations were designed to be arms-length from government and this group was to then report back to the Minister of Health. PAG member nominations were submitted and subsequent selection was balanced by expertise, perspective, geographical region, and gender.\(^{20}\)

Figure 3 illustrates that PAG was to be involved early on. Its start in Phase 2 (of 6) in the public involvement plan simply reflected the fact that phase 1 was the immediate outcome of the 1997 National Forum meetings.

**Figure 3: Objectives of a Public Involvement Plan and Role of PAG**

---


\(^{20}\) A citizen "lay" representative was later added to the PAG.
Figure 4: Phase 2 – Planning Workshop and Issue Identification


PAG members met on four occasions and held conference calls between meetings. In brief, PAG was responsible for conducting the following public opinion information sessions:

1. Six citizen forums
2. Telephone survey of 1,500 Canadians
3. Survey mailed to stakeholder organizations
4. Survey posted on website
5. Informal feedback from the public through letter and e-mails.

The consultation framework consisted of both (1) a “representative” model, and (2) an “open” model (Figure 5). The terms used were to reflect the idea of balancing self-selected participation with “representativeness”.

4.5.1 Representative Model

4.5.1.1 Citizen Forums

The citizen jury model was employed to carry out six citizen forums in each region of the country. Prior to each of the six forums, a random mailing of 2,500 invitations was sent to members of the Canadian public in search of forum participants. The letters informed prospective participants that prior knowledge about xenotransplantation was not necessary because they would receive reading materials before the forum (approximately 8 hours worth of advanced reading). A selection committee considered the returned applications for gender, age, mother tongue, urban/rural location, occupation.

The six citizen forums, each consisting of 14-23 citizens, met on two and a half consecutive days (total N=107 panelists). Of this number, 56 were female or 52 percent of the total number. The citizen forums were held in these six regions: Saskatoon (March 2001), Halifax (April 2001), Vancouver (May 2001), Toronto (May 2001), Quebec City (June 2001), and Yellowknife (July 2001). The choice of locations was as much an acknowledgement of the importance of regions and their diversity, which remains a hallmark of Canadian politics. The consultation process began in March and ended in July 2001. The data analysis occurred between August and September 2001.


Selected forum participants participated in an orientation dinner on Friday night. They also had the opportunity to listen and learn from selected xenotransplantation experts who gave presentations on the following day. This was an open session to which the public and media were invited. In the afternoon of the second day, panelists discussed the merits of Canada’s proceeding with xenotransplantation and if so, how? This afternoon deliberation was closed. Forums were professionally facilitated and “captured by professional recorders”. At least two PAG members (including 1 co-chair), a Health Canada official and a representative of Health Canada’s Expert Advisory Committee on Xenograft Regulation attended each forum as observers. Travel costs for panelists were reimbursed, one dinner and two lunches were provided, and an honorarium of $100 was given.

In terms of the expert panels participating in each regional site, the make-up typically consisted of a transplant scientist or medical practitioner; a veterinary medicine specialist with expertise in zoonosis; an animal rights or welfare representative; a bioethicist; and a transplant recipient-patient. There were 35 experts in total for the six sites and 15 of these experts were female.

Such a citizen consultation process naturally raises the question of power asymmetries which can arise from differences in expertise, opportunities for interrogation and challenge, and provision of an explicit link or channel to the decision-making center. All three dimensions can be accounted for in the process elements of the consultations. Differences in expertise were addressed with the provision of a substantial information base to participants, so they would not be starting from a position of ignorance on the issue. The assumption was not to bring these participants up to the level of scientific expertise but to a reasonable level of knowledge and understanding to address the policy question of interest. The presentation of “experts” was also not a one-way street but provided the lay participants with opportunities to pose questions and even on occasion to contest some expert assertions. Finally, there was an official guarantee that the report would be presented to the Minister of Health, which indeed took place.

A major problem or challenge that arose with the consultation process was that despite the large number of letters of invitation sent out to citizens in each region inviting participation in the consultation, the response at each site was extremely limited. There were about 2,500 letters of invitation sent out in each region and on average, about 10 percent responses indicating interest in participating was obtained. The final sample of citizen forum panelists was essentially balanced on gender and age but was skewed to the higher strata on education and income. These weaknesses were a function of the respondents replying to the letters of invitation, reflecting a more generalized issue with the types of individuals drawn to participate in citizen fora.
4.5.1.2 Telephone Survey

This tool was used to gather public opinion of 1,519 randomly selected adult Canadians. It was conducted in March, 2001. The telephone survey consisted of some 60 questions. The survey was designed to probe opinions on the following areas:

- The shortage of organs, tissues and cells for human transplantation
- The degree of knowledge on XTP
- The acceptability of human and animal transplants
- The benefits and risks of XTP
- The use of animals in medical research
- The conditions under which XTP would be approved
- The level of agreement to a XTP by oneself or family members
- The redirection of health care dollars to XTP
- The decision to proceed with XTP

One question on the survey asked respondents to rate the importance of personal views on different aspects of XTP (where 1 was “not at all important” and 10 was “very important”. These aspects included: their views on animal welfare, the risks of XTP, the individual’s right to choose a health care option; health care costs; respecting nature’s boundaries; and the importance of saving human lives. The relative importance observed from the survey is interesting from the perspective of a respondent sample that had little to no knowledge about XTP:

- To save human lives: 87%
- Right to choose health care option: 85%
- Views about health care costs: 73%
- Respecting nature’s boundaries: 72%

---

Risks of XTP 70%
Animal welfare 63%

These survey results were noted in the final report of the Canadian Public Health Association as one outcome of the set of consultations conducted under the “Representative Model”. However, as we discuss later in this report, the importance given to this public opinion survey was more limited than the importance attributed to the citizen forums.24

4.5.2 The Open Model

The open model, in contrast to the representative model, was designed to give different stakeholder communities an opportunity to participate in the XTP discussions.

4.5.2.1 Website and On-line survey

The CPHA website (http://xeno.cpha.ca) went online in November 2000 and was promoted in mailings, media and public session of the citizen forums. This source provided members of the public with basic information about XTP. This site included news stories, mailings to download, and an overview of the consultation process in Canada (including the public forums, and a section entitled “Have your say” – a website survey25 to collect public opinion (367 submitted opinions before the deadline).

4.5.2.2 Mail-in Survey

The mail-in survey (87 questions) was designed for stakeholders such as people affiliated proponent groups for animal rights and welfare, environmental protection, and persons having differing expressed ethical, religious, cultural, etc. beliefs. A stakeholder database was created and a combined total of 3700 information packages were sent out in December 2000 and March 2001. So that feedback from stakeholders could be incorporated by PAG, the completed surveys needed to be returned by July 31, 2001. PAG received a total of n =216 completed mail-in surveys from stakeholders.

4.5.2.3 Letters, E-mails, Public Sessions

These were an informal means for members of the general public to express their opinions to PAG and the CPHA. Members of the public were encouraged to mail letters or use e-mail to contact and express their opinions to the CPHA. As noted previously, members of the

25 Website: “Have Your Say” (http://www.xeno.cpha.ca/english/questionnaire/survey.asp)
public were given time during the citizen forums to ask questions or provide input. A total of 122 members of the Canadian public contributed their opinion in this manner.

### 4.5.3 Television, Radio and Print Media

- The Cable Public Affairs Channel (CPAC) filmed the public sections of the first citizen forum and aired segments nationally for several months. This drew public attention to the issue of xenotransplantation.
- The CBC (national public broadcast system) program *Health Matters* aired a 20-minute program on XTP.
- RDI Quebec (French equivalent of CBC’s Newsworld) conducted a one-hour call-in show on xenotransplantation.
- CTV (national private broadcast system) covered the Toronto forum on its national news.

### 4.6 Outcomes

The six regional citizen juries became the central element in the assessment of public views and deliberations because the citizen participants were considered to have been well informed, had interacted with an expert panel that included a broad range of expertise, and engaged in thoughtful deliberations. This assessment was made by Health Canada’s internal evaluation report which further noted that of the methods used in the CPHA consultation, the citizen juries were the most effective at developing an informed public on “complex, controversial issues with a biomedical component.”

*The findings of this consultation were that Canada should refrain from approving clinical trials of xenotransplantation until critical issues were resolved, and other options to address the critical organ shortage could be explored.*

One of our participants suggested that since that time the government has not made any definitive statements about xenotransplantation, so it is hard to say whether the consultation itself had any larger impact – or “whether, I guess, it was simply a way of saying okay, we’ve done the public consultation and now we’re going back as usual” (AL). As yet, in Canada, there have been no clinical trials for xenotransplantation. We discuss this point in greater detail in our subsequent exploration and analysis of the notion of “impact”.

---

5 The Meanings of Impact on XTP Policy\textsuperscript{27}

5.1 Impacts in the literature

The impact of public consultations is often measured in terms of concrete effect on policy: how do policy outcomes reflect the findings of public consultations? Consultations may also be described as having an impact on public knowledge on an issue, through social learning: this is often assessed through evaluation criteria developed as part of consultation design.

Many scholars have made contributions to the literature on evaluating consultative processes in relation to science and technology, including critiques of different models or specific events. The work of Rowe and Frewer provides a rigorous overview and research agenda. In their 2000 piece, the authors compare models according to evaluative criteria such as resource accessibility, cost-effectiveness, and task definition. Deliberative exercises may, for example, be robust in terms of unpacking the nuances of an issue, but their small scale may work against their strength to influence policy, which is described as “variable but not guaranteed”\textsuperscript{28} Larger scale activities – surveys, referenda and the like – may seem representative but allow the participant no opportunity to qualify answers or ask questions. In later work, the authors review scholarship on public participation, noting that “institutional and societal responses to a particular exercise may be manifest months or even years after an exercise has finished”\textsuperscript{29} (p. 520). This means, in turn, that researchers face the challenges of not only identifying impacts, but evaluating them in the long-term. Goodin and Dryzek stress the importance of deliberative processes as “micro-political innovations”\textsuperscript{30} involving mini-publics, or collections of individuals which are not statistically representative but have some claim to representativeness on the basis of including a range of demographics and perspectives on the issue. They also explore several possible impacts of such processes: actual policy making; having recommendations taken up in the policy process; informing public debates; testing the popularity of policy ideas before they are concretized; legitimating policy, confidence or constituency building; popular oversight to ensure accountability, especially in controversial matters; and explicitly resisting co-option by consultation. While they note that mini-publics and their micro-political innovations can have impacts on the macro-political, they caution against limiting analysis to the content of policy alone, and emphasize the difficulty of tracing direct impact of any input through complex political processes. The problem is often how to link micro processes to their macro impact.

\textsuperscript{27} This section on Impacts consists of excerpts from a paper currently under review on “Institutional Policy Learning as ‘impact’ of public consultation: the Canadian xenotransplantation experience”, M. Jones and E. Einsiedel.


In this literature we find compelling the suggestion that the challenge of tracing impact can be addressed by extending the scope of observation and analysis; especially as some impacts are only manifest over time. In the case presented in this report, we see evidence of many of the possible impacts listed above – ensuring accountability, informing the public, and testing ideas – which emerge in the course of our discussion. Our principal argument, however, resolves around the impact of the Canadian xenotransplantation consultation on Canadian health governance.

5.2 Learning as institutional impact

In an analysis of Canadian public consultations on xenotransplantation, one author observed that there is evidence of institutional learning in broader policy communities as an impact. To clarify, although an objective in public policy consultation design is to produce an impact on policy – through take-up of recommendations, for example – the range of possible impacts of a consultation are not limited to issue-specific policy outcomes, per se. Thus, while Canada remains without a xenotransplantation policy, this was not the only possible impact.

In their introduction to a special issue of Theory and Society on institutionalism, Mohr and Friedland note there is little consistency to how the term ‘institution’ is defined, despite it being a key concept of sociological theory.\footnote{Mohr JW and Friedland R (2008) Theorizing the institution: foundations, duality, and data. Theory and Society 37:421-426} For the purposes of this paper we draw elements from two useful definitions. Sociologist W. Richard Scott, a key figure in institutionalist scholarship, defines institutions as “social structures that have attained a high degree of resilience” which provide stability to social life with the support of three pillars - cultural-cognitive, normative, and regulative\footnote{Scott WR (2001) Institutions and Organizations, 2nd ed. Thousand Oaks: Sage}. The regulative pillar is particularly relevant to our study, as it concerns how rules are developed, sanctioned and enforced, particularly in regulatory structures such as the state. This is partly maintained through carriers, or systems that may serve as a conduit for institutional ideas; for example, in the regulative pillar, a technology assessment protocol could be a routine carrier. Relational systems, referring to interpersonal or interorganizational linkages, are also important carriers as they delimit the way power circulates among actors in an institution\footnote{Scott WR (2003) Institutional carriers: reviewing modes of transporting ideas over time and space and considering their consequences. Industrial and Corporate Change, 12(4): 879-894.}. Another articulation, aligned with new institutionalism and specific to science policy, is provided by Frickel and Moore who define institutions as “relatively durable sets of practices and ideas that are organized around social activities and that in various ways shape the contour and experience of daily life”\footnote{Frickel S and Moore K (2006) Prospects and challenges for a new political sociology of science. In: Frickel S and Moore K (eds) The New Political Sociology of Science: Institutions, networks, and power. 3-31. London: University of Wisconsin Press} (p. 8). In this conception, scientific knowledge systems have an embedded relationship with political institutions, in which the distribution of power is structured. In this sense, institutions embody
routinized (and often taken-for-granted) ways of working which set parameters for the decisions made by organizational actors.

Common elements to these definitions are: a) the importance of routines – the commonplace courses of action followed regularly -- in stabilizing institutions, which allows certain ways of thinking to remain taken-for-granted until destabilization occurs; and b) the importance of relationships between actors, in terms of how power circulates. In relation to our analysis, the routines which characterize policy making as part of the regulative pillar of health governance, circumscribe ways of approaching policy development. “Organizations are difficult to change, and when change occurs it is often only on the surface”\(^{35}\) (p. 411). Yet, the possibility of change does exist in the circulation of ideas, and power, between organizational actors.

This is where learning comes in. Institutional learning has appeared in the literature to describe evolving designs and processes as connected regions, particularly in the European context, interact and draw lessons from each other.\(^{36}\) In relation to political institutions, policy learning refers to the tendency of governments to find solutions to current intractable problems by drawing from the experience of other settings or other times.\(^{37}\) Policy learning derives from Peter Hall’s 1993 application of social learning to policy choice (Pemberton 2000), with his use of the concept of paradigm change within social learning playing a particularly influential role in learning studies\(^{38}\).

In this report we take the approach that by gathering the recollections of key policy actors and observing changes in policy practices and structures, we can investigate institutional learning stemming from a particular policy moment in the past: the Canadian public consultation on xenotransplantation. Institutional learning over time is particularly relevant where public engagement is concerned, as for many nations effective consultation is an ongoing learning process which becomes more sophisticated with each attempt at engagement. As noted earlier, institutional impacts may not manifest for years after a consultative event. With the benefit of reflection, as we argue, learning may result in observable changes in routines, actors, and even organizational values.

The method we used in this Canadian case began with documentary research (web, policy documents, and scholarly literature) which informed the development of a semi-structured interview guide. Two versions of the guide were developed to facilitate interviews with either

---

stakeholder/“consultees” (e.g. a patient advocate), or organizers/initiators of consultations (e.g. a representative of Health Canada). The latter group is the source of material used in this paper. This version of the guide was loosely structured to probe for participants’ perspectives on:

- **The general policy context**: recollections of policy discussions, technology assessments of xenotransplantation, and related policy context and similar issues; personal questions or concerns in this policy area
- **Public consultations**: recollections of the process leading up to the decision to consult; who was involved; what expectations were held by organizers; the extent to which xenotransplantation was seen as requiring a similar approach to one or more other issues
- **Outcomes**: identification of the consultation’s impacts, if any, on policy or regulation; impacts on this issue compared to impacts on similar issues; what, if any, lessons were learned
- **Final thoughts**: open-ended additional remarks; discussion of how hindsight might influence the interviewee’s approach to a similar issue in future

5.3 Description of Canadian public consultation

(Note that we have provided a more extensive description of this consultation process and context in Section 4 so will not be repeated here.)

5.4 Outcomes

The recommendation was made that Canada should refrain from approving clinical trials of xenotransplantation until critical issues were resolved and other options to address the organ shortage could be explored. Since that time, the Government of Canada has not made any definitive statements about xenotransplantation as an outcome of its various consultations with experts and publics; there have been no clinical trials, nor has the policy been finalized. It is difficult to determine if this is a policy decision based on public consultation, or simply going back to business as usual. The consultation itself was subject to a certain amount of critique. Some noted concerns with the methodology and limitations to representativeness while others interpreted the lack of a specific decision as Health Canada not adhering to fora recommendations. On the basis of observations as a participant in the consultation (and considering those of the independent evaluator), Einsiedel developed an evaluative

---

framework based on the literature in constructive technology, assessment and deliberative democracy. This framework is broken down into three areas of evaluation:

- institutional/organizational arrangements (independence, transparency, resource allocation, task definition, and timeliness);
- process criteria (representativeness, resource accessibility, and deliberation – discussion/equality); and
- outcomes (participant learning, public debate, participant satisfaction, and policy influence).

This author identifies several generally effective aspects of the consultation— including, for example, the event’s independence, transparency, timeliness, and some procedural aspects – but notes a “disjunction” between citizens and organizers over task definition: while organizers defined the consultation question in narrow terms, asking whether Canada should proceed to clinical trials, the citizen panelists ranged more broadly on issues around regulatory preparedness, animal issues, allocation of health care resources, and alternatives to addressing the organ shortage challenge. In other words, these jury participants chose to examine the technology in its broader social, political and economic contexts, refusing to be circumscribed by the narrow operational question of whether to proceed to clinical trials, a question which could imply an ordained technological path.

There were two official evaluations carried out on this consultation. One was via an independent evaluator, Natalie Kishchuk, enlisted by CPHA. The other was an evaluation conducted by the Biologics and Genetic Therapies Directorate, or BGTD (formerly part of the Therapeutic Products Programme). This latter was the assessment we found most intriguing because of the significant organizational position of the BGTD within the Ministry. Not only does xenotransplantation fall within its regulatory purview as a directorate for science-based assessment, but it was the largest of six review directorates in Health Canada’s Health Products and Food Branch, and as such was an influential actor in Health Canada policy. We had the opportunity to view both these documents and their summary of lessons learned.

Although the two evaluations conducted of this consultation both reported that citizens’ perceptions changed upon receiving more information, the independent evaluator for CPHA

---

found a diversity among the experiences of citizen panelists in terms of how their perceptions changed after receiving more information.\textsuperscript{43}

Generally speaking both reports present positive assessments of the way the consultation was organized and run – particularly in terms of the arm’s-length status of CPHA, the citizen fora as the most valuable method to glean public input, transparency, and the capacity for individuals without professional scientific training to quickly become informed on xenotransplantation. However, there were some disparities between reports in terms of tone and emphasis. While the BGTD evaluation frequently notes the capacity for members of the public to absorb technical knowledge and understand the issues, it still retains some commitment to hierarchical views of expertise. During the consultation, participants were asked to identify what level of influence, on a 1-10 scale, they thought different stakeholders should have “in policy or regulatory decisions about xenotransplantation (or other controversial biomedical issues)” (p. 53). To the stakeholder category “general public”, average levels assigned by forum participants was 8.3; by the PAG, 6.6; and by the Expert Advisory Committee, 4.3. The findings of this survey led to this “Lessons learned” statement in BGTD’s evaluation:

“Relative weighting of information in policy development may or may not result in a decision that is fully consistent of public views. Whether or not the final decision on xenotransplantation fully reflects “the publics”’ views as derived from this consultation, a critical piece of this initiative will be not only to provide feedback to the “public” on the decision itself - but also it will be important to explain the decision making process and the rationale for the decision made.”\textsuperscript{44}

In contrast, the independent evaluation, also emphasizing the capability of diverse publics in understanding and speaking to complex policy issues, argues that “Findings from this evaluation raise questions about the role of experts and suggest that alternatives to the expert-based model should continue to be explored”.\textsuperscript{45} Interestingly, since then we can identify a shift in the official policies and practices of Health Canada that align more closely with the independent evaluator’s report than with the BGTD report of that time, suggesting a destabilization of the paradigm for public consultation. Despite material obstacles that may remain (such as the current government in power or resource limitations) there is a shift in the perspective held by organizational actors regarding public consultation. We will explore these more in the Analysis section.

\textsuperscript{43} The HPFB report, in contrast, notes this as an advantage of deliberative methods, as an informed public could assure “public input would be credible, and therefore useful as an element in decision making” (17).

\textsuperscript{44} Health Canada, 2003, 54.

\textsuperscript{45} Kishchuk, 2002, p. 5.
5.5 Analysis: Institutional learning as impact

At the time of earlier analyses of the consultation it was too soon after the event to determine what long-term institutional impacts might be. At this writing it is clear to us that lessons were learned from the earlier xenotransplantation consultation which, we suggest, have permeated broader policy culture at Health Canada. We have thus far presented a narrative of the rise of XTP as a policy issue in Canada. Now we turn to an account of subsequent events and conditions, suggested by those we interviewed as evidence of the longer term impacts manifest in cultural and structural changes within its policy organizations. As we stated earlier in this section, two central themes in the conceptualization of institutions (i.e. which suggest ways to test institutional learning) are the importance of relationships and actors, and the importance of accountability and engagement practices as stabilizing routines.

5.5.1 The importance of public actors and their expertise

Complex political organizations may resist outside expertise, particularly where there is a decision-making hierarchy, and particularly in science-based organizations where the science / not-science boundary is defended. The depiction of expert and non-expert perspectives in the BGTD evaluation may have reflected the dominant culture at the time, but it also reflects a culture open to change in terms of how it views expertise. For example, the report notes that despite inconsistencies in the experts and information provided at various regional fora, the final recommendation did not differ greatly across fora, in part because participants had time to develop both interest and a level of knowledge regarding the issue. BGTD, a complex multidisciplinary section of an even more complex multidisciplinary organization, the Health Policy and Food Branch (HPFB), was aware that a monolithic expert view is not possible; “there are differing perspectives on the issues - no one set of experts can be seen as representing “expert” views”\(^{46}\) The recognition that reasoned deliberation among diverse actors can achieve a valuable outcome, despite the sometimes messy process it takes to get there, is, we feel, indicative of a lesson learned.

Acknowledging the value of social adjudication represents a significant change for policy, and especially regulatory, practice. It reflects a shift from an entirely ‘sound science’ based approach to one that recognizes some problems are beyond the scope of science alone. Consultation allows the organization to explore policy options for issues where a solution is not readily available. It enables brainstorming between actors with different sets of experience, allows ideas to be explored and adopted or dismissed, and has the potential to strengthen communication between diverse stakeholders. The question of how public views and broader social values are accounted for in the policy process, however, remains an

\(^{46}\) Health Canada, p. 50.
ongoing challenge for predominantly expert-based systems. BGTD acknowledged these challenges:

“Consulting with the general public was new to the Directorate and there was limited expertise or experience within the Directorate in undertaking public involvement initiatives. Unlike today, there were no manuals, or templates to guide the initiative and no established infrastructure through which to seek guidance, direction or approval to move the project forward.”

The temporal difference noted here – “ unlike today” – is a reference to the work of the Office of Consumer and Public Involvement (OCAPI), which Health Canada established in 2000 to promote an infrastructure for in-house public engagement expertise. Although it was a small office at the time the consultation was run, it has since grown in terms of staff, resources, and profile, and has a horizontal responsibility to develop materials and capacity (the manuals and templates) across directorates to support consultation initiatives within HPFB. As documented in the evaluation report, BGTD discussed the “lessons learned” from the CPHA consultation with OCAPI (Health Canada 2003, 46). Those we interviewed connected to Health Canada felt that lessons learned from the xenotransplantation consultation directly supported the work of OCAPI and in this way contributed to its growth (KH, AL). In turn, OCAPI’s cooperation with BGTD’s evaluation of the consultation contributed to some analysis in terms of how the xenotransplantation experience had broader implications. The following point, for example, is footnoted as “Discussion with OCAPI officials”:

“...In part, these lessons provide some direction as to what worked, how things might be done differently next time or what factors need to be considered in designing and implementing future efforts. Some of [these] lessons reflect issues that are not unique to the xenotransplantation issue alone and have broader implications for government public consultation initiatives (e.g. How to encourage public input to ensure a representative response).”

OCAPI was involved in organizing two citizen fora, similar to the CPHA consultation, in 2005. The topics for these fora were two politicized technologies: silicone gel-filled breast implants and Cox-2 non-steroidal anti-inflammatory drugs. These events served the dual purpose of investigating the issues, and piloting an evaluation model of consultation to be used in future. Lessons learned from these evaluations were applied in the development of a Policy on Public Input, launched in 2007 and binding as guidance for regulatory review across Health Canada. This was revolutionary in the Canadian regulatory context as it establishes a mechanism to not only attribute value to citizen knowledge, but to integrate it into regulatory

---

49 Regulatory scientists generally understand it is impossible to eliminate risk.
decision-making. It further allows for a broader definition of relevant expertise than simply that from formal scientific training, indicating that the Minister may seek advice from stakeholders “with knowledge and experience in different areas, particularly those who use or might use the regulated product, to broaden the information available to make an informed evaluation of the risk and benefit associated with a product. As KH told us, “there are unknowns and uncertainties and there are times when we need to involve additional citizen perspectives”. Part of the policy focuses on controlling for conflict of interest (see below) for participants. It uses the language of transparency and openness, particularly with regard to the basis for regulatory decisions. This relates to our earlier discussion of paradigm change in policy learning. Dolowitz and Marsh suggest that learning processes may be driven by technological change. Although xenotransplantation may have been seen as having the potential to change the paradigm of regenerative medicine (still unrealized), the fact that this technology was characterized by uncertainty and risk allowed it to challenge the paradigm for science policy development. We interpret what has happened as a shift from a science-only paradigm (as the basis for decision-making), to a paradigm of science-at-the-centre (supplemented by other forms of expertise, knowledge, and evidence).

5.5.2 Accountability routines

One area of health governance affected by the learning processes of the xenotransplantation consultation is, we argue, the establishment of new mechanisms for government accountability. Health Canada’s internal evaluation of the CPHA consultation noted, in the context of “lessons learned”, that in future consultations the initiating department should articulate clearly at the outset its objectives, its commitment to the process, and exactly how findings would be used. While this conclusion may not seem exactly fresh to those who study democratic engagement, it is important to recognize this “lesson” as part of a broader expression of the need for accountability mechanisms in government. A cumulative understanding has emerged - from consultations and other activities - that citizens often have no way of knowing what information is taken into account when regulatory or policy decisions are made, and as a result, see transparency and accountability as important features of government practice. In essence, how can we know what factors, public input or otherwise, have gone into making an official decision? This is an area where we might argue that policy learning is ongoing rather than a fait accompli. Policy officials continue to grapple with how to balance their need for policy formulation to occur in camera, with the need to operate transparently for public accountability.

In the case of the CPHA consultation, the decision on the part of the regulator to select an arm’s-length body as organizer was explicitly related to accountability issues (as noted by KH, above). The internal BGTD evaluation makes a similar statement:

“Whether or the extent to which a consultation should be carried out at “arms length” will depend on the climate of public trust of government (at the time of xenotransplantation consultation there was little trust in government), the government agency’s track record in handling critical issues, and the extent to which the subject matter is controversial.\footnote{Health Canada, 2003, 27.}

That, combined with earlier concerns about in-house expertise, set the scene. In Scott’s view\footnote{Scott W, 2003.}, empirical research on carriers of institutional elements might ask how types of carriers affect the way elements are received. We suggest that here, conventional protocols for consultation (i.e. by the regulator) were no longer tenable; the arm’s-length relationship between Health Canada and CPHA allowed credibility to be attached to the consultation. In this case, the destabilization of an existing routine allowed relational systems to shift and carry new ideas into organizational practice. The evolution of accountability structures continues.

In the years following the CPHA xenotransplantation consultation, Health Canada has made moves towards transparent accountability through the creation and adoption of new instruments. Along with the Policy on Public Input (discussed above), the Health Products and Food Branch instituted the use of Summary Basis of Decision (SBD) notices, which are published online and explain the reasoning behind regulatory risk/benefit decisions regarding the approval of therapeutic products for market; and the Voluntary Statement of Information (VSI)\footnote{At this writing the VSI is not finalized.}, which asks participants in a public consultation to reveal any potential (primarily financial) conflicts of interest they might have with regard to the subject matter of the consultation – for example, shares in a drug company - so this record can be made available. For some time now, concerns about bias in the participation of industry-supported patient groups\footnote{Batt S (2009) Who pays the Piper: patients’ groups and industry funding. In Anne Ford and D. Saibil (eds) The Push to Prescribe: Women and Canadian Drug Policy. Toronto: Canadian Scholars’ Press.} have led to the development of mechanisms to scrutinize the financial interests of consultation participants.

We concur with Goodin and Dryzek that a consultation’s impact will at least partially depend on the system in which it takes place\footnote{Goodin and Dryzek, 2006.}. From what we know about our interview participants and the context in which we work, we do not see the long-term effects we have identified as merely an incidental result. Rather, it seems likely to us that the value of integrating different knowledge bases and forms of experience/expertise was part of a growing appreciation by organizational actors engaged in the xenotransplantation consultation (i.e., rather than their distant superiors with decision-making responsibilities). It was these policy analysts and regulators who used their ground-level influence to change their own practices and
perspectives, and lead a vanguard of change within the regulator. This is the type of impact referred to in the literature which can only be observed from a temporal distance.
6 Conclusion

According to those we interviewed, state-sponsored consultations of publics on xenotransplantation in Canada was the result of a “perfect storm” (LaPrairie): concerns about lack of supply of organs, the potential of rectifying this through xenotransplants if the necessary research was conducted, the rise of precautionary and ethical concerns, the imminence of clinical trial applications, combined with “a little bit of breathing room because the science wasn’t quite there”. In combination with the immediate climate of distrust fostered by the tainted blood scandal, we also heard this described as a “window of opportunity” (KH).

The element of serendipity suggested here is noteworthy. The CPHA consultation occurred at a time when circumstances had raised concerns about the accountability of health policy development. One option policy makers have, when the state’s accountability is brought into question, is to demonstrate good faith by being open with and engaging citizens in policy processes. In that sense, it may be difficult to attribute causation of the changes in Health Canada’s public engagement framework to the issue of xenotransplantation itself. However, the complexity of the issue combined with the timing of its appearance on the policy landscape made it an essential element of the process of policy learning in health governance. The moment at which xenotransplantation became an experimental site for Canadian public consultation practices, it became linked with challenges to existing ways of practicing policy in the regulator. Organizational actors in the regulative functions of health governance were already aware that public consultation can enhance citizens’ perceptions of the state’s accountability; this is, after all, one of the reasons consultation was done on the issue of xenotransplantation. The way the public was consulted, however, demonstrated an openness to learning new lessons about how and why to engage. Because of this openness and the method of consultation employed, we see changes to relationships, as organizational actors learn that the multidimensional nature of the issue requires collaboration across branches at the outset of the policy process. We see a broadening range of actor involvement, as the experience of involving arm’s-length bodies and stakeholder advisory committees teaches policy makers within Health Canada the validity of expertise outside the sanctioned regulatory offices. In conjunction, we also see a destabilization of the routines associated with closed, expert-driven regulatory practices. We further see material impacts as the organization develops its own capacity for expertise in public engagement through OCAPI and its activities.

Canada still has no XTP policy – and one could argue that this lack of an articulated decision to move forward could still be construed as a “decision”. As we noted earlier, it would be naive to suggest a policy outcome or decision as resulting singularly from a public consultation. The scientific evidence of the technology’s efficacy at that time still remained shaky, and Canada, unlike the US or the UK, did not have as strong a research investment
in this area. Furthermore, an increasing number of questions around virus transfer from animals to humans over and beyond XTP (including cases such as West Nile, Ebola, Nipah, and HIV-AIDS) may also have contributed to a more precautionary stance.

Nevertheless, evidence remains of institutional learning regarding openness and transparency in the governance of Canadian health. We also note that Canada has recently proposed several amendments to the Food and Drugs Act, and introduced a new Consumer Product Safety Bill – all of which have a focus on transparency and openness. It remains to be seen whether transparency will work as members of the public might expect.
7 References


Gauthier, C. and Griffin, G. (2007). Public participation in informed decision-making on animal use in Canada. AATEX 14, Special Issue, 197-201 Proc. 6th World Congress on Alternatives & Animal Use in the Life Sciences August 21-25, Tokyo, Japan


Health Canada Website: “About Health Canada” (http://hc-sc.gc.ca/english/about/about.html)


### 8 Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BGTD</td>
<td>Biologics and Genetic Therapies Directorate, or BGTD (formerly part of the Therapeutic Products Programme)</td>
</tr>
<tr>
<td>CCAC</td>
<td>Canadian Council on Animal Care</td>
</tr>
<tr>
<td>CFHS</td>
<td>Canadian Federation of Humane Societies</td>
</tr>
<tr>
<td>CPHA</td>
<td>Canadian Public Health Association</td>
</tr>
<tr>
<td>CRT</td>
<td>Campaign for Responsible Transplantation</td>
</tr>
<tr>
<td>HPFB</td>
<td>Policy and Food Branch</td>
</tr>
<tr>
<td>OCAPI</td>
<td>Office of Consumer and Public Involvement</td>
</tr>
<tr>
<td>VSI</td>
<td>Voluntary Statement of Information (statements that typically describe any potential conflicts of interest)</td>
</tr>
<tr>
<td>XTP</td>
<td>Xenotransplantation</td>
</tr>
</tbody>
</table>
9 XTP Canadian Policy Chronology

1997. National Forum on XTP – Clinical, ethical, and regulatory issues was created. Co-led by an ethicist and scientist, the Forum recommends development of an expert working group and significant investment in public consultation.

Expert Working Group is created.

July 1999: Health Canada released for public comment the draft Proposed Canadian Standard for XTP.


March 1999: Health Canada issued A Notice to Hospitals: Clinical Use of Animal Cells, Tissues or Organs to Treat Patients.

Both the above Notices communicated Health Canada’s intent to develop appropriate regulations for XTP.

Fall 1999: An Expert Advisory Committee on Xenograft Regulation was formed “to provide Health Canada with timely advice on medical, scientific, ethical and communication issues related to the regulation of xenografts.”

March 2000: Health Canada sponsored a Xenotransplantation Surveillance Workshop, which brought together infectious disease and other experts to discuss issues concerning xenotransplantation surveillance in Canada.

April 2000: In response to recommendations identifying the need for public consultation, Health Canada developed a Public Involvement Plan for xenotransplantation and sponsored a Planning Workshop to obtain input to the plan. As a step toward implementing the plan, Health Canada funded the Canadian Public Health Association to form a Public Advisory Group and to conduct a public consultation on xenotransplantation.

2000 A WHO electronic consultation is conducted. This was co-led by Canadian and US policy officials (Mr. Andre La Prairie and Dr. Louisa Chapman)

October 2000: OECD/WHO sponsor an expert consultation in Paris, bringing together some 70 participants from countries then hosting XTP clinical trials. Andre La Prairie (Health Canada) co-chaired this meeting.
December 2000: Dr. David White, formerly with Imutran and Cambridge University, is appointed the Novartis-Stiller Chair at the Univ. of Western Ontario.

2001: Six citizen juries are conducted in six regions around the country. Consultations with stakeholder groups and a national public opinion Survey were also conducted.


September 2002: Dr. David White, XTP scientist, is at the center of a medical controversy covered in the media. White was working with a team in Mexico city that is transplanting pigs’ islet cells into diabetic teenagers.
10 List of Interviewees

10.1 Policy Analysis & Regulation

1. Keith Bailey, Retired, former Director of Biologics and Genetic Therapies, Health Canada
2. Ian Gemmill, Medical Officer of Health, Canada
5. Lyne Létourneau, consultant on animal welfare, Health Canada
6. Elizabeth McGregor, organized 1999 Science, Ethics and Governance international meeting; Industry Canada
9. Louisa Chapman, Center for Disease Control (CDC)

10.2 Citizen Groups: Patient advocacy, animal rights/welfare, XTP science

10. David White, XTP Scientist, Canada/UK (funded by Sandoz; Imutran)
11. Vivian McAlister, Transplant Surgeon/Researcher, Canada
12. Liz White, Director, Animal Alliance, (Now: Board of Directors, Animal Alliance & Leader of the Animal Alliance Environment Voters Party)
14. Robert Van Tongerloo, Retired, Previous Executive Director Canadian Federation of Humane Societies Canadian Federation of Humane Societies
15. Alastair Gordon, Head, Islet Foundation
16. Fritz Bach, XTP Scientist, Harvard University; Retired xenotransplantation researcher; formerly funded by Sandoz; called for moratorium on XT and public debate to be incorporated in U.S. policy process
17. Alix Fano, Campaign for Responsible Transplantation, USA
18. Maggy Jennings, Royal Society for the Prevention of Cruelty to Animals (RSPCA) and member, UKXIRA
19. Dan Lyons, Uncaged Campaigns