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COALITION BUILDING AND PUBLIC OPINION

New Reproductive Technologies and Canadian Civil Society

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Abstract

The process of technology assessment is evolving. The process of policy development for technology is the least understood in the cycle of technology assessment. The process of policy development, which should involve extensive consultation and a broad-based research and evaluation program, is often fraught with difficulties and can cause further analysis or the assessment process to come grinding to a halt. This article reviews some social, political, and ethical issues and the role of civil society in influencing the technology assessment process for new reproductive technologies in Canada. It is written from the perspective of one of the Deputy Directors of Research and Evaluation for the Royal Commission on New Reproductive Technologies and highlights the strengths and difficulties of technology assessment when civil society and technology assessment come face to face. A brief update by a policy analyst in Health Canada on the current situation of legislation on new reproductive technologies has been provided and is included at the end of this article.

Keywords: New Reproductive Technologies, Technology Assessment, Women's Health

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It was the original intent that a companion article appear, written from the perspective of the government, which would review the current status of reproductive technologies and summarize the data to date. However, all attempts to obtain such a perspective proved to be extremely problematic because the Canadian government is still trying to write legislation in response to the recommendations of

the Royal Commission on New Reproductive Technologies, six years after the recommendations of the Commission were submitted. Instead, a brief update by a policy analyst in Health Canada about the current situation of legislation on new reproductive technologies is included at the end of this article.

BACKDROP: THE SOCIAL AND POLITICAL CONTEXT

On October 25, 1989, the Canadian federal government announced that a Royal Commission would be established. In Canada, a Commission of Inquiry, in the form of a Royal Commission, is a vehicle that allows for an arm's-length review of a contentious issue and makes recommendations back to the government of the day. The Commission of Inquiry had as its mandate to report back to the Canadian government on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal, and economic implications and the public interest, recommending what policies and safeguards should be applied. In particular, it was asked to examine the implications for women's reproductive health and well-being; the causes, treatment, and prevention of male and female infertility; assisted conception treatments; social and legal arrangements related to reproduction; embryo research; sex selection; genetic alteration; and the use of fetal tissue. Clearly, the mandate was broad, in fact, more comprehensive than any other commission or inquiry on this topic in any other country at the time.

This Royal Commission was established as a result of an intensive lobby by a national coalition of women who were increasingly concerned about the proliferation of new reproductive technologies, such as infertility treatment and prenatal diagnosis. The Coalition for a Royal Commission on New Reproductive Technologies was spearheaded by two prominent Canadian women: one a well-known academic in the field of family and women's studies, Dr. Eichler, and the other a lawyer, politician, and wife of a former Prime Minister of Canada, Maureen McTeer. Their high profile allowed frequent and substantial contact with senior officials and the Minister of Health, which was critical to the momentum of this issue.

The Coalition coincided with a contentious parliamentary debate on abortion and a federal decision to ban all federally funded research using fetal tissue. In the spring of 1989, there was also a perceived need to identify a women's issue that would help to deflect the dissent around the issue of abortion. The establishment of a Royal Commission on New Reproductive Technologies was announced in the spring (April) Speech from the Throne.

Encouraged by the success of the establishment of the Royal Commission, the Coalition continued to lobby the government, in this case the Prime Minister's Office, to honor their selections for Commissioners, Chair, and Director of Research. In the end, many, but not all of the appointments were pulled from the Coalition, in the belief that other opinions and perspectives had to represented. The Prime Minister's Office (PMO) had a delicate balance among perspectives, including: pro-life and pro-choice, medical and anti-medical, feminist, industry, ethical and legal; also included were proponents of a complete halt or moratorium on all new reproductive technologies with no investigation, inquiry, or evaluation. In addition, it was crucial that there be solid and adequate representation from all parts of Canada and representation from the two major language and cultural groups of French and English.

PROCESSES USED BY THE COMMISSION TO EVALUATE NEW REPRODUCTIVE TECHNOLOGIES

There were two main streams of work used by the Commission. These streams of work provided, for the first time in Canada, a comprehensive picture of infertility and new reproductive technology use in Canada as well as the social, ethical, and legal implications of using or not using these technologies. These two streams of work were the Research and Evaluation and the Consultation and Communications Programmes. The Research and Evaluation Programme was headed by Sylvia Gold, a former President of the Canadian Advisory Committee on the Status of Women. The Research and Evaluation Program was structured into four working groups, each headed by a deputy director with significant research and evaluation experience in the particular fields of study.

The frameworks for the Research and Evaluation Programme were developed using some of the early documentation put forward by the original Coalition members and by informal discussions with a cross section of academics, policy makers, and advocates in the area. This process was used in order to identify research that had already been done, gaps in the research, and researchers who should be involved in the Research and Evaluation Programme. These frameworks evolved as the Consultation and Communications programme quickly brought to the table the many concerns, viewpoints of Canadians, and research needs that clearly had to be addressed. Four working groups were established: Causes and Prevention of Infertility, Treatment and Circumvention of Infertility, Prenatal Diagnosis and Genetics, and Fetal Tissue and Embryo Research.

Over 130 research projects were commissioned or supported, representing 70 disciplines, 21 Canadian universities, 27 hospitals and other institutions, and 300 scholars, not all in the university or academic setting. Those that were published included:

- Analysis and inquiry into the prevalence risk factors and prevention of infertility, methods of assisted reproduction, prenatal diagnosis and genetics, research involving human zygotes, the use of fetal tissue, and their social, ethical, and other implications;
- Analysis of the experiences of other countries dealing with the technologies;
- Understanding the current context within which the technologies exist, including the values of Canadians and the societal systems that interact with reproductive issues, such as the health, education, and legal systems and other institutions;
- An evaluation of relevant areas of law and ethics.

The second stream, the Consultation and Communications Programme, listened to Canadians across the country as well as international experts. It also helped inform the public about the issues contained in the mandate of the Commission. There were public hearings in 17 centers across Canada, with more than 2,000 individuals participating. There was a toll-free telephone line that allowed more than 6,000 individuals to transmit their viewpoints. Information meetings with national groups interested in the issues allowed for these perspectives to be well represented and reflected in the Research and Evaluation Programme. National surveys involving over 15,000 individuals explored Canadians' values and attitudes around these issues. Newsletters and updates were distributed as were over 250,000 pieces of information, such as information kits, brochures, and information used by journals, newspapers and television networks. Synthesis of the hearings and written submissions were analyzed electronically, based on key word searches on themes such as

women's health, industry, medical profession, infertility advocacy, etc., to allow for a comprehensive and rigorous analysis of the input that so many Canadians had spent a great deal of time preparing. These syntheses by the Consultations and Communications Programme were made available to the Commissioners and the Research and Evaluation Programme staff as they were completed. Policy briefings for each hearing, based on the participants and the provincial context, were also prepared for the Commissioners so that the social, economic, and health context was explicit in their considerations.

GUIDING PRINCIPLES AND ETHICAL FRAMEWORKS

From the very beginning, the Commission felt it important that their work, deliberations, and recommendations be guided by a broad ethical orientation—an ethic of care—which gave "priority to the mutual care and 'connectedness' between people and communities, and attempts to prevent conflict instead of resolving conflicts that have already occurred"(1). This broad ethical orientation allowed guiding principles to be developed and integrated into the assessment of how a technology's use "should be viewed, and what conclusions would be made." These principles included: individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, non-commercialization of reproduction, appropriate use of resources, accountability of those who hold power, and balancing individual and collective interests, given the Charter of Rights of Freedoms that had previously expressed the Canadian stance on the relationship between the individual and the collective.

NEEDS-BASED TECHNOLOGY ASSESSMENT APPROACH

One of the first questions asked of the Research and Evaluation Programme was why there was a *need* for such technologies and what was *the extent of the problem* that drove this demand. Obviously this was not a clear-cut question that could rely solely on past fertility surveys. Who provided the definition of infertility, how it was assessed, and in what social, economic, and political context were all questions that were considered.

The extent of the interventions and processes, such as donor insemination and surrogacy, to address infertility were assessed not only in terms of efficacy but more importantly, significant work accumulated on *relative effectiveness, cost-effectiveness, and cost benefit*.

In addition, the research and evaluation utilized, wherever possible, evidence that was based on meta-analysis processes, which allowed for relative risks and odds ratios to be calculated. This was particularly important in the interventions area, i.e., the treatment of infertility (drugs and in vitro fertilization).

A critical focus of the Commission's work involved producing the *weight of evidence* that could be judiciously reviewed by Commissioners, which included classic approaches to technology assessment while integrating legal, ethical, and social considerations such as gender.

The link with the policy context for such technologies and realities, such as the Canadian health care system and federal/provincial jurisdiction, was an important interface between the Research and Evaluation Programme and the Consultation and Communications Programme. International reviews and precedents were handled by both streams or programs; however, the processes for analysis sometimes suffered from a lack of coordination.

RESULTS AND RECOMMENDATIONS

The Commission concluded that the government, "as the guardian for the public interest, must act to put boundaries around the use of the new reproductive technologies, and must put in place a system to mange them within those boundaries, not just for now, but, equally important, in an ongoing way" (1).

They first recommended "legislation to prohibit, with criminal sanctions, several aspects of new reproductive technologies: embryos in research related to cloning, animal/human hybrids, the fertilization of eggs from female fetuses for implantation, the sale of eggs, sperm, zygotes or fetal tissues and advertising for, paying for, or acting as an intermediary for preconception (surrogacy) arrangements" (1).

Second, the Commission recommended that the federal government establish a regulatory and licensing body, a National Reproductive Technologies Commission (NRTC), with licensing required for the provision of new reproductive technologies to people. They felt that only the federal government could set up such a system, and it was important that the government fulfill its responsibility to protect citizens and society. It was felt that with the areas of regulatory responsibility to be managed by the NRTC, "a consistent country-wide system for the regulation for reproductive technologies and provision of related services would emerge" (1).

The Final Report of the Commission, "Proceed with Care," was perceived by the Commissioners as a blueprint for how Canada, "with its unique institutions and social make-up deals with new reproductive technologies, regulates their use and ensures that future developments or use are in the public interest" (1).

WHAT MY MOTHER NEVER TOLD ME ABOUT TECHNOLOGY ASSESSMENT: DISSENSION, LAWSUITS, AND DISMISSALS— SOME PERSONAL OBSERVATIONS AS DEPUTY DIRECTOR OF RESEARCH AND EVALUATION OF THE ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGIES

The Canadian government clearly took a commendable step in supporting such a Commission with such contentious issues. From its early days, this Commission had, as its dubious honor, the reputation for being one of the most contentious Commissions in Canadian history. The issues with which it had to deal were clearly one of the reasons that the stakes were so high. As one of the Deputy Directors of Research and Evaluation, in charge of the working group on the circumvention of infertility, I had the opportunity and honor to be involved with the workings of the Commission from its early days. The processes for addressing these issues, particularly from the research and evaluation front, issues that touched so many Canadians from so many different perspectives, led to great angst among staff, Commissioners, and those who worked with us and against us.

Right from the beginning, the original Coalition set out the suggested research areas to be addressed and submitted them to the Chair prior to their first Commission meeting. This was part of their attempt to take control over the research agenda; they saw themselves as representing the rights and demands of the women of Canada. In addition, their initial candidate for Director of Research was not selected; instead a senior feminist historian/academic, with no declared bias on the issues of new reproductive technologies, was selected. This selection was met with great criticism by the Coalition members and those Commissioners from the original Coalition, who subsequently wrote a letter questioning her appointment to the

Prime Minister. The Director of Research resigned in the next weeks and Sylvia Gold, a candidate with significant political experience on feminist issues, was selected.

However, the more than 40,000 individuals who gave individual or group depositions to the Commission and the 300-plus researchers representing a wide range of disciplines did not always agree with each other, the Coalition, or the overt and often publicly articulated positions of the Commissioners. Concepts such as "weight of evidence," relative effectiveness, and meta-analysis were considered suspect because some Commissioners felt they were driven by medical models of evaluation. However, while to a certain degree their questioning was relevant, significant effort was given to social, feminist analysis of these issues and to integrate this analysis with the other medical, social, and economic analyses. Yet, the polarization remained and in fact became more pronounced as the Commission did its work.

The substantive work of the Commission was severely hampered by the conflicting demands, personalities, and ideology of the Commissioners and senior management. Some Commissioners felt overmanaged and controlled by the Staff of the Commission. The style of management was driven by career bureaucrats, who were used to managing and controlling external agendas, and while this may not have been the innate management style of the Chair, it soon became so. Many of the original Commissioners, who were also members of the Coalition, railed against this nonfeminist style of decision making. Staff were caught in the middle trying to listen to all sides and reflect the demands of the Commissioners, the Chair, the senior management, and the Canadian public. Governance issues, particularly over the role of the Chair, soon overrode substantive issues of research and policy analysis, which led to the firing of four of the original Commissioners. Mistrust on all parts led to undermining the research process, documents being leaked to the press by staff members, and lawsuits for perceived breaches of contracts (which were never substantiated or followed through). Some researchers who were working on contract with the Commission were "blackballed" at the Learned Society meetings (the annual gathering of Canadian academic societies) that year.

In the end, the mistrust was so great that national associations, such as the Association of Social Scientists for Canada, demanded that the research process be made more transparent; the entire senior Research and Evaluation Programme staff were dismissed just as the final report was to be written, an unexpected and unusual action by a Royal Commission Chair. The major syntheses, representing weeks of intensive summary, which had just been completed and presented orally to the Commissioners prior to the dismissal of the senior researchers at the Commission, was embargoed and never sent to Commissioners for their use in their final deliberations and drafting of the final report.

In the end, a 15-volume report was issued with 293 recommendations made by the Commission to the Government of Canada. While there were still issues that could have been addressed or evaluated in a different context perhaps, the research stands as a legacy of the Commission as a Programme that was tremendously rigorous and which rested on the weight of the evidence.

Two years after the submission of the report to the Government of Canada, the government was still "considering" the 293 recommendations. Senior bureaucrats were in a delicate situation, given the widespread acrimony and the continued action on behalf of the original Coalition, the fired Commissioners, and the other organizations, such as the National Action Committee on the Status of Women, who set up their own committee to act as a watch dog. Internally the federal

department responsible for coordinating the response to the report (Health Canada) formed its own mini-research and policy program, bringing some of the very same individuals who conducted research and policy studies for the Commission, to appear before committees and task forces established within the bureaucracy. In the meantime, professionals, who were clearly feeling beleaguered and threatened, took concerted and strong action on certain aspects, especially as they related to practice guidelines.

THE QUESTIONS WE ARE LEFT WITH AND THE LESSONS WE HAVE LEARNED

Did the debate in civil society, among citizens on issues that tore at the very soul of individuals, families, and society, become counterproductive? Would it have been possible to conduct this inquiry in a way could have prevented some of the acrimony and still get the well-financed work done, if even at a grueling pace. What did it cost for the federal government to feel comfortable with the results, through their own research and policy analysis processes? Did the citizens' participation and rights around governance go too far, as suggested by some, or should we always consider the opportunity and the ensuing debate and friction as part of good health policy formulation? Should technology assessment stay clear of such consensus approaches or continue to learn how to better integrate wide perspectives, interests, and methods of analysis?

An important lesson remains that the political/social context *could not* be separated from the research and evaluation process on an issue that would ultimately alter the way Canadians would make decisions around resource allocation, quality and ethics of care, and equity and health, not only in reproductive health but in other aspects of health care. As a former British Health Minister, Sir George Young, once said, "The solution to many of today's medical problems will not be found in the research laboratories but in our parliaments. For the prospective patient the answer may not be the cure by incision at the operation table but by decision at the cabinet table" (2).

Some of the decisions have reached the cabinet table and the government is taking action. What are these actions, how are they being implemented, and what has been the impact?

CONCLUDING COMMENTS

It is now over *six years* since the Royal Commission submitted its recommendations to the government of Canada for action. Significant work has taken place by the government in determining the best course of action but little has had a legislative response. It appears that one of the key issues is to integrate such legislation within a framework of reproductive health, which has now been developed and released for discussion in a limited fashion. Final action requires the commitment of the government to this issue as a priority for legislation. Canadians will be well served by such action.

REFERENCES

1. Proceed with care. Final report of the Royal Commission on New Reproductive Technologies. Ottawa: Minister of Government Services, 1993.
2. Kyle, Ken. Presentation on tobacco control strategies. Ottawa: Canadian Cancer Society, 1994.