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# SUBMISSION TO THE CANADIAN ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGIES

BY THE
VANCOUVER WOMEN'S HEALTH COLLECTIVE

## Preface

The federal government is to be recognised and thanked for creating the Royal Commission on Reproductive Technologies. The overwelming interest and response to the Commisson throughout Canada indicates the importance of the complex issues at stake. Once national opinion has been gathered, the real challenge lies in integrating Canadian concerns and priorities with government policy and medical practices.

The Vancouver Women's Health Collective was founded in 1971 on the principle of self-help, to promote women's active participation in and management of their own health care. Since then, an information and referral centre has been developed with extensive files, reference books and journals on all aspects of women's health. The Health Collective is also involved in providing educational workshops and in publishing women's health information. The goals and work of the Health Collective reflect a commitment to provide clear, detailed information to enable women to make informed choices about their own health care in a supportive environment.

This submission has been written by women in the Health Collective with a variety of reproductive experiences, including those who are personally dealing with the treadmill of testing and surgery due to infertility.

## Brief

The following submission focuses on:
1. the treatment and prevention of women's infertility
and 2. the implications of *in vitro* fertilisation (IVF) and gamete intra-fallopian transfer (GIFT) for women's health and well-being, because of the radical nature of their intervention.

## Definition of Infertility

Women in Canada are medically defined as infertile if they have been attempting to get pregnant for one year without success, or they have had three miscarriages.

**Recommendation:**

**1. The Canadian definition of infertility needs to be extended to the World Health Organisation's definition of two years for a couple attempting to become pregnant.**

## Social Context of Infertility

> *"The most difficult feeling for me has been one of aloneness. I had no idea there were so many people dealing with infertility. I went to several doctors before one even acknowledged the fact that we not alone in our sadness about not being able to have children." (Salzer,1986:124)*

Infertility should be viewed as a very common condition in Canada, where it affects 15% of couples who fit into the current one year definition of infertility.

It has been described as an invisible problem in a fertile world, causing much emotional and physical pain which tends to be personalised and kept secret. It deserves and requires more recognition, more support and more reources in terms of prevention.

Infertility appears to be a biological challenge to the medical profession who attempt to "cure" the presenting problem. Infertility becomes a "problem" for women when it is defined as such by others. Through respectful and supportive consultation and information-sharing, it need not be regarded as such a deep inadequacy.

Alternatives to biolgical parenting are not widely acceptable in our society, which strongly promotes motherhood for women.

**Recommendations:**

**2. Research is needed on the attitudes of the general public and of infertile men and women towards medical and social (including cultural) options.**

**3. Infertile people must have full information on the availability, risks and effectiveness of all social and medical options for the management of infertility; then have free choice in the use of these options.**

**4. Broader public education is needed to raise the social awareness of life choices available to infertile people, including adoption, foster parenting and child-free living.**

**5. Socialisation through the media and education needs to be challenged with regards to sex-role stereotyping and positive models of alternatives to biological parenting promoted.**

## Emotional Effects of Infertility

> *"I cannot conceive or bear children. I am infertile. My infertilty is a blow to my self-esteem, a violation of my privacy, an assault on my sexuality, a final exam on my ability to cope, an affront to my sense of justice, a painful reminder that nothing can be taken for granted. My infertility is a break in the continuity of life. It is, above all, a wound- to my body, to my psyche, to my soul. The pain is intense." (Saltzer,1986:10)*

Emotionally, infertility triggers a powerful response; changing life forever. The process of grief involves surprise, denial, loneliness (especially if a woman is single or lesbian), anger, depression and finally (and hopefully) "resolution" and acceptance. In addition, a deep sense of sadness, of failing, accompanies the monthly reminder of infertility. Jealousy and resentment of others with "easy" or unwanted pregnancies, and particularly those with young children is common.

All too often, women blame themselves or their partners. Time-tabled sex, the endless routine of tests and examinations, and the invasiveness of surgery all compound the magnitude of infertility in one's life. The stress on relationships created by infertility is immense, either strengthening or breaking the partnership.

**Recommendations:**

**6. Supportive and non-directive counselling should be available to infertile people and to birth mothers considering having their children adopted.**

**7. Counselling services should be covered by provincial medical plans and should be non-discriminating in terms of race, ethnic background, marital status and sexual orientation.**

**8. Adequate funding should be available to establish infertility support groups in every region.**

**9. Funding for counselling and support services should be independent from commercial interests, including infertility clinics and treatment centres.**

**Prevention of Infertility**

> *"As a young woman, I spent the first ten years of being sexually active trying to prevent pregnancy. If I had been told that having an IUD had serious risks associated with it that could jeopardise my future fertility and that abdominal pain could indicate a pelvic inflammatory disease, I could have easily prevented the current reality of my infertility. This information was not presented clearly or responsibly to me."*

The World Health Organisation estimates that for the cost of one live IVF baby, 100 women could be prevented from becoming infertile.

Tubal infertility was the original reason why IVF and related technologies were developed. Tubal infertility is a leading cause of women's infertility, occuring in 30 to 40% of infertile women. It accounts for 12 to 20% of all infertility in couples.(Bryant,1990:17) A large proportion of tubal infertility is preventable, because it results from tubal damage due to infection. These infections may be caused by sexually transmitted diseases, by any surgery which through a woman's cervix, or by an intra-uterine device used for contraception.

The most common cause of tubal infertility is Pelvic Inflammatory Disease, or PID. Research shows that 11 to 17% of women become infertile after a single episode of PID. This rate doubles after two episodes and 50 to 60% of women who have had three episodes of PID are infertile.of pelvic inflammatory disease.(Brunham,1983, Eschenbach,1986, and Westrom,1980) The rate of ectopic pregnancy also increases dramatically in women who have had PID; a woman is 7 to 10 times more likely to have an ectopic pregnancy after having had PID.(Brunham,1983, Westrom,1980 and Todd et al,1987)

The rate of PID in Canada has increased substantially over the past 20 years. Between 1967 and 1977, the number of Canadian women hospitalized for PID increased by over 50% Hospitalizations for ectopic pregnancies caused by PID also increased by 40% during the same time period.(Brunham,1983)

Approximately 75 to 85% of cases of PID are caused by sexually transmitted diseases which move up from a woman's vagina into her pelvic organs.(Westrom,1980 and Todd et al,1987) Chlamydia trachomatis is currently the most common sexually transmitted disease in Canada. Five times as many

women were diagnosed with lower genital tract infections in 1986 as compared to 1980.(Todd et al,1987)

Up to 70% of women with chlamydial infections of the vagina or cervix have no symptoms. This means that often women are undiagnosed for long periods of time. PID caused by Chlamydia in some cases also causes very mild symptoms and is not diagnosed. Women who are found to have blocked fallopian tubes and other signs of previous PID during an infertility investigation, but who have no clinical history of PID, often have high levels of antibodies to Chlamydia. (Canadian PID Society,1990)

Women who use IUD's are three to nine times more likely to develop PID than women who do not use IUD's. This is thought to occur because infections travel up from the vagina and cervix into a woman's uterus via her IUD string. Some women with IUD's also develop PID without exposure to sexually transmitted diseases. IUD's are known to increase a woman's chances of becoming infertile from PID.

Many doctors do not insert IUD's in young women or women who wish to have children in the future. However, some doctors still insert them in young women, or in women they judge to be monogamous and therefore at lower risk of infection. The decision to insert IUD's in certain women only is questionable, both because women may be monogamous, but their sexual partner may not, and because women who do not want children in the future should not be put at risk for PID.

Infections may also travel from a woman's vagina and cervix to the uterus and tubes through operations such as D&C's, hysterosalpingograms, endometrial biopsies, therapeutic abortions and hysteroscopies. Women may develop PID as a result of the spread of sexually transmitted diseases vaginally into the uterus, or simply develop as a post-operative infection from other bacteria.

Some doctors give antibiotics prophylactically before these operations. This may help to prevent PID. However,there is also a risk of creating resistant strains of bacteria through the widespread prophylactic use of antibiotics. This could make it more difficult to treat infections in the future.

If women are not diagnosed and receive appropriate treatment for PID promptly, they are more likely to develop blocked tubes and other long-term effects from an episode of PID. Unfortunately, diagnosis of PID is difficult, and a significant amount of cases may be undiagnosed and untreated, particularly if Chlamydia trachomatis causes the infection. Researchers estimate that 30 to 50% of PID is not diagnosed.(Washington et al,1986) Unfortunately, some women

with pelvic pain are not taken seriously by their doctors, which delays adequate treatment. Often, hospitalization and intravenous antibiotic treatment is the most effective treatment for acute PID.

Women's sexual partners are not always tested for infection and treated with antibiotics, leading to re-infection and recurring episodes of PID. As the rate of infertility increases dramatically if a woman has PID more than once, sexual partners should always be treated.

There are many other causes of infertility that are preventable, which need to be investigated and controlled. Both men and women may develop infertility as a result of exposure to toxic chemicals and radiation in the workplace. Efforts to strictly regulate exposure to toxins and to enforce those regulations should help to prevent infertility.

Diethylstilbestrol (commonly known as DES), is a drug which was widely given during pregnancy in the 1940's through to the 1960's and it is an example of an unsafe medical technology which has caused higher rates of infertility in both women and men exposed before birth. Thorough testing of pharmaceuticals and medical technologies to ensure that they don't increase the risk of infertility is an important preventative measure.

Additionally, surgery on a woman's cervix increase a woman's risk of developing fertility problems. Operations such as cone biopsy and cryosurgery are commonly performed for abnormal Pap smears. Severe dysplasia and carcinoma in situ require surgery. However, mildly abnormal Pap smears can be managed much more conservatively. A woman can be asked to return for Pap smears every 3 months. Often, a mildly abnormal Pap smear returns to normal without own. If it becomes worse, the woman can have surgery.

Ironically enough, some procedures and drugs used in infertility treatments may cause infertility. This includes procedures and drugs used during IVF. Currently, women are risking their fertility when they have IVF and related procedures such as GIFT for male infertility.

**Recommendations:**

**10. The prevention of infertility needs to be regarded as the priority for funding and medical commitment. Considering the high cost, low success rate, and risks to women's health with IVF, we believe that priority should be given to funding for programs to prevent (particularly tubal) infertility, rather than programs to expand on IVF.**

11. There needs to be research on the preventable causes of infertility, including the role of environmental factors, workplace hazards, contraceptives, iatrogenic causes, sexually transmitted diseases and emotional factors.

12. Programs to prevent the spread of sexually transmitted diseases and PID need to be implemented. This should involve: public education, the free distribution of condoms (particularly to young people), expanded programs for the diagnosis of sexually transmitted diseases (especially chlamydia), and better education to health care providers on the diagnosis and treatment of PID.

13. Public education is needed that is non-judgemental and addresses the complex issues surrounding sexuality in our society. This should cover: the negative attitudes towards women's sexuality make it hard for women to show that they have planned ahead of time to have sex by having a condom with them, differences in power between women and men make it difficult for women to ask men to use condoms or insist on their use and abusive sexual relationships which may make this impossible.

14. Free, safe birth control needs to be available. The use of condoms and other barrier methods during sexual intercourse is the most effective way to prevent the sexually transmitted diseases.

15. IUD's need to be banned in Canada, because of the large numbers of women who develop PID as a result of IUD use. Stocks of these contraceptive devices should be destroyed, to avoid "dumping" in developing countries.

16. All sexually active people, and sexual partners of those with PID, need compulsory, annual routine testing for sexually transmitted diseases. This should not depend on a doctors assessment of whether a woman is likely to have several sexual partners and therefore be at risk of developing sexually transmitted diseases. General practitioners need to receive regular up`to`date information on the diagnosis and proper combined antibiotic treatment for PID.

17. Chlamydia and other PID's should be reportable diseases in Canada.

18. Post-operative infections should be prevented by adopting a more conservative approach to medical procedures through a woman's cervix and also by testing women for sexually transmitted diseases, especially Chlamydia, prior to any operation through the cervix.

19. Prevention programs could build on the current AIDS education, to cover all sexually transmitted diseases.

**20. A review of medical interventions and contraceptives with reference to their potential to cause infertility is needed. Priorities should be given to alternatives that do not risk a person's fertility. In promoting informed choice, prior to surgery or other medical treatment a discussion of risks of infertility is necessary.**

**21. IVF and GIFT should not be used in cases of male infertility, to risk a woman's future fertility.**

**22. The effectiveness of infertility prevention programs needs careful evaluation.**

## Access to Infertility Diagnosis and Treatment

> *"We found the financial strain of infertility just as difficult as all of the emotional pressure. Since our treatment went on for five years and required several surgeries, months of fertility drug treatment and numerous office procedures, the bills were considerable. Even with medical insurance, our portion was staggering. A large percentage of my pay cheque went toward these costs. There just wasn't any money left for getaway weekends, vacations or other extras. It seemed we were cornered in every area of our life."(Harkness,1987:33)*

The idea that married couples, especially those that are white, middle-class and able-bodied, provide the most stable and balanced homes in which to rear children, restricts access to parenting. This is particularly so for people with disabilities, people of colour, working class people, lesbian and single people seeking treatment.

For those people that live in outlying areas, access to diagnosis, treatment and reproductive technologies is clearly difficult. Those whose religious or cultural beliefs uphold the sacredness and privacy of conception are bound to find the procedures involved in infertility testing and treatment difficult to deal with.

New reproductive technlogies are very expensive for the consumer who qualifies.The number of infertile married couples that can afford $3,500 to $4,000 for the first months treatment at the IVF program at University Hospital, Shaunessy Site, in Vancouver is necessarily limited. The true costs of IVF and GIFT have been under-estimated by considering only the direct costs of one treatment cycle, without including the cost of high risk obstetric care and neonatal intensive care for the disproportionately high numbers of multiple births and babies born prematurely.

**Recommendations:**

**23. Access to infertility testing and treatment should open to all, free of discrimination on the basis of marital status, sexual orientation and disability.**

**24. If new reproductive technologies continue to be available, access should not be financially limited to only those who can afford to pay the high cost of treatment; means-tested coverage should be available.**

**25 The true cost of IVF and GIFT needs to be calculated: including the cost of drugs, materials and human resources for all treatment cycles, successful and failed for all women enrolled in a program and the cost of the greater intervention required obstetrically and neonatally. This true cost needs to be considered in relation to the costs of other forms in infertility care, both medical and social, and to each live birth.**

**26 In order to monitor the equity of access to new reproductive technologies, all centres should be required to report on the demographic and social characteristics of clients, with this information available to the public.**

**27 Appropriate mechanisms for the monitoring and review of access and screening decisions need to be developed, with back-up enforcment powers.**

## Effectiveness of IVF and GIFT

> *"There were so many disapointments along the way. Was it worth all the emotional and physical stress and anguish to try again? It took six months before I was able to answer that question in the affirmative...The previous two experiences had humbled me somehow. I knew my body better, it was something I could never take for granted. This time, four ova were retrieved, four fertilised and divided satisfactorily, and four were transferred! I was euphoric. Many of my fellow patients, as well as my friends at home were ready to knit booties for us. Ten days following the transfer, I had a pregnancy test. The doctor called me with the results. To my disbelief and dismay, I was not pregnant" (Harkness,1987:177)*

The success rates quoted in Canadian clinics can be misleading. For example, the Toronto Fertility and Sterility Institute in 1986 stated that they had a 20 to 25% success rate for IVF. (Pappert, Feb.1988, Globe and Mail) Based on the number of live births (which surely should be the basis of such a statistic), the Institute should have said that they had a zero percent success rate to accurately reflect the fact that they had had zero live births. This is an

extreme case, but the best epidemiological research indicates that IVF has limited effectiveness. The 1988 report released by the Ministere de la Sante et des Services in Quebec gave a zero to five percent success rate and the national rate in the United States is four to five percent being live births.

Clinics do this by including in their success rates the total number of pregnancies, regardless of those pregnancies that end in miscarriage or are ectopic (four out of ten IVF pregnancies result in miscarriage and three out of one hundred are ectopic, requiring urgent surgery. Chemical pregnancies, which result in menstruation can also be included.

Pregnancy rates independent of treatment are high. In Canada, ten percent of women become pregnant while on the waiting lists for IVF and GIFT programs, a figure that is higher than all but the best clinics success rates. In addition, one out of five "successful" births results in a much higher than average multiple birth rate, and three out of one hundred are triplets. Multiple births necessarily involve higher risk and greater intervention.

In 1988, the Australian government reported that they found no evidence to suggest that treating infertility with IVF has a higher success rate than no treatment at all.(Corea and de Witt,1989:260)

Despite limited birth rates with IVF and GIFT, the media continues to focus on less frequent success stories, emotively representing reproductive technologies as miracle cures for infertility.

**Recommendations:**

**28. Definitions of success rates in Canadian clinics need to be nationally standardised to mean the number of live births per 100 treatment cycles.**

**29. The effectiveness, short-term safety and cost of new reproductive technologies must be scientifically determined through multi-centred, randomised, clinical trials. As a treatment for a given cause of infertility, new reproductive technologies should be compared with other medical options and with no treatment. Clinics need to demonstrate that they are indeed effective, rather than experimental, in terms of safely increasing the number of live births. Any treatment which is not shown to be effective in randomized controlled trials should be discontinued.**

**30. Where a single treatment is used for a range of medical conditions, as in the case of IVF and GIFT, effectiveness trials need to be carried out for each condition. For**

**example, IVF needs to be tested separately for tubal infertility, unexplained infertility, cervical mucous problems and male infertility. If IVF or GIFT is found to be ineffective either in comparison to doing nothing or alternative treatment, its use for a specific condition should be discontinued.**

## Risks with IVF and GIFT

> *The joy of working with these couples is that they're the best patients in the world and follow your instructions to the letter. If I tell my patient that the latest infertility cure is to stand on your head on the sidewalk at high noon, they'll only ask, "Should I put a towel on the ground or just place my forehead directly on the cement?" It's heartbreaking for me when they don't succeed." (Harkness,1987:46)*

In such an emotionally charged arena, it can be difficult for infertile people and the medical profession to realistically evaluate that the chances for a successful outcome are not worth the risks involved in treatment.

A person may be infertile, but otherwise healthy. This changes the calculation of acceptable risk in a medical treatment. The admonition "to do no harm" is all the more important when discussing acceptable risks for infertility treatments.

Serious risks are associated with IVF and GIFT. The ovarian hyperstimulation syndrome, which involves a dangerous swelling of the ovaries and the formation of cysts, occurs in one to two percent of women treated with ovulation inducing drugs. It can also cause excessively high secretions of estrogen (as much as a woman would normally produce in up to two yars of ovulation (Fishel and Jackson,1989:310). Cancer of the ovaries, breast and endometrium have been linked to high levels of natural estrogen. This can be disguised by a long latency period between exposure to abnormally high levels of estrogen and the development of malignant tissue.

Clomiphene citrate (with the brand name Clomid) is a drug commonly used in infertility treatment, particularly with IVF and GIFT. Used to induce ovulation, it is frequently given to women in doses exceeding the manufacturers (Merrel Dow) recommendaton of 50mg a day. This is without having been tested at those levels for safe consumption. Clomid has a long life in the body. While 51% of the dose is excreted after five days, traces of the drug are still found in faeces six weeks after it is administered.

Clomid has a chemical profile similar to DES; the long-term adverse effects of which are well-documented and clearly linked with next-generational infertility.

Facts and Comparisons state that 14% of women on the recommended daily dose of Clomid experience abnormal ovarian enlargement. The rate of birth defects is listed at 58 out of 2369 pregnancies. There is concern about the higher rates of neural tube defects in children born after the stimulation of ovulation with Clomid.

Human Menapausal Gonadtropin or HMG (with the brand name Pergonal) is a natural hormone also used to stimulate ovulation. However, it causes an overall incidence of hyperstimulation in 1.3% and some degree of hyperstimulation is found in 50% of conception cycles. Moderate ovarian enlargement is experienced by 20% of women taking this drug. Birth defects are cited at 5 out of 287 pregnancies.(Facts and Comparisons)

In addition to the serious side effects caused by ovulation stimulating drugs,there are a host of more minor adverse reactions ranging from irritability, depression and abdominal discomfort to hot flashes and nausea. Women undergoing IVF and GIFT also need to deal with the risks of surgery under general anaesthetic, ultrasounds and sonograms.

There is an increased rate of complications in IVF and GIFT pregnancies. These pregnancies are frequently complicated by hypertension, first trimester bleeding, general anesthetic, embolism and the delivery of IVF and GIFT pregnancies by cesarian section. At the IVF clinic in London, Ontario, the percentage of deliveries by cesarian section between 1984-1987 was double the national average of 17.9% (not including multiple gestation which occurs in approximately 25% of IVF pregnancies and which are all delivered by cesarian section). This is very high considering the World Health Organisation recommended a cesarian rate of 10-15%

The risks of IVF and GIFT to the fetus and baby are considerable as well. The National Perinatal Statistics Unit in Australia established a register of IVF pregnancies and births. They reported data on 12 IVF centres between 1979 and 1985 and found a high incidence of pre-term delivery and low birth weight. Babies born through IVF are five times more at risk to develop spina bifida and seven times more likely to have transposed major blood vessels of the heart. The perinatal mortality rate for IVF babies is four times, and the neonatal mortality rate twice that, of the general population(World Health Organisation Report on IVF).

It is of concern that, given the Canadian definition of infertility, couples are turning to IVF and GIFT after only

one year of infertility and testing. Due to the risks associated with IVF and GIFT, it is alarming that these methods are being used for male infertility, as less invasive, less risky and more reliable procedures like Artificial Insemination by Donor (AID) can be used if the woman is fertile.

**Recommendations:**

**31. Case-control studies are needed to evaluate the short-term and long-term risks of ovulation induction and other technological procedures.**

**32. More stringent guidelines in the indications for ovulation induction need to be developed.**

**33. Limits should be placed on the number of artificially stimulated cycles that women undergo. Three courses are seen as an adequate theraputic trial for ovulation.**

**34. The practice of ovulation induction for the purpose timing pregnancy or regulating the menstrual cycle should be discontinued.**

**35. The practice of ovulation induction in normally ovulating women for the sole purpose of oocyote donation should be discontinued.**

**36. The practice of using IVF and GIFT in cases where infertility is due to low effective sperm count or the cause is unknown should be discontinued, given the current risks associated with these procedures to a woman's health.**

**37. All Canadian clinics should follow the guideline set out by the European Society on Human Reproduction and Embryology that limits the number of eggs or embryos transferrred during a treatment cycle to be no more than three.**

## Quality Assurance of IVF and GIFT

Given that new reproductive technologies are invasive, expensive and involve serious risks, it is of concern that no adequate system of quality assurance has been developed in Canada. Such a system should include: certification of all service providers, mandatory reporting of data, ongoing monitoring using selected indicators and independent audit and enforceable sanctions for non-compliance.

In addition, because of the current lack of information on long-term risks, it would be helpful to develop a registry of all women undergoing treatment, and the results of treatment including adverse effects and babies born.

As well as consumers, medical insurance plans and the health care system, producers also need to be involved in the quality assurance of new reproductive technologies. Both the pharmaceutical companies who produce fertility drugs and manufacturers of medical equipment have a much to gain from the development of new reproductive technologies, as do the clinics which offer these "treatments". Any discussion of safety and effectiveness involves a manufacturer's responsibility to produce a product under certain standards.

It is important to ask why it is that technologies such as IVF and GIFT have not been subjected to rigorous testing for safety and effectiveness before they have been accepted onto the Canadian market. Although these technologies utilize drugs which have already undergone an approval process, these drugs are being used in a different way, at different dosages and for different purposes. Both the Health Protection Branch of Health and Welfare Canada and the manufacturers have a responsibility to ensure that these drugs are safe and work well.

Technologies developed for use during IVF and GIFT also need to be used with caution. Needle aspiration of oocytes could cause long-term damage to a woman's ovaries. Repeated ultrasounds to a woman's pelvic area could also cause harm. The history of "old" reproductive technologies such as DES, thalidomide, the Dalkon Shield, and the Copper 7 IUD and the harm which they have done to women and their children indicate that manufacturers can allow profits to come before concern about safety. Rigorous testing of reproductive technologies is essential.

**Recommendations:**

**38. Certification of reproductive technology providers must be tied to thorough training and demonstrated skill. Each clinic must have at least one such certified provider who assumes direct responsibility for dispensing ovulation drugs, evaluating potential new clients, evaluating clients wishing to repeat treatment cycles, and training and supervising other clinic personnel.**

**39. There needs to be mandatory reporting of all treatment cycles and all babies born as a result to provide the basis for quality assurance. Additionally, record linkage of new reproductive technology registries with birth defects and cancer registries would provide useful data for monitoring adverse effects of treatment.**

**40. All monitoring and audit of clinics needs to be done by an independent team. Sanctions for non-compliance with established standards should include closing the centre. Results of this independent monitoring and audit should be available to the public.**

**41. Activities primarily for the purpose of developing or contributing to general knowledge in all treatment centres need to be clearly labelled as research and differentiated from activities that are primarily for the purpose of enhancing the well-being of an individual client. There should be no incentives for clients to participate in research.**

## Conclusion

In working to promote women's active participation in and management of their own health care, the Vancouver Women's Health Collective recognises the personal pain of infertility, the value of diagnosis and the power of informed individual choice on how far to take infertility treatment.

However, we have serious concerns regarding the current risks of IVF and GIFT to women's health and the adequacy of quality assurance of these procedures within Canada. As a result, we recommend that IVF and GIFT be accorded experimental status in Canada, until the necessary research and controls demonstrate their safety and efficacy for women and children's health.

The key to successfully implementing a comprehensive system of reproductive technologies that is sensitive to the needs of infertile individuals, while maintaining its planned integrity as a whole - involves **dialogue** and honest **evaluation.** Well-informed lay people (particularly women) need to form the core of community participation in planning and monitoring reproductive technologies to ensure that these technologies are held accountable to the interests of the Canadian public.

The decisions women make regarding fertility are of critical importance to Canadian society. The decisions made in the public sphere about reproductive technologies have a huge impact on individual lives. Let our voices help shape the organisation and future of these reproductive technologies so that they benefit the long-term health and lives of women and children in our country.

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## Summary of Recommendations:

**Definition of Infertility**

1. The Canadian definition of infertility needs to be extended to the World Health Organisation's definition of two years for a couple attempting to become pregnant.

**Social Context of Infertility**

2. Research is needed on the attitudes of the general public and of infertile men and women towards medical and social (including cultural) options.

3. Infertile people must have full information on the availability, risks and effectiveness of all social and medical options for the management of infertility; then have free choice in the use of these options.

4. Broader public education is needed to raise the social awareness of life choices available to infertile people, including adoption, foster parenting and child-free living.

5. Socialisation through the media and education needs to be challenged with regards to sex-role stereotyping and positive models of alternatives to biological parenting promoted.

**Emotional Effects of Infertility**

6. Supportive and non-directive counselling should be available to infertile people and to birth mothers considering having their children adopted.

7. Counselling services should be covered by provincial medical plans and should be non-discriminating in terms of race, ethnic background, marital status and sexual orientation.

8. Adequate funding should be available to establish infertility support groups in every region.

9. Funding for counselling and support services should be independent from commercial interests, including infertility clinics and treatment centres.

**Prevention of Infertility**

10. The prevention of infertility needs to be regarded as the priority for funding and medical commitment. Considering the high cost, low success rate, and risks to women's health with IVF, we believe that priority should be given to funding for programs to prevent (particularly tubal) infertility, rather than programs to expand on IVF.

11. There needs to be research on the preventable causes of infertility, including the role of environmental factors,

workplace hazards, contraceptives, iatrogenic causes, sexually transmitted diseases and emotional factors.

12. Programs to prevent the spread of sexually transmitted diseases and PID need to be implemented. This should involve: public education, the free distribution of condoms (particularly to young people), expanded programs for the diagnosis of sexually transmitted diseases (especially chlamydia), and better education to health care providers on the diagnosis and treatment of PID.

13. Public education is needed that is non-judgemental and addresses the complex issues surrounding sexuality in our society. This should cover: the negative attitudes towards women's sexuality make it hard for women to show that they have planned ahead of time to have sex by having a condom with them, differences in power between women and men make it difficult for women to ask men to use condoms or insist on their use and abusive sexual relationships which may make this impossible.

14. Free, safe birth control needs to be available. The use of condoms and other barrier methods during sexual intercourse is the most effective way to prevent the sexually transmitted diseases.

15. IUD's need to be banned in Canada, because of the large numbers of women who develop PID as a result of IUD use. Stocks of these contraceptive devices should be destroyed, to avoid "dumping" in developing countries.

16. All sexually active people, and sexual partners of those with PID, need compulsory, annual routine testing for sexually transmitted diseases. This should not depend on a doctors assessment of whether a woman is likely to have several sexual partners and therefore be at risk of developing sexually transmitted diseases. General practitioners need to receive regular up`to`date information on the diagnosis and proper combined antibiotic treatment for PID.

17. Chlamydia and other PID's should be reportable diseases in Canada.

18. Post-operative infections should be prevented by adopting a more conservative approach to medical procedures through a woman's cervix and also by testing women for sexually transmitted diseases, especially Chlamydia, prior to any operation through the cervix.

19. Prevention programs could build on the current AIDS education, to cover all sexually transmitted diseases.

20. A review of medical interventions and contraceptives with reference to their potential to cause infertility is needed. Priorities should be given to alternatives that do not risk a person's fertility. In promoting informed choice, prior to surgery or other medical treatment a discussion of risks of infertility is necessary.

21. IVF and GIFT should not be used in cases of male infertility, to risk a woman's future fertility.

22. The effectiveness of infertility prevention programs needs careful evaluation.

**Access to Infertility Diagnosis and Treatment**

23. Access to infertility testing and treatment should open to all, free of discrimination on the basis of marital status, sexual orientation and disability.

24. If new reproductive technologies continue to be available, access should not be financially limited to only those who can afford to pay the high cost of treatment; means-tested coverage should be available.

25. The true cost of IVF and GIFT needs to be calculated: including the cost of drugs, materials and human resources for all treatment cycles, successful and failed for all women enrolled in a program and the cost of the greater intervention required obstetrically and neonatally. This true cost needs to be considered in relation to the costs of other forms in infertility care, both medical and social, and to each live birth.

26. In order to monitor the equity of access to new reproductive technologies, all centres should be required to report on the demographic and social characteristics of clients, with this information available to the public.

27. Appropriate mechanisms for the monitoring and review of access and screening decisions need to be developed, with back-up enforcment powers.

**Effectiveness of IVF and GIFT**

28. Definitions of success rates in Canadian clinics need to be nationally standardised to mean the number of live births per 100 treatment cycles.

29. The effectiveness, short-term safety and cost of new reproductive technologies must be scientifically determined through multi-centred, randomised, clinical trials. As a treatment for a given cause of infertility, new reproductive technologies should be compared with other medical options and with no treatment. Clinics need to demonstrate that they are indeed effective, rather than experimental, in terms of safely increasing the number of live births. Any treatment

which is not shown to be effective in randomized controlled trials should be discontinued.

30. Where a single treatment is used for a range of medical conditions, as in the case of IVF and GIFT, effectiveness trials need to be carried out for each condition. For example, IVF needs to be tested separately for tubal infertility, unexplained infertility, cervical mucous problems, male infertility, etc. If IVF or GIFT is found to be ineffective either in comparison to doing nothing or alternative treatment, its use for a specific condition should be discontinued.

**Risks with IVF and GIFT**

31. Case-control studies are needed to evaluate the short-term and long-term risks of ovulation induction and other technological procedures.

32. More stringent guidelines in the indications for ovulation induction need to be developed.

33. Limits should be placed on the number of artificially stimulated cycles that women undergo. Three courses are seen as an adequate theraputic trial for ovulation.

34. The practice of ovulation induction for the purpose timing pregnancy or regulating the menstrual cycle should be discontinued.

35. The practice of ovulation induction in normally ovulating women for the sole purpose of oocyote donation should be discontinued.

36. The practice of using IVF and GIFT in cases where infertility is due to low effective sperm count or the cause is unknown should be discontinued, given the current risks associated with these procedures to a woman's health.

37. All Canadian clinics should follow the guideline set out by the European Society on Human Reproduction and Embryology that limits the number of eggs or embryos transferrred during a treatment cycle to be no more than three.

**Quality Assurance of IVF anf GIFT**

38. Certification of reproductive technology providers must be tied to thorough training and demonstrated skill. Each clinic must have at least one such certified provider who assumes direct responsibility for dispensing ovulation drugs, evaluating potential new clients, evaluating clients wishing to repeat treatment cycles, and training and supervising other clinic personnel.

39. There needs to be mandatory reporting of all treatment cycles and all babies born as a result to provide the basis

for quality assurance. Additionally, record linkage of new reproductive technology registries with birth defects and cancer registries would provide useful data for monitoring adverse effects of treatment.

40. All monitoring and audit of clinics needs to be done by an independent team. Sanctions for non-compliance with established standards should include closing the centre. Results of this independent monitoring and audit should be available to the public.

41. Activities primarily for the purpose of developing or contributing to general knowledge in all treatment centres need to be clearly labelled as research and differentiated from activities that are primarily for the purpose of enhancing the well-being of an individual client. There should be no incentives for clients to participate in research.