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THE INFERTILITY DILEMMA: REPRODUCTIVE TECHNOLOGIES AND PREVENTION

Canadian Advisory Council on the Status of Women

Conseil consultatif canadien sur la situation de la femme

THE INFERTILITY DILEMMA

NFERTILITY
BP 1989-3E

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WOMEN

BACKGROUND PAPER

THE INFERTILITY DILEMMA: REPRODUCTIVE TECHNOLOGIES AND PREVENTION

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February 1990

Canadian Advisory Council on the Status of Women

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Table of Contents

List of Tables

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Executive Summary

Infertility negatively affects many individuals in Canada, and it appears that the numbers may actually be increasing. New reproductive technologies (NRTs) designed to treat infertility are thus welcomed by many as a means of relieving the distress experienced by so many infertile women and couples.

However, success rates of the new therapies remain low, and the techniques experimental. In addition, these reproductive therapies have an impact on society far beyond the medical/technological sphere from which they are developed and administered. These effects are discussed in some detail in this paper, because they may influence many women's access to this aspect of reproductive health.

One effect of the focus on the technologies themselves is the potential for overlooking the possibilities of less technologically exciting, but potentially more cost-effective means of dealing with infertility. Programs designed to prevent sexually transmitted diseases (STDs), particularly among young women, have such potential. However, many barriers exist, including lack of knowledge of the antecedent factors, little evaluation of existing programs, and an emphasis towards curative medicine. These must be addressed before we can expect gains to result from the implementation of preventive programs.

This paper provides an overview for the non-medical reader of the impact of NRTs which are designed to treat infertility. It also explores the possibilities and feasibility of developing preventive approaches to infertility. Finally, the paper outlines the future research requirements and changes in social policy which may facilitate such a shift in emphasis from cure to cause. While this paper does not attempt to be the definitive statement on these issues, it is hoped that it will draw the focus of the discussion on infertility away from that of a medical problem with a technological "fix", to that of a reproductive health concern which requires societal consideration and input from many disciplines.

Introduction

> Sometimes I sit in church and listen to the junior choir, and see a little girl singing away, and all the time she's looking for her mother in the congregation. And then her mom sees her and waves, and the little girl waves back and they both smile. And I know I'll never experience that.[1]

The anguish expressed in the above quote has been felt by others throughout history. Attempts to find a solution to the personal and social dilemma of infertility also have a long history; the Old Testament account of Abram and Sarai's infertility, and their search for a biological heir for Abram is but one example. Their joint decision that he should impregnate Sarai's slave, Hagar,[2] speaks to the perceived seriousness of this problem even many centuries ago.

What is relatively new, however, is the belief that, for many individuals, infertility is curable. A physician/researcher in new reproductive technologies (NRTs) recently said, "In 1988 the uterus remains the only absolute requirement for pregnancy".[3] The phenomenon of infertility is being drawn into a new arena — the arena of biological problems for which there are biological cures. When juxtaposed against the emptiness expressed by many infertile couples,[4] the prospect of a cure understandably attracts a great deal of attention.

However, the potential impact of NRTs on society affects a number of issues, potentially going far beyond the direct benefits for those attaining successful treatment, and the indirect benefits for the practitioners of this medical specialty. These issues range from such philosophical dilemmas as defining the role and rights, if any, of the embryo, particularly before implantation, to the seemingly purely practical aspects of deciding whether the desire to bear a child is actually a medical problem, and, if so, whether the health-care system should therefore pay for its treatment. Past position papers on these issues, and the call for a royal commission, reflect the concerns of many people about the potential impact of these newer technologies on women, and on society in general.[5] Although many valuable discussions of the social and contextual issues of the NRTs exist, and will be referred to elsewhere in the paper, most medical/ethical/social writers focus on the potential impact of the technologies themselves. Alternative ways of addressing the total issue of infertility and reproductive health in the Canadian context are not discussed as frequently.

The debate on the potential impacts of widespread technology is a compelling one, and must continue. However, we should not lose sight of the fact that these technologies largely represent cures for reproductive illnesses, and do not address the more global issue of maintenance and promotion of reproductive health. Although the hope for curative therapies for human medical conditions is a common and understandable one, the potential for prevention is one which is equally attractive to many.[6] Indeed, The Health Promotion Framework — which includes increasing the prevention effort and emphasis on self-help, mutual aid, and the creation of healthy environments — is seen as the preferred future direction for health maximization in Canada.[7] Because infertility, like other undesirable

reproductive outcomes, has multifactorial causes, many of which are not yet understood, this area of health promotion is a challenging one. However, the focus on curative technologies for those couples who are known to be infertile should not preclude the serious consideration of **preventive** programs as being major contributors to reproductive health in Canada.

This paper focuses on drawing the issue of infertility out of the sickness/cure arena in which it is often confined. In doing so, it provides an overview of cure and prevention efforts as well as many of the key aspects of the impact of infertility. It outlines the background information on the probable magnitude of the infertility problem in Canada, and of the possible causes which would be amenable to prevention. The current status of curative and preventive strategies is described and, through this discussion, the areas of greatest research need are identified. Finally, the paper outlines those changes in social policy identified as having the potential to ameliorate current issues of concern. It is hoped that, by placing the discussion of infertility into a broader framework than the sickness/cure dichotomy, the current debate on NRTs also will be placed in the perspective of the potential for improved reproductive health for all women in Canada.

Infertility and Reproductive Health: An Overview

Most of this paper deals with the problem of infertility which is defined as the inability to conceive a viable pregnancy within one year of intercourse.[8] It must be emphasized, however, that this is a rather arbitrary cut-off point, and has no particular biological significance. Research done almost forty years ago, for example, found that 91.2% of 1,727 pregnant women had conceived within the requisite one year. Of the remaining 8.8%, who would have been defined as "infertile",[9] over half conceived during the following year without medical intervention. Thus, if these women had gone to an infertility clinic after twelve months of unsuccessful attempts to conceive, the "cure rate" would have been over 50% in the first year, even if no therapy were used.

Of course, all of the women in the above study eventually conceived and thus were not truly sterile. Estimates in 1948 placed the rate of permanent infertility at 10% of couples.[10] Using this background rate of 10%, and assuming that the experience of the women in the study reflected the typical experience of the remaining 90% of the population, the overall rate of infertility would be 17.9% (10% sterile plus the 8.8% of the remaining 90% of the population who did not conceive within one year). Of these infertile women, 44% (all but the 10% who were truly sterile) would go on to conceive without medical intervention.

If two years of unprotected intercourse were required before the definition of infertility was made, and the same background permanent infertility rate of 10% was assumed, the overall rate of infertility would be 13.8% in this sample, with a spontaneous cure rate of 27.5%. Obviously, then, the numbers chosen to define "infertility" affect both the perceived magnitude of the problem, and the apparent

cure rate. This must be borne in mind whenever infertility rates and therapeutic success rates are discussed.

Infertility is, therefore, a relatively common problem. However, it is by no means the only reproductive health issue of current concern. The 1988 National Consultation on Research Needs in Sexuality and Reproductive Health identified many areas of reproductive health which require attention, including:

- prevention of unwanted pregnancy;
- prevention of sexually transmitted diseases;
- prevention of pelvic inflammatory disease (PID);
- improved birth outcomes (fewer premature and low birth weight infants, for example);
- research into social, psychological, cultural, economic, and other determinants of contraceptive and sexual behaviours; and
- socioeconomic status and its relationship to reproductive health.[11]

Similar objectives have been highlighted by the U.S. Department of Health and Human Services.[12]

While this may seem to cast an impossibly broad net around reproductive health (and it should be noted that these are only the **highlighted** areas of concern), all of these factors are, in fact, interrelated. As will be seen, prevention of sexually transmitted diseases (STDs) and pelvic inflammatory disease (PID) will result in prevention of a certain proportion of infertility. Research into high-risk behaviours, such as "unsafe" sexual practices, will affect all three outcomes (STDs, PID, and infertility). Finally, eliminating inequities in reproductive health across socioeconomic strata would decrease the prevalence of infant mortality, and could influence the prevalence of infertility as well as access to care to some extent. Although this paper can focus only on issues most directly related to infertility, the impact of addressing the broader fields of reproductive health should be borne in mind. Some of the policy issues at the conclusion of this paper address these concerns.

Infertility and New Reproductive Technologies: The Issues of Curative Therapy

Most discussions of the impact of NRTs begin with the exploration of their role as solutions to reproductive health problems. In fact, the rubric of NRTs covers many different therapeutic modalities and addresses quite a wide range of potential reproductive dysfunctions. Because only some of these are pertinent to the topic of this paper, a brief outline of the available technologies, and the reasons for further consideration of some but not others, will help to focus the later discussion.

Generally speaking, the term NRT applies to technologies which address one of two possible concerns. One group of technologies examines the characteristics of the already conceived fetus. This group of technologies includes amniocentesis[13] or chorionic villus sampling[14] of at risk pregnancies, or prenatal screening for defects

such as neural tube defects.[15] Such testing may be followed by selective abortion or, rarely, prenatal therapy (if possible), depending upon the circumstances. These new and highly specialized technologies have generated great interest, but are mentioned only to indicate the spectrum of NRTs and to point out the necessary exclusion of many NRT-related issues in this paper. The focus of this paper necessarily will be on those technologies designed to address the needs of the infertile woman (or couple).

Many treatments for infertility exist, and not all of them are considered under the usual rubric of NRTs. For example, treatments which involve only drug therapy (as for the purposes of inducing ovulation) are widely used, either alone or in conjunction with the new technologies. However, they are not commonly considered as new "technologies" when used alone. Further, surgery on either partner (such as in vasovasostomy, to reverse a previous vasectomy, or tuboplasty to repair tubal damage, or surgery to treat endometriosis) are such common procedures that the NRT label is usually not applied to them. This paper will consider the therapies which involve some manipulation of gametic material (sperm or ova), whether or not they also involve subsequent handling of fertilized eggs (embryos or "pre-embryos", as they are now often called).

The simplest technologies are those limited only to the artificial insemination of a woman by semen produced by a donor (AID), or in some circumstances, by her husband/partner (AIH). In this case, the semen is placed into the cervix of the woman wishing to become pregnant; she may have also received some medications to regulate the time of ovulation. However, the woman's Fallopian tubes and uterus must be intact and functioning normally for this intervention to be successful.[16]

In more recent technologies, the ova and/or zygote (the ovum which has been successfully fertilized by a sperm cell) may also be the subject of therapy. In vitro fertilization (IVF), the technique responsible for the celebrated birth of Louise Brown, and the technique associated with the common term "test tube babies", involves the surgical removal of ova from the female; drugs which stimulate ovulation are routinely used to optimize the timing and to increase the available number of eggs. This often leads to multiple ovulation, and, if all fertilized ova are successfully implanted, can lead to multiple births. Semen, generally provided by the husband, but, where sperm quality is questionable, possibly by a donor, is combined with the ova in the laboratory. Those eggs which are successfully fertilized and in which cell division occurs are then re-inserted into the woman's uterus, where it is hoped they will implant and result in a successful pregnancy. Several refinements, which are directed toward improving the fertilization or successful implantation rate, are also under investigation. However, a key feature of this technique is its usefulness in instances where the Fallopian tubes are incapable of transporting the ovum (pre- and post-fertilization).[17]

Another closely related technique is termed gametic intra-fallopian transfer (GIFT). This technique involves removal of the ova as for IVF, but the sperm and unfertilized ova are replaced into the Fallopian tube for fertilization and subsequent development. Thus, this technique is appropriate where the woman has at least one normal Fallopian tube; the therapy has been attempted for women with a wide range of causes of infertility.[18]

Finally, many writers include surrogacy as one of the new reproductive technologies. In fact, as the story of Abram, Sarai, and Hagar illustrates, this is scarcely a new phenomenon. What may have "modernized" surrogacy is the new convention of impregnating the biological mother using AID techniques, the "donor" being the biological father. While the social ramifications of surrogacy are potentially very great, most of them relate to the legal status and rights of the adoptive and biological parents, and to the concept of payment for reproductive services, rather than to the technology itself. Thus, surrogacy will not be discussed at length when NRTs are reviewed elsewhere in this paper.

Issues Regarding Infertility-related New Reproductive Technologies

Although the processes dealing with the "cure" of infertility seem straightforward enough, they have a potential impact on many spheres of life. While there is a great deal of overlap in the consequences, for the purposes of simplicity, these will be divided into three major areas: the medical and technical issues, social and contextual factors, and concerns related to the financial costs to society of infertility treatment.

Medical and Technical Issues

As would be expected, the medical context in which infertility treatment occurs comes under scrutiny whenever the technologies themselves are discussed. The examination of these medical aspects ranges from general questions regarding the current and appropriate roles of physicians in these processes, to the definitions and rates of success of the processes themselves.

Some writers criticize the medical context of infertility therapy, noting that physicians are in sole control of access to most of the means of treatment. This stance echoes current criticisms of the "medicalization" of society in general, as espoused by Ivan Illich.[19] The debate on the appropriate balance of power in health-related issues in our society is a complex one, and is beyond the scope of this paper. However, the debate has raised some specific criticisms of infertility-related care as well as suggestions for change. Proponents of demedicalization have suggested, for example, that the "lower technology" procedure of AID could well be carried out by non-physicians or women's health collectives.[20] However, such commonly used safeguards as screening of semen donors for STDs (including HIV-1, the virus that causes AIDS), which are procedures involving laboratory and medical techniques, are often not discussed by proponents of demedicalization. Because the risk of such exposures would be expected to be similar in the non-medical clinics, the use of

these technological tests must be considered, regardless of where the procedures are carried out.

Further, while it is true that medical intervention is not required to effect insemination, most other infertility therapies do necessitate medical technology and specialized training. However, one does not have to take over the actual execution of a technology before some "demedicalization" can occur. Much could be accomplished, for example, by ensuring that explanations of potential therapies are thorough and include a discussion of the likelihood of personal or physical discomfort, as well as a realistic estimate of the success rate. Counselling regarding the more subjective issues of therapy may be useful for both successful and unsuccessful clients. Practitioners have noted that even the best attempts to provide such information are limited by the extent to which couples believe that this intervention may provide some new (if slim) hope for success.[21] As a result, it would be beneficial to have workshops which examine ways to provide this information by involving clients as truly active decision-makers in medical therapy, rather than as passive recipients of technology.

The discussion of medicalization is not complete without a consideration of the potential gender-based causes and effects of this phenomenon. In current practice, new reproductive technologies are almost always carried out on the bodies of women. While some writers view the technologies as an ultimate benefit to women, recent feminist literature sounds strong cautionary notes about these technologies, and of their possible contribution to the "patriarchal approach to reproduction".[22] Full involvement of women themselves (and not just as "patients") in the discussions regarding the future role of these technologies is urgently required to limit their potentially negative social impacts.

Another critique of these technologies is that they often do not actually cure the underlying biological disorder of infertility. Rather, their goal is to treat what could be described as the "symptom" of infertility, i.e., the couple's unrequited desire for a child. Some question whether the inability to conceive the desired child is, in fact, a **medical** problem. Those who argue that it is state that infertility is usually due to some kind of identifiable, or unidentifiable but presumed, biological abnormality. However, others argue that those desiring assistance in achieving conception could be viewed as expressing a desire to attain a goal (a child) which cannot be easily attained. According to this second viewpoint, the underlying biological disorder is merely the obstacle to this achievement.

However, the issue of whether infertility therapy is of less value if it is often not curative of the underlying disorder is best considered in the context of other medical therapies. Many existing therapies, including the treatment of vision defects, diabetes, or high blood pressure, usually do not correct the underlying abnormality. Appropriate treatment can, however, improve the quality, and often the actual length, of an individual's life. To discount infertility therapy on the grounds that it is noncurative is therefore incompatible with the acceptance of many other valuable therapies.

It is also true that many of the new technologies used to treat infertility are, in fact, experimental. Those who feel uncomfortable with this aspect of the technologies may describe the women who undertake such treatments as "guinea pigs",[23] whose participation benefits researchers in the medical system.[24] One key issue here is that of informed consent. In other words, do the women undertaking a course of invasive therapy really understand the risks involved, or are they persuaded to take part by an inflated belief in the potential benefits of the therapy? Some practitioners in the area point out the difficulty prospective patients may have in weighing the risks and benefits, even when well explained, because the value of the benefit — the much wanted child — is so high that it outweighs almost any description of risk.[25]

Beyond this aspect is a basic concern, implied by some people, that research should not be carried out on human subjects. Unfortunately, this is not a realistic ideal. Even the most rigorously tested therapies may have new or unexpected effects on human subjects when applied in practice and thus require human trials and regulatory approval before widespread use is permitted. The real tragedy would be to fail to collect the data on risks and effectiveness of early therapy attempts (in other words, to fail to recognize the research aspects of the techniques), so that monitoring of these events becomes impossible. Such research could involve a simple registry of all treatment attempts, their side effects, and outcomes, but ideally would consist of full-scale clinical trials.

The paradigm which now represents the best design for the investigation of new therapies is the randomized, controlled clinical trial.[26] In this design, the couples would be divided into two groups: those who receive the new treatment, and those who receive the standard therapy (or, if no standard exists, no therapy at all, or a placebo). Couples who agree to take part in such a study must agree to participate regardless of which treatment group they are assigned to. After agreement, their assignment to one group or the other is done completely at random, with no interference by the participants, or the investigators. Both groups are then followed to see whether the new therapy truly results in a higher success rate than the standard therapy. In the case of infertility therapies, particularly those using ovulatory stimulants, long-term follow-up of the treated women (whether or not they ever bear a child), and of any offspring, would also be an essential part of the study.

For many potential study participants, the difficulty in this type of design is not the experimental nature of the new therapy, but the possibility that if they are randomly chosen for the non-treatment group, some new and potentially helpful therapy may be "withheld" from them, even if this "withholding" is only temporary. However, the alternative is to apply the therapy without proof that it is actually useful. Past experience points out the need for caution before a new treatment is made available for common use. We have but to consider the problems associated with diethylstilbestrol (DES), whose efficacy was not proven by randomized trials,[27] and gastric freezing,[28] once a popular but, as was later discovered, a totally ineffective therapy for ulcers.

Thus, the problem with NRTs as research techniques may not be that such research is occurring, but that current research is not being carried out in a definitive way to ensure the effectiveness of these technologies. To prove effectiveness, it must be demonstrated that treated couples were more likely than untreated or alternatively treated couples to bear living, healthy children, without developing other physical or psychological side effects, over a reasonable period of time. One published study, in which response to therapy during active treatment was compared with pregnancy rates of infertile couples not under active treatment, failed to show a dramatic effect.[29] The authors of this study also called for randomized trials to prove the efficacy of the techniques.

While controlled trials are rare, several published studies of clinical success rates exist, and are presented in the following tables. These uncontrolled studies are often difficult to compare because of different patient populations, small sample sizes, and inconsistency in the definition of success. The latter problem was highlighted by Ann Pappert's 1988 article in the *Globe and Mail*,[30] which surveyed success rates of Canadian clinics and found the tendency was to report pregnancy rates, and not live birth rates. Further, some scientific studies report "chemical pregnancies", i.e., very early pregnancies that have not yet resulted in a pregnancy which is noticeable either by the woman herself or by usual clinical diagnostic methods. Because nearly a quarter of these very early pregnancies are expected to be lost before they are clinically detectable,[31] these chemical pregnancies should not be defined as clinical "successes". Similarly, because clinically evident miscarriage is also quite common, simple pregnancy rates give an inflated estimate of what most couples would consider their goal — a healthy baby.

Tables 1 to 4 provide a sample of published success rates of the various technologies. Unless otherwise stated, it is assumed that success rates refer to pregnancies, not live births. Several patterns can be seen. First, success rates per cycle are generally lower than the ultimate success rate, as many couples undergo several cycles of therapy. (A "cycle" refers to one attempt at ovulation, recovery, fertilization, and implementation. If this attempt fails, another can be made in a later menstrual cycle.) Second, as predicted, the success rates have wide ranges because patient selection varied from study to study. Very high success rates, however, only occur when the number of cycles per patient is very large or sample sizes are extremely small, which indicates that we can have little faith in any generalization of the results.

Unfortunately, there is little value in comparing these success rates with pregnancy rates for women who did not undergo these therapies, again because the clinical populations are so selected. For example, these women may have had infertility for a longer time than the "average", or the couple may have different underlying disorders than other untreated series. As previously mentioned, clinical trials with a control group would be necessary to determine whether these success rates are substantially better than another therapy or no therapy at all.

Table 1: Artificial (Intrauterine) Insemination with Donor Semen (AID), Success Rates[a]

	Number of couples presenting for therapy	Number of cycles	Number of women who had a live birth	Number of pregnancies	Number of miscarriages	Number of ectopic pregnancies	% of women who became pregnant	% of pregnancies per treatment	% with live birth
Huszar et al., 1984	100[b]	250[b]	NR	15	3	–	15.0	6.0	NR
Yeh and Seibel, 1987	139	760	64	75	11	–	54.0	9.9	46.0
Millet and Jondet, 1979	604	2,411	222[c]	342	48	2	56.6	14.2	36.7
Steinberger et. al., 1979	185	974	NR	133	NR	NR	71.9	13.7	NR
David et al.,[d] 1979	1,188	5,398	364[e]	529	82	4	44.5	9.8	32.8

Sources: See note 32 on page 33.
Notes: NR = Not reported.
a. Excludes from consideration women whose pregnancies were still ongoing at the time of report.
b. Approximation.
c. Including 3 multiple births.
d. Only first successful pregnancy attempt (i.e., ending in live birth) considered.
e. Including 18 multiple births.

Table 2: Artificial (Intrauterine) Insemination with Husband's Semen (AIH), Patient Characteristics and Success Rates[a]

	Number of couples presenting for therapy	Number of cycles	Number of women who had a live birth	Number of pregnancies	Number of miscarriages	Number of ectopic pregnancies	% of women who became pregnant	% of pregnancies per treatment	% with live birth
Byrd et al., 1987	68	229	NR	26	4	--	38.2	11.3	NR
Serhal et al., 1988	62	113	9[b]	13	1	--	21.0	11.5	15.3
Davajan et al., 1983	120	NR	NR	53	NR	NR	44.2	NR	NR
Glezerman et al., 1984	25	NR	8	13	5	--	52.0	NR	32.0
Goldfarb et al., 1984	21	29	--	1[c]	--	--	4.8	3.4	0.0
Ulstein, 1973	45	263	12	19	7	--	42.2	7.2	26.7

Sources: See note 33 on page 33.
Notes: NR = Not reported.

a. Excludes from consideration women whose pregnancies were still ongoing at the time of report.
b. Plus 3 ongoing pregnancies.
c. Ongoing pregnancy.

Table 3: In Vitro Fertilization — Embryo Transfer (IVF-ET), Patient Characteristics and Success Rates

	Number of couples presenting for therapy	Number of cycles	Number of women who had a live birth	Number of pregnancies	Number of miscarriages	Number of ectopic pregnancies	% of women who became pregnant	% of pregnancies per treatment	% with live birth
Boutteville et al., 1987	501	950	NR	199	NR	NR	39.7	20.9	NR
Salat-Baroux et al.,[a] 1988	18	18	3	4	1	--	22.2	22.2	16.7
Wood et al., 1985	831	1,533	22[b]	153	40	--	18.4	10.0	13.6[c]
Meldrum et al., 1987	NR	154	37[d]	47	9	0	NR	30.5	24.0[e]
Yuzpe et al., 1988	578	942[f]	86[g]	160	20	12	27.7	17.0	14.2[h]
Jones et al., 1984	319	560	43[i]	105	35	--	33.0	25.0	13.5
Sher et al., 1986	172	206	NR	64	11	1	37.2	31.1	29.7[j]
Russell et al., 1986	25	23	NR	6	--	--	26.1	26.1	NR
Frydman et al.,[k] 1986	35T	35	NR	8	NR	NR	22.9	23.5	NR
	34C	34	NR	4	NR	NR	11.8	11.8	NR
Guzick and Rock, 1986	575	1,057	NR	146	NR	NR	25.4	13.8	NR
Marrs et al., 1983	71	71	1[l]	9	3	--	12.7	12.7	1.5[m]
Imoedemhe et al., 1988	52	95	NR	16	NR	NR	30.8	16.8	NR

Sources: See note 34 on page 34.
Notes: NR = Not reported.

a. Donor oocytes.
b. Multiple births.
c. Up to 13.6% (NR).
d. Including 14 multiple births.
e. Calculated per treatment cycle.
f. Embryo transplants.
g. Including 4 neonatal deaths; 108 infants born; 41 ongoing pregnancies.
h. Healthy babies.
i. Up to 27 ongoing pregnancies.
j. Less than 29.7% (NR).
k. Two treatment groups analysed separately.
l. Plus 5 ongoing pregnancies.
m. 8.5% if all current pregnancies deliver.

Table 4: Gamete Intra-Fallopian Transfer (GIFT), Patient Characteristics and Success Rates[a]

	Number of couples presenting for therapy	Number of cycles	Number of women who had a live birth	Number of pregnancies	Number of miscarriages	Number of ectopic pregnancies	% of women who became pregnant	% of pregnancies per treatment	% with live birth
Guastella et al., 1986	43	44	0[b]	17	2	1	34.9	34.1	NR
Corson et al., 1986	15	19	1[c]	4	1	–	26.7	21.1	7.7[d]
Asch et al., 1988	8	8	3	6	–	–	75.0	75.0	60.0[e]
Zouves et al., 1988	61	79	NR	9	NR	NR	14.7	11.4	NR

Sources: See note 35 on page 34.
Notes: NR = Not reported.
a. Small series of one or two women are not reported.
b. 14 pregnancies still ongoing.
c. 2 pregnancies still ongoing.
d. Up to 20% if current pregnancies all result in live birth.
e. Up to 75% if current pregnancies all result in live birth.

In general, AID (artificial insemination of a woman by semen produced by a donor) has pregnancy rates of about 40% to 50% per couple, with multiple cycles per couple being the norm. The very low figure in Table 1 is for couples who have already failed to conceive with AIH; the very high figure refers to a study where the mean number of cycles given was over 6 per patient. AIH (artificial insemination of a woman by semen produced by a husband or partner) rates of success are marginally lower (Table 2).

For IVF (in vitro fertilization), the success rates are lower; the largest and most reliable studies indicate pregnancy rates of 18% to 33% (Table 3). However, a Canadian study — which excels in the care and honesty with which it presents its results[36] — reports a pregnancy rate of 26.1%, but a "take-home baby rate" of only 15%. From this, it is possible to conjecture that true success rates may be somewhere in the range of 10% to 15%; indeed, this estimate is echoed by practitioner statements.[37] Pappert's estimates of the "take-home baby rate" at Canadian clinics ranges from 3% to 13%.[38] Currently, GIFT (gametic intra-fallopian transfer) studies are all small scale and thus success rates are hard to estimate; the few larger studies appear to have success rates comparable to IVF (Table 4).

The success rates outlined in the tables offer some hope to the infertile couple. Currently, these technologies are often offered to patients with selected characteristics (particular underlying disorders, or failure at other treatment methods, etc.), and so their impact on the therapy of all infertile couples is hard to predict. However, these success rates are far removed from media reports that 50%[39] to 70%[40] of infertile couples can be helped. These high estimates are based both on the relatively frequent "spontaneous" cure of infertility that occurs if the one-year cut-off is used (as mentioned earlier), and the possibility of higher cure rates for some forms of infertility not treated by NRTs. Thus, it is understandable that infertile couples who believe the new technologies offer new hope may enter a program with expectations that exceed the reality.

Social and Contextual Issues

The discussion above has already alluded to some of the possible social issues surrounding the problem of infertility and its treatment. One key question directly referred to is the "commodification" of reproduction.[41] This term refers to the definition of the sperm, ova, fetus (and, perhaps, the desired child itself) as commodities available for ownership to qualified consumers. This is a particular concern when "donation" of ova, sperm, and, in the case of surrogacy, the gestational uterus, actually involves monetary gain for the donor. This creates the potential for a system where those who can afford the commodity are "buying", directly or indirectly, from those who may only donate the requisite gametic or other material out of financial need. The potential for victimization of women of lower socioeconomic status in this circumstance is very real, and has been discussed thoroughly elsewhere.[42]

Even if a system is created which forbids the selling of biological goods or services related to reproduction, inequities can occur. This is perhaps more likely when direct payment is required for infertility-related services, as occurs currently in several Canadian provinces.[43] In the United States, for example, where universal medical coverage has not been deemed a governmental priority, Black women are almost twice as likely to actually be infertile, but are less likely to report seeking medical care for infertility treatment.[44] Further, women of lower educational or income levels were less likely to seek treatment.

However, many reasons, other than the obvious financial barriers, may be postulated for this inequity. For example, it is possible that the prohibitive cost for poor women of rearing a child in the current social context may be as large a deterrent as the cost of conceiving one. Further, Black and/or poor women may be less aware of available therapies and may be less likely to be informed of them by their primary care physicians. Although all of these rationales are highly conjectural, this discrepancy speaks to inequities in access to care which have been noted in a report by the U.S. Office of Technology Assessment.[45] Further, however tempting it is to blame these inequities on financial barriers to care, the more pervasive conditions which relate to being in a disadvantaged group may be equally responsible. Finally, others have noted that indirect financial barriers to care may also occur. For example, couples who live in a rural area must pay greater accommodation expenses to remain close to the infertility clinic during prime treatment periods.

Additional inequities in access to infertility treatment are addressed and discussed in detail in other sources.[46] Most of these critiques underline the systematic favouritism in infertility (and adoption) services offered to those in a stable "nuclear" family. Historically, individuals who are able to conceive children without any medical or social intervention have had no controls placed on their rights to reproduction, whereas those who do require such assistance must undergo the scrutiny of others. It is difficult to resolve this inequity, however, given the perceived responsibilities of a third party in protecting the interests of a child in whose destiny they are involved (no matter how remotely).

Another difficult contextual issue which relates to the products of conception is the role of the embryo itself. Real and imagined scenarios which create conflicts provide fuel for difficult debate. The questions regarding destroying or freezing pre-embryos, or of experimentation on zygotes or embryos, for example, have been addressed in medical research forums and have resulted in the production of some guidelines.[47] Ethicists also have addressed these controversies.[48] This very complex area will require input from many individuals both within and outside the medical and research community.

A final contextual issue has been discussed less frequently, but is a provocative one and is worthy of consideration. In her writings on reproductive choice, Barbara Katz Rothman refers to the history of contraception in recent decades, as well as to the subsequent development of small family size as the cultural norm. If infertility therapy, because of its availability, similarly becomes culturally expected, the reluctance of the infertile couple to cease cure attempts may increase, even though they

may find these attempts non-beneficial and even detrimental to their quality of life. Even now, practitioners refer to the inability of some couples to defocus from the search for fertility as a central life goal.[49] Others conjecture that the social overemphasis on the importance of motherhood in a woman's life adds unnecessary pressure to seek therapy. Past patients refer to the difficulty in deciding when to give up, because they hope that just one more cycle of therapy may produce results. The ability to refuse and to stop such therapy, without cultural stigmata or mental anguish, also needs to be supported and addressed.

Cost-related Concerns

As infertility therapies become more widely available, and research continues to improve current therapy, the issue of cost becomes an inevitable topic of discussion. The societal expense of infertility can rise when either of two events occurs: the demand for infertility services increases, or the cost of successful treatment rises. Both issues will be addressed here.

The **demand** for infertility treatment reflects several underlying factors. Demand could increase when infertility becomes more common and/or when those who are infertile become more likely to seek care than before. Data from the first half of the 1980s suggest that a combination of these factors may now be occurring.

The prevalence of infertility in developed countries is often cited as up to 15% of all couples.[50] A recent survey confirmed the level at about 14%.[51] Again, this refers to the medical definition of infertility as previously stated, and does not necessarily reflect the numbers of couples who seek and obtain medical care, or who become pregnant after the "one year" definition, but before care is sought. The rate of childlessness after several years of marriage, a common index of infertility in worldwide surveys, indicates that the rate may be much higher in other areas of the world, particularly in central Africa.[52]

Survey data from the United States indicate that approximately 2.4 million American women are currently infertile, and that the mean time to treatment for such women (couples were not considered in this survey) is about nineteen months.[53] Black women were found to be more likely to be infertile.[54] Comparisons of this survey with earlier data do not reveal striking increases in the overall rate of infertility, although there is a significant increase (from 3.6% to 10.6%) among women aged 19-24 since 1965.[55]

The above survey, while it is the "state of the art" in North America, has several problems. It is cross-sectional, meaning it only collects information on women at one point in time. Thus, unlike a prospective study, it is not able to comment on past influences and causes of infertility with much assurance. Further, it has collected data on women only, with little sexual history or couple-related information.

A Canadian fertility survey estimated that infertility affected less than 7% of women surveyed, but noted that the discrepancies in rates between the United States and Canada could have been due to the wording of the Canadian questionnaire.[56] Thus, the population of infertile couples in Canada cannot be identified with

assurance. Further, the possibility was not addressed that some disadvantaged groups in Canada may experience greater risks of infertility than others.

Despite the fact that the U.S. survey did not reveal a sharp increase in the prevalence of infertility, it is acknowledged that the demand for treatment is increasing. Some increase would be expected merely because the large cohort of individuals collectively called the "baby boomers" is now at the age when they would be seeking such services. U.S. studies cite an increase in total visits for infertility services,[57] as well as in the proportion of all medical visits in which infertility services are sought.[58] Many reports of clinic services refer to long waiting lists for care.[59]

Increased demand for care actually may reflect issues other than an increase in prevalence. For example, the previously cited reports in the lay media which imply that cure rates of 50% to 70% are possible[60] may actually increase demand by implying that new hope is available. Physicians may also do this indirectly; as more technologies become available, the couples who become eligible for the "new" therapy, and have been unsuccessful in the usual modalities, will naturally be referred for these new treatments. Further, the relative unavailability of adoption as an alternative in recent years[61] may influence some to seek care earlier (so that they may get on waiting lists as early as possible), or to stay on waiting lists or to continue with care longer, as no adoptive child becomes available to make discontinuance a viable/desirable option.

The costs of infertility therapy to the public are also sensitive, of course, to the actual costs per single course of infertility diagnosis and therapy. This is particularly important if one treats infertility as a non-discretionary medical condition, which, in Canada, implies that costs should be covered by universal health-care programs. Currently, Canadian clinics have variable types of funding, from full governmental support at some Ontario clinics, to couple costs of up to $5,200 per cycle of therapy.[62] It should be realized, however, that even where costs are shared (apparently on the assumption that the desire for a child is a discretionary event), or in jurisdictions where medical care is not covered by insurance programs, there are costs to the general public other than the direct expenses of the clinical program itself. For example, the costs of research to allow further development of the technologies totalled over $3 million in Canada in 1987.[63]

Estimates of the programs' direct costs have indicated wide variations due to different outcomes or technologies considered in the analyses. One study estimated a cost of $10,700 (U.S., 1986 base) per pregnancy; the costs per liveborn infant, therefore, presumably would be greater.[64] Other estimates vary from $2,500 (U.S., 1987 base) for a diagnostic workup, whether or not it is successful;[65] $3,916 (Canadian, 1988 base) for a diagnostic and early therapeutic workup not including IVF, which was costed at $3,000 per cycle;[66] to approximately $25,600 (U.S., 1985 base) for a diagnostic workup, one round of tuboplasty, and three cycles of IVF.[67] These wide variations make it difficult to realistically estimate the costs to society.

A common theme in all of the cost-related data, however, is an acknowledgement of the savings that could be generated by the prevention of infertility. One approach is to consider the costs of programs designed to prevent pelvic

inflammatory disease (PID), a common cause of tubal infertility. It has been estimated that, in the United States, more women become infertile every month as a result of acquiring PID than have been successfully treated by IVF worldwide since the therapy became available in 1978.[68] Further, if condoms were used by only 4% of the population at risk, the incidence of PID would steadily decrease.[69]

The potential for preventive programs has been considered in recent years as a result of the high costs of successful infertility therapy and an ideological preference for prevention of disease. Before such programs can be effectively implemented, however, detailed information on etiology, interventions, program effectiveness, and costs should be gathered. A consideration of these data will form the framework of the discussion of preventability of infertility which follows.

Prospects for the Prevention of Infertility

Infertility can be prevented only if a clear understanding of its causes and effective means of prevention exist, together with the political and professional will and funding to apply these means.

Causes of Infertility

The immediate causes of infertility relate to some disruption in the "normal" state of human reproductive capability. Most clinical reports, for example, attempt to define the physiological cause of infertility as one of the following:

- male factors;
- female factors (tubal defect, ovulation/endocrinological deficiency, endometriosis, other factors);
- idiopathic (no identifiable cause).

Three clinical studies reported that male factors accounted for infertility in 18% to 30% of couples for whom a diagnosis was possible.[70] With regard to female factors, tubal defects were considered the primary cause in 12% to 20% of couples, ovulation defects in 15% to 30%, and endometriosis in 3% to 25%. Idiopathic infertility has been estimated to occur in 3% to 30% of couples.[71] Variations in the percentages primarily reflect differences in patient selection in various clinical reports.

All of the biological causes of infertility are not yet known. However, many of these immediate causes do not arise spontaneously, but themselves are due to other underlying or pre-existing factors. In the case of male infertility, such factors as exposure to lead[72] or dibromochloropropane (a pesticide),[73] or the mumps virus after puberty[74] have been suggested to cause some cases of infertility. Such physical problems as undescended testes[75] or varicoceles[76] can also be responsible. Other factors, such as smoking[77] and marijuana use[78] have also been suggested, but these have not been proven. However, most of the preventable factors now studied involve those which influence female fertility. The best studied factors include past

contraceptive history, past obstetrical history, STD exposure, and the woman's age when she begins to attempt to conceive. Other factors, such as excessive exercise,[79] smoking,[80] and caffeine intake,[81] are thought to be risk factors, but the data are thus far equivocal.

Contraceptive History

Early data indicated that the past use of an intrauterine device (IUD) was a risk factor for infertility in women. Several studies and reviews have indicated that pelvic inflammatory disease, a common risk factor for infertility, is associated with IUD use,[82] although many studies fail to separate out other possible risk factors, such as the number of sexual partners and the type of device. Other analyses of pooled data indicate that this past risk may have been overstated, and that IUDs themselves present perhaps a small (but probably significant) increase in risk. Barrier methods[83] and the oral contraceptive,[84] conversely, have been reported to actually protect against sexually transmitted diseases (STDs) and PID.

Studies examining the relationship of contraceptive history to infertility itself have produced similar results. Barrier methods are found to protect against infertility.[85] IUDs as a group have been noted to increase risk, although this did not apply to copper-containing IUDs in one study,[86] and was borderline for copper-containing IUDs in another.[87] Interestingly, women who had only one sexual partner did not have an increased risk with IUD use.[88]

Oral contraceptives have been demonstrated to cause some delay in conception once they are discontinued.[89] However, they have rarely been linked to long-term infertility. One study which did report such an association speculates that the IUD was selectively used only for women with proven fertility, leaving oral contraceptives to be selectively used by women who were actually subfertile.[90]

Thus, the use of barrier methods for sexually active women would seem to be an effective means of infertility prevention. However, more research which examines the influence of related factors, such as exposure to STDs and the number of sexual partners, would clarify the role of other contraceptives in infertility risk.

Past Obstetrical History

Worldwide, it is suspected that the influence of infections related to childbirth or mutilative traditional practices such as clitoridectomy have an impact on infertility.[91] In North America, the role in infertility of past ectopic (tubal) pregnancies and induced abortion has been a subject of study.

Ectopic pregnancies can have several links to infertility. First, they may both be symptoms of the same problem — the tubal blockage that leads to difficulty in fertilization of the ovum may also cause difficulty in transport of the zygote, leading to an ectopic pregnancy. Second, if the tube is removed surgically during treatment of the ectopic pregnancy, the chances of subsequent fertility decrease. Finally, if the ectopic pregnancy ruptures, the resulting inflammation and scarring may further damage the motility of the remaining tube. Thus, it is not surprising that past ectopic

pregnancies are linked to future infertility,[92] nor that prior infertility is associated with subsequent ectopic pregnancy.[93]

Some studies have reported an association of PID after induced abortion, presumably because dilation of the cervix allows pre-existing infections to travel up the cervix and into the Fallopian tubes.[94] The presence of *Chlamydia trachomatis* in the cervical canal at the time of induced abortion has also been found to predict an increased risk of post-abortal PID.[95] Further work to study the influence of routine antibiotic therapy in the prevention of PID has been suggested.[96]

Sexually Transmitted Diseases

Of all the potentially preventable causes of infertility, sexually transmitted diseases (STDs) probably have the greatest impact on the population in general. It is estimated that, in some U.S. populations, 20% of infertility is due to STD.[97] Of all the STDs, *Neisseria gonorrheae* and *Chlamydia trachomatis* are of most interest to the infertility problem.

Neisseria gonorrheae is the bacterium that causes gonorrhea. In Canada, its incidence increased steadily from the 1950s until it peaked in 1982. Since then, rates have decreased in Canada;[98] the decline in U.S. rates began in 1975.[99] However, rates in Canada continue to increase among girls aged 1 to 4 and 10 to 14,[100] which has highlighted the need for more energy to be directed toward prevention and intervention in sexual abuse of children. The peak age of risk is, in general, becoming younger for girls.[101] In 1986, 5.43 per 1,000 girls aged 15 to 19 were reported to have acquired gonorrhea. This was the age group of highest risk; before 1985, gonorrhea was more likely to occur in 20- to 24-year-old females.[102] For males, the age group at greatest risk is still the 20- to 24-year-old group.[103] Although rates for individual age groups and provinces are available in Canada, other demographic features (such as socioeconomic status and race) of high-risk groups are not commonly available.

It is generally believed that even though these diseases are reportable, these figures are underestimates. The lack of reporting occurs because many affected individuals (especially females) are asymptomatic,[104] and therefore do not seek care for STDs. In addition, some studies indicate that physicians fail to report as many as 80% of known cases of STDs in some areas of Canada.[105]

Chlamydia trachomatis has replaced gonorrhea as the most common STD in the U.S.;[106] however, because reportable figures are not yet available for Canada, confirmation of a similar trend here is not possible. However, it is known that mucopurulent cervicitis (MPC) and nongonococcal urethritis (NGU), conditions commonly related to Chlamydia, are far more common than gonnorhea. In Alberta, for example, MPC/NGU is more than three times as common as gonorrhea.[107] A study of adolescent girls attending a pediatric gynecology clinic in Ottawa found that 14.7% of the young women were infected with Chlamydia, most of them asymptomatically.[108]

Barrier methods of contraception protect against Chlamydia[109] and gonorrhea;[110] vaginal contraceptives may provide additional protection.[111] Oral contraceptives may also protect against PID.[112]

STDs are well known to be related to pelvic inflammatory disease, an inflammation of the Fallopian tubes which can lead to permanent damage. Gonorrheal organisms have been isolated from the tubes of 10% to 70% of women with PID,[113] and Chlamydial organisms in up to 65% of cases.[114] In recent years, the relative importance of Chlamydia in PID has increased, just as its overall incidence has increased.[115] It is estimated that women's risk of acquiring PID with either gonorrheal or Chlamydial STDs ranges from about 12.5% in teenagers to 4% in women aged 30 to 34.[116] Thus, teenagers are especially vulnerable to long-term complications of STD exposure.

Worldwide, the incidence of PID appeared to be increasing, at least until early in the 1980s.[117] Canadian reports have actually shown a slight decrease in hospitalization for PID in recent years, although this may be due to more cases being treated as outpatients[118] (PID is not a reportable disease in Canada). However, rates for 25- to 29-year-old women continue to increase. PID may also be underreported due to asymptomatic cases or failure to diagnose the condition; one study reported that only 25% of women with tubal scarring (evidence of past PID) actually reported a past infection.[119] Current U.S. figures estimate that 3% of all teenagers acquire PID in any given year.[120]

As would be expected, STDs and PID increase the risk for subsequent ectopic pregnancy. Women with ectopic pregnancies have been found to be more likely to have antibodies (indicating past infection) to Chlamydia than women with intrauterine pregnancies.[121] Similarly, gonorrhea has been estimated to increase the risk of ectopic pregnancy by a factor of five.[122] Ectopic pregnancy rates have increased in most Western populations in recent years.[123] In Canada, they have increased from a frequency of 5.7 per 1,000 pregnancies in 1971 to 12 per 1,000 pregnancies in 1983/84.[124] As previously noted, because ectopic pregnancies are closely linked to tubal infertility, these rates may foreshadow an equal increase in female infertility as well.

PID is also known to be a risk factor for infertility itself. A prospective study indicated that 23.3% of women with PID subsequently became infertile, compared with a rate of 6.7% in a non-infected control group.[125] Frequent infections lead to infertility in up to 75% of women.[126] Increased severity of the initial disease also increases risk.[127] If the current rates of infection among teenagers continue, one can presume that about 20% of all young women will acquire PID before the age of 20. If nearly a quarter of these become infertile, we can expect 4% to 5% of the next reproductive cohort of women to have tubal infertility. Based on the current background infertility rate of 15%, roughly a 33% increase in infertility could occur.

Thus, STDs, particularly gonorrhea and Chlamydia, put women at greater risk for PID and ectopic pregnancy, both of which imply a greater risk for infertility. Prevention programs directed at STDs, and particularly at teenagers who are the most likely to develop such sequelae as PID and infertility, would seem to be promising means of preventing infertility. The actual effectiveness of such programs will be evaluated later in this paper.

Age

A commonly cited reason for the current perceived increase in infertility is a trend toward delayed childbearing in recent years. It is undoubtedly true that the age at first birth is increasing for women in Canada; the median age was 22.8 years in 1971 and 24.6 years in 1982.[128] This is due both to an increased age at first marriage and to a greater delay between marriage and the birth of the first child. A similar pattern exists in the United States.[129]

It is also known that women's fertility decreases with age. Some researchers attribute this in great part to the effect of having been married longer at older ages, which could be correlated in turn with less frequent intercourse, and thus, less chance for exposure to pregnancy.[130] However, recent French data examining the fecundability of women using artificial insemination, which removes the variable frequency of intercourse from the equation, showed that fertility declines slightly after the age of 30, and sharply after age 35.[131] Others argue that the sharp decrease in fertility may not occur until the late thirties, and attribute the above findings at least in part to the selected population of women found in infertility clinics.[132]

The causes for this increase in infertility with age can only be speculated upon. They may reflect normal changes in the hormonal axis, or merely a longer history in which to have acquired past STDs and their sequelae. Endometriosis, one cause of infertility, also tends to increase with age.

Increase in age has another effect on a woman's likelihood to seek treatment for infertility. Not only may the time required to conceive be somewhat greater, but the need for intervention is more urgent for the older couple because they have compressed the time in which childbearing can occur. Thus, the 35-year-old woman may seek (and receive) investigation more promptly than the 22-year-old, even if the time of known non-conception is the same for both. In addition, some clinics have "upper age limits" beyond which they will not attempt treatment, thereby also shortening the time available at this end of the reproductive age spectrum. Thus, the role of declining fertility with age is more complex than first analyses of the data may indicate.

Other Considerations

The preceding discussion focuses on potential causes of infertility which most researchers believe to be preventable. However, there may well be other preventable factors which are not well understood. The examples of environmental exposures to caffeine and smoking, for example, are not yet fully explored. Although we are aware that excess leanness or extremes in physical exercise lead to amenorrhea (lack of menstrual periods) in females, the role of less extreme levels of either factor on fertility and ovulation is not well understood. Similarly, the causes of infrequent ovulation in females are partially explained hormonally, but the causes of the underlying hormonal changes also are not well understood. Clearly, these areas require more study; prevention requires a thorough understanding of causation.

Finally, the focus in this paper on female-related causes and preventive strategies is neither accidental nor reflects a particular bias, but merely indicates the state of current understanding. We know that males with low sperm counts, or with abnormal sperm motility, are likely to be infertile. However, the factors which lead to abnormal sperm count or motility are not well known. As stated in the recent review by the U.S. Office of Technology Assessment, this means that:

> . . . efforts on prevention and treatment are largely guesswork. Some contend that studies of the reproductive health of men have been poorly designed and are too inadequate to draw any firm conclusions.[133]

Thus, more research on causes of male infertility (which may be amenable to prevention) are required.

Several other pathophysiologic disturbances, such as abnormal cervical mucus or immunologic factors, are being researched. Although research in these areas can provide valuable insights into infertility therapy, prevention is not possible unless the underlying causes of these abnormalities are themselves known.

Thus, although research into several factors associated with infertility suggests future directions for prevention of infertility, many gaps in our knowledge remain. Further research into male factors, and hormonal factors (both male and female), are specifically required before meaningful preventive programs directed at these causes are possible.

Preventive Programs

Interest in the prevention of infertility is relatively recent. Thus, few data actually evaluate past preventive attempts. One article describes a very individual approach, in which individuals (both male and female) who have not become parents were asked to answer a questionnaire assessing their risk of subsequent infertility.[134] However, because the usual advice given in response to positive risk factors is to see one's physician, this approach is oriented to treatment rather than prevention. Indeed, one wonders what an individual who is not in a personal position to bear children at this time is to do about seeking care for infertility; seeking to conceive earlier than planned may not be a practical alternative, regardless of the medical advice given.

Most population-based programs directed towards true prevention of infertility attempt to deal with STD prevention. Fuelled by fears of AIDS, programs which teach "safer sex", including condom use, are becoming commonplace. They may indeed have a spin-off for fertility if, in fact, they are effective. However, there is no reason to face the future with the glib optimism of one writer, who calculated the costs of an infertility prevention program by multiplying the number of infertile couples by the wholesale cost of one condom (presumably per lifetime!).[135] The many obstacles to the prevention of unwanted sequelae of sexual intercourse need to be carefully addressed if success is to be achieved.

The best-evaluated sexuality programs in recent years may be those designed to prevent unwanted pregnancy in adolescence, not STDs. At the outset, it must be acknowledged that pregnancy is an outcome with obvious and relatively immediate sequelae, at least when one compares it to the prospects of infertility many years in the future. Thus, one would expect lower success rates with programs to prevent infertility because of a lower perceived susceptibility (one of the key components of the Health Belief Model used in preventive programs).[136] For teenagers in Canada, fear of pregnancy associated with intercourse is a much more commonly cited fear than the fear of an STD (64% versus 3% for Grade 11 females).[137]

It is widely known that sexual activity is becoming more common among teenagers. In the U.S., 1971 surveys indicated that 30% of young women aged 15 to 19 had experienced sexual intercourse; by 1979, the figure had increased to between 46% and 50%.[138] A 1987 survey in Canada indicated that 46% of Grade 11 females, 81% of female dropouts aged 16 to 19, and 73% of female college students had had intercourse.[139] It is therefore not surprising that teenage pregnancy increased in the 1970s and the 1980s.[140] Of the many programs set up to lower this rate, most have been relatively focused, involving classroom educational programs and/or the availability of contraception clinics. In one study, high school clinics were shown to decrease repeat pregnancies among teenaged girls.[141] Combined educational and clinic approaches in one well-designed controlled trial indicated that, in schools with the program, age at first coitus increased and pregnancy rates decreased.[142] Despite frequently stated concerns to the contrary, such programs have not been shown to increase sexual activity among the teenagers who receive them.[143]

As previously noted, however, these data may not easily be extrapolated to similar programs designed to prevent STDs and, indirectly, infertility. Certainly, many obstacles to preventive activities, such as the use of contraceptives, are the same in both instances. Infertility, unwanted pregnancy, and STDs are biological phenomena, which our society prefers to divorce from the largely social phenomenon of sexual intercourse. Teenagers tend to avoid contraceptives because their purchase acknowledges premeditation of intercourse[144] and its possible consequences.

Similarly, teenagers generally avoid even discussing sex with their partners beforehand.[145] Girls, in particular, have difficulty being assertive in sexual relationships, which is at least partially due to their belief that intercourse is primarily a means to expressing or acquiring love and affection.[146] Young males, in contrast, cite curiosity or physical attraction as the most likely reasons to initiate sexual intercourse.[147] As well, boys are socialized to take the lead in initiating intercourse. Current programs attempt to address these issues, encouraging young women to take control of their own sexuality, and making them aware that their expectations of the social consequences of intercourse are not generally shared by their partners. Some programs, directed at both boys and girls, also develop skills in communication, such as ways to talk to a prospective partner about condom use. These methods hold promise, but large-scale evaluative studies are required to assess their impact.

As noted, the shift in program focus from simply pregnancy prevention to both STD and pregnancy prevention introduces new problems. Barrier methods used to prevent STDs are frequently thought to interfere with sexual pleasure more than oral contraceptives, which were used more frequently in the pregnancy prevention programs. On the other hand, the ability to obtain condoms without a prescription may limit (or even eliminate) the problems many teenagers have in asking their physicians for contraceptives.[148] Another key difficulty lies in the commonly held belief that almost all STDs are easily curable, that the possibility of AIDS is remote and, therefore, prevention is of limited value. Ways must be devised to make known the long-term risks of even common STDs.

The old attempts to control STDs, before they were easily cured, are now referred to as "moral prophylaxis".[149] Although these means were largely felt to be ineffective,[150] some individuals and groups would like to see obstacles to care put in place, stating that free STD clinics have increased STD incidence by decreasing its unpleasant sequelae.[151] However, the increasing teenage pregnancy rate, despite its major consequences, again underlines the difficulty young women (and society in general) have with linking sexual relationships to biological consequences. Thus, it is likely that the only effects of financial obstacles to STD treatment would be to deny many young women the chance of avoiding subsequent infertility and to increase the total "infected pool" of individuals in society, thereby making STD spread much more likely.

Encouragement for the future success of preventive efforts is strengthened by a number of developments. The cited contraceptive programs directed at teenagers have proven effective, gonorrheal rates have declined (both of which indicate some success at control), and awareness among teenagers of the protective value of condoms has gradually increased[152] (although practices have not changed). However, to be effective, good information on the programs' efficacy in changing risk behaviours and outcomes is needed. As well, programs which provide information to the general community, and not just individuals, require further evaluation. One such trial of a comprehensive STD prevention program is underway in France.[153]

The political will to research and carry out these programs is required. Interestingly, in the same year that Canadian government funding agencies spent $3.5 million on basic NRT research, only slightly over $400,000 was spent on public health and health services research activities related to reproductive disorders.[154] Special funding programs to encourage more research in this promising area are required to redress this imbalance.

Whenever one considers the development of preventive programs, the issue of cost-benefit must be addressed. In other words, is there evidence that the preventive programs applied to large segments of the population will actually save money when compared to the curative programs, which are expensive for each individual attending them, but are generally applied to relatively few members of the population? These calculations are often based on estimated program costs and success rates. Unfortunately, these data are largely unavailable for preventive programs, as many of them have not yet been implemented or rigorously evaluated. However, some estimates on the feasibility of such programs can be made.

First, one must recognize that not all infertility can be prevented with our current knowledge. Thus, discussion will be limited to those types of infertility related to sexually transmitted disease, as these are best described in terms of preventable causes. The previous calculation of a 4.5% infertility rate due to STDs will be used. As noted, other Canadian authors have estimated the average costs of $3,900 for a diagnostic and preliminary therapeutic workup, and $3,000 for each of three IVF treatments;[155] therefore, the total cost of each cycle of care can be estimated at $12,900. If we then surmise that only 75% of women with STD-related infertility sought care, the costs would be $9,675 for each woman whose infertility is related to STDs. On a population basis, this sum translates into $387 for every woman in the target age group. If applied to preventive programs, this would be considered a most generous budget.

Of course, the above assumptions cannot be considered a full cost-benefit analysis. The cost of more than one pregnancy per infertile woman is not included, for example. In addition, the savings resulting from not having other costs of STDs, such as treatment of the diseases themselves, and of PID therapy are not included; if they were to be considered, the preventive budget would be even larger. Thus, although these figures are gross estimates (which deserve further testing), it appears likely that creative preventive programs could release substantial funds to indirectly generate their own budgets, if they were effective in reducing STD rates.

Finally, it should be noted that this discussion relates only to cost-benefit, which is a dollar-to-dollar comparison of approaches. Cost-effectiveness, which balances costs with the desired outcomes (in this case, a healthy baby), could also be considered. In this regard, effective prevention of STD in women whose infertility is directly STD-related will presumably result in a positive outcome for the majority of women (a small number will have other underlying causes of infertility, or will have a partner who is infertile). However, as previously noted, the application of the NRT cures for infertility currently results in the desired outcome only in a minority of cases. In addition, the social and psychological costs to women undergoing invasive therapy are difficult to figure into the equation, but should not be forgotten.

Delay of conception to later ages is another potential cause of infertility which could be addressed. A common extrapolation of the information regarding the increased age at first birth is the assumption that women are now delaying childbearing for the sake of their careers. One editorial in the prestigious *New England Journal of Medicine* suggests, for example, that

> [p]erhaps the third decade should be devoted to childrearing and the fourth to career development, rather than the converse, which is true for many women today.[156]

However, this advice is suspect for several reasons. First, no data have confirmed that career development is the primary reason for the delay. It is equally possible that other societal conditions, such as longer educational programs, or rising housing prices, are as important in this delay. In other words, it may just take longer now for women to acquire the conditions they consider necessary for rearing a child. Further, one must question the assumption that career development and childbearing are necessarily mutually exclusive. For example, if wants or needs

dictate that the mother continue to work in the paid labour force, adequate child care may be effective in encouraging women to have their families at a younger age, without fearing for the quality of care the children may receive.

Research is needed to determine the conditions considered critical for women now contemplating when to start their families, so that any existing obstacles which may prevent women from starting families as early as they may choose can be identified and addressed. Again, regardless of the biological/medical arena in which infertility is discussed and treated, the bearing of children is not solely a biological phenomenon, but is also a social decision. Prevention of the biological problems of infertility entails creating the necessary social conditions.

Implications for Policy and Research

Although the treatment of infertility is a medical and technological challenge, many of the causes and most of the consequences of infertility are not medical, but social. Thus any considerations of the new reproductive technologies must emphasize the personal and social aspects, along with the biological ones.

The following section highlights considerations for public policy and research which arise from the previous discussion. It is not intended to be comprehensive, but outlines several areas in which further work could result in increased understanding and equity in the field of infertility-related services.

Medical and Technical Issues

Currently, many of the techniques used to treat infertility are experimental in nature. This should not be seen as inherently undesirable. However, as research technologies, they should adhere to the high standards of ethics and methodology required to carry out research on human subjects. First, prospective parents must give their full informed consent of risks and probable failure rates of the therapies. When expressing success or failure rates to participating couples or women, only live births should be considered. Second, research must involve a control group and, preferably, a randomized control group. This could be done without unduly withholding therapy from controls if only three cycles were used for comparison. If a randomized control group is deemed ethically impossible, then, where waiting lists occur, these couples could be enlisted as controls until therapy is available. Finally, long-term follow-up of women and offspring for unexpected side effects must be carried out and a registry to facilitate future follow-up must be developed.

Decisions regarding **biological** suitability of a woman or couple for particular infertility treatments (medical indications and contraindications) are primarily medical decisions. These should be made by medically trained staff and their peers and discussed directly with the woman or couple. The final decision to undergo biologically suitable treatments then rests, of course, with the informed woman

herself. However, decisions regarding other features of "suitability", for example, the stability of a marital relationship, the ability to provide for a child financially, etc., are clearly not medical decisions. Thus, if any such criteria are deemed necessary for the operation of a clinic, they should only be made by multidisciplinary teams (ethical, sociological, and consumer groups, for example), and not only by health professionals operating the clinics.

While the "medicalization" of infertility therapy is acknowledged, it should also be noted that the therapy is not without risk. Even AID, a relatively straightforward procedure, carries with it now a risk for transmission of the HIV-1 (AIDS) virus for which screening should routinely occur at all clinics. Thus, any move to consider social and legal acceptance of therapy by alternative groups should demand equally high standards of care to minimize risk. In addition, it should be recognized that many of the "technological" approaches to infertility therapy can only be appropriately carried out in specialty clinics, but that full sharing and disclosure of information with the woman undergoing the procedure is mandatory.

The role and rights of the embryo are unclear. In particular, the ethical issues of research on very early embryos are still debated. Again, many of the concerns are not medical or technical, and thus the groups deciding on the ethical standards of research should not be dominated by medical or technological experts. While some guidelines for such research do exist in Canada, multidisciplinary groups should be struck to develop and review guidelines for research, and to review individual proposals for research funds. Each technology also should be evaluated separately, as each has different levels of intrusiveness and technology that have an impact on decisions made regarding them.

Many features of the epidemiology of infertility are still poorly understood in Canada. These features include the prevalence of infertility in the Canadian population and the existence, if any, of particular risk groups for infertility or its antecedents. Information on disabled women and women of different ethnic backgrounds and economic conditions is particularly lacking. Another misunderstood feature is the prevalence of some STDs and PID. Chlamydial disease and PID should be nationally reportable diseases, to allow some estimate of the magnitude of the health impacts of these conditions.

Further research also needs to focus on identifying the causes of infertility. Such research would include:

- investigation of the role of other mutable factors in causing infertility, such as exercise, caffeine, smoking, and potential environmental causes;
- investigation of antecedent factors and possible therapies of male infertility, given that women are the focus of most infertility research and treatment;
- effective screening programs for gonorrheal and chlamydial diseases, to detect asymptomatic disease, should be piloted and rigorously evaluated.

Evaluation should include following women to determine the impact of early detection of STDs on the incidence of PID and infertility. If this proves to be positive, the consideration of the costs of infertility therapy should be calculated into any cost-benefit analyses. Many STD control programs routinely trace the contacts of

individuals with gonorrheal disease to control its spread in the community. However, many jurisdictions do not provide funds to contact trace chlamydial disease. The potential impact of this disease on long-term fertility necessitates finding funds to carry out more active disease control programs.

Social and Contextual Issues

Systems which allow payment for the donation of reproductive goods or services are in danger of creating a two-tiered system of access, where poor women are encouraged to provide gametes or reproductive services for affluent women. Thus, payment for any reproductive goods and services should not be allowed.

If payment were outlawed, this would not preclude women from choosing to donate gametes on an altruistic basis (similar to blood donations today) or volunteering to carry a pregnancy. However, one probable effect would be a very limited supply because gamete donation is a much more intrusive procedure than blood donation. More importantly, outlawing payment would diminish the possibility of women undertaking these actions out of financial desperation, rather than free choice.

If infertility research and therapy are to be publicly funded, either directly or indirectly, then all members of the public should have equal access to services. If rationing of services is required, means other than financial criteria should be used to determine the requisites of access. Again, these criteria need to be discussed by multidisciplinary and consumer groups, as well as professionals.

The impact of infertility on a woman or couple who desire a child should not be minimized. Nevertheless, in view of low success rates which occur with the higher level technologies, some counselling facilities which explore alternatives should be available for couples contemplating and undergoing these therapies. These should include support groups consisting of couples which never achieved a viable pregnancy and "exit counselling", when a patient or couple decides to cease therapy.

The most direct antecedents of infertility are biological factors. However, some of these biological disruptions, especially those related to tubal infertility (which is one indication for IVF) have their roots in social and interpersonal practices. Thus, preventive programs which consider the breadth of these issues are required. In other words, Canada needs to develop a healthy public policy with respect to infertility.

The requisite features of such a public policy can only be fully developed as the underlying causes of infertility are better described. However, for discussion purposes, components of such a policy might include three elements.

First, the inalienable right of women, including very young women, to control over their own bodies and, as part of this, their own sexuality, must be recognized. A social milieu which fosters this attitude, rather than the attitude that sexual desirability (and thus activity) is primary to a woman's self-worth, is key to the development of any healthy public policy.

It is acknowledged that this recommendation seems somewhat amorphous, and that concrete steps which could be taken to achieve this goal may seem well beyond the focus of this paper. However, past social experience with smoking has taught us that the simple knowledge that an activity has delayed health risks is not enough to deter many individuals from engaging in it.

However, recent changes in public perception of the social desirability of smoking behaviour have been associated with declining smoking rates in North America. Thus, if social attitudes to women's decision-making in sexuality could be similarly influenced, young women would not only be educated on the "healthful" choices to make, but would be enabled to act on those decisions. However, this type of milieu will only be created through careful examination of societal beliefs and values, and through well-designed attempts to portray more positive attitudes through the media and public policy. More research and development in this area are required to facilitate success.

Second, educational programs should be in place in all schools. A fundamental goal of sexuality programs for adolescents should be to allow teenagers, and particularly young women, to take control of their own sexual decisions. This requires the provision of educational experiences which discuss realistic expectations of sexual relationships as well as information and peer-assisted counselling about short- and long-term biological sequelae of early sexual activity.

Third, research to identify specific barriers to behavioural change is required. Beliefs, knowledge, and attitudes which contribute to the propensity to early or unprotected intercourse, particularly among teenaged girls, need to be determined. Obstacles which prevent the use of adequate contraceptive protection in a sexual relationship (financial, embarrassment, lack of availability of condoms when required, beliefs regarding their use) should be identified and addressed in educational programs and public policy. The efficacy of various preventive strategies needs to be investigated.

If conception delay is found to be a clear antecedent of infertility, once confounding factors are addressed, the reasons for conception delay themselves bear examination. This may include studying such factors as the role of child care in Canada. Are women delaying conception because they cannot afford adequate child care until they have built up financial security over several years? Or are such factors as housing prices, or societal expectations of the requisites for childbearing, more germane? Or do we also need to examine the lack of availability of maternity leaves in part-time or non-union jobs, or educational programs? Unless the necessary social conditions are in place, women will not heed such simplistic advice as that suggesting they begin attempting to conceive earlier.

Social programs should support a wide range of family constellations and sizes. Childlessness should not be seen as an abnormal family constellation.

The disproportionate amount of research funds available for basic research versus applied prevention research should be addressed by funding agencies. However, funding should be linked to adequate evaluation of such programs.

Other Concerns

Prevention programs are often difficult to justify, because proof of efficacy in individual cases is often lacking, and rewards are often delayed. However, in view of an assumed ideological preference toward disease prevention, and the real likelihood of cost-benefit, energy should be directed toward these programs. This does not imply that the funds should be withdrawn directly from infertility therapy funding; because only a small proportion of infertility is currently preventable, treatment is the only consideration possible at this time. (Even for the causes now known to be preventable, we are currently treating women who were failed by the lack of realistic prevention information in the past.) However, if an impact is made on the actual prevalence of infertility, the funding required for such programs will decline as today's teenagers enter their prime reproductive years. The funding used today for effective preventive programs may therefore result in ultimate savings.

New developments in infertility therapy address a real social concern. However, it should be recognized that other reproductive concerns, such as prevention of unwanted pregnancy, prematurity and low birthweight infants, are equally key to community reproductive health. As well, much of the research suggested will benefit many other areas of reproductive health. For example, continued research into safe and effective contraception should consider the contraceptive's effectiveness against STDs, and whether it has the propensity to itself cause infertility in future. Decision-making which allows appropriate timing and spacing of pregnancy has an impact on low birthweight rates, as well as having a possible effect on infertility prevalence. The key to all research is to focus not just on one outcome, but the total context of social and biological determinants of reproductive health. The ultimate goal is for women to be able to control their fertility, and the creation of an environment conducive to the optimal outcome of pregnancy.

Conclusion

Infertility negatively affects the quality of life of many individuals in Canada. Indeed, it would appear that the number of individuals affected may actually be increasing. As the prevalence of this condition increases, and the public belief that technology can respond to these problems becomes more widespread, the demand for services will also increase.

However, the success rates of the newest therapies remain low, and the techniques quite experimental. Thus, the short- and long-term results of therapy must be collected and analysed, and this information must be clearly communicated to prospective consumers and the media. In addition, while the biological challenges of infertility are best met by those trained in the medical specialties related to their study, these groups are not the best (and certainly not the only) qualified to address the ethical and cultural issues which relate to these technologies. An atmosphere of open and genuine discussion of controls and concerns of these therapies needs to be

created to facilitate discussion between the technologists and multidisciplinary groups which include consumers.

While the debate on NRTs has, to date, focused on the technologies themselves, it should be recalled that infertility's antecedents and effects are largely outside the technical sphere. Although many gaps in knowledge and opportunity exist which undermine chances for immediate success in preventive policies, it is realistic to state that cost-effective programs for infertility prevention are entirely possible. If progress is to be made in combatting infertility, then, the major battleground of the future may well be in the community itself, and not merely in the "test tubes" of research laboratories. Thus, focusing solely on new reproductive technology research runs the risk of overlooking opportunities for diminishing the impact of infertility which affects and disturbs so many women and couples in Canada.

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Glossary

AID: see Artificial Intrauterine Insemination with Donor Semen

AIH: see Artificial Intrauterine Insemination with Husband's Semen

Amenorrhea: lack of menstrual periods

Amniocentesis: a surgical procedure for obtaining a sample of amniotic fluid, used in diagnosing certain genetic defects or possible obstetric complications

Amniotic fluid: the watery fluid in which the embryo is suspended

Artificial Insemination: a reproductive technology which involves placing sperm into the cervix of a woman

Artificial Intrauterine Insemination with Donor Semen (AID): a reproductive technology which involves the intrauterine insemination into the cervix of a woman with semen from a donor

Artificial Intrauterine Insemination with Husband's Semen (AIH): a reproductive technology which involves the intrauterine insemination into the cervix of a woman with her husband's/partner's semen

Chlamydia (trachomatis): a sexually transmitted disease which can cause tubal damage in women

Chorionic villus sampling: a surgical procedure for obtaining a sample of the membrane surrounding the embryo, used in diagnosing certain genetic defects

DES: see Diethylstilbestrol

Diethylstilbestrol (DES): a synthetic estrogen drug prescribed to pregnant women between 1941 and 1971

Ectopic pregnancy: a pregnancy occurring elsewhere than in the cavity of the uterus

Embryo: product of conception in first twelve weeks of conception

Endometriosis: the occurrence of endometrial tissue outside the uterus, frequently forming cysts containing altered blood

Fetus: product of conception more than twelve weeks after conception

Gamete: a mature sexual reproductive cell (sperm — male or ovum — female)

Gamete Intra-Fallopian Transfer (GIFT): a new reproductive technology involving removal of the ova, and insertion of sperm and unfertilized ova into the Fallopian tube for fertilization and subsequent development

GIFT: see Gamete Intra-Fallopian Transfer

Gonorrhea: a sexually transmitted disease

Infertility: the inability to conceive a viable pregnancy within one year of penile-vaginal intercourse

Intrauterine Device (IUD): a contraceptive device implanted in the uterus for reversible contraception

In Vitro Fertilization (IVF): a new reproductive technology involving the surgical removal of ova from a woman (often after the taking of drugs to stimulate ovulation), fertilization of the eggs with a husband's/partner's/donor's semen, and reinsertion of successfully fertilized eggs into the woman's uterus

IUD: see Intrauterine Device

IVF: see In Vitro Fertilization

MPC: see Mucopurulent cervicitis

Mucopurulent cervicitis (MPC): an inflammation of the cervix, or opening of the uterus; a condition commonly related to Chlamydia

Neisseria gonorrheae: the bacterium that causes gonorrhea

New Reproductive Technology/ies (NRT): technologies recently developed to address one of two concerns: the needs of the infertile woman (or couple), and the characteristics of the already conceived fetus

NGU: see Nongonococcal urethritis

Nongonococcal urethritis (NGU): an inflammation of the urethra (usually in males), not due to gonorrhea; a condition commonly related to Chlamydia

NRT: see New Reproductive Technologies

Pelvic Inflammatory Disease (PID): an inflammation of the Fallopian tubes which can lead to permanent damage

PID: see Pelvic Inflammatory Disease

Pre-embryo: an embryo in its earliest stage, specifically, before implantation in the uterus

Sexually Transmitted Diseases (STDs): diseases transmitted through sexual contact

STD: see Sexually Transmitted Diseases

Tuboplasty: a surgical procedure to repair tubal damage

Varicocele: a varicose condition of the spermatic veins of the scrotum

Vasovasostomy: a surgical procedure to reverse a previous vasectomy

Zygote: the cell produced by the union of two gametes, before it undergoes cleavage