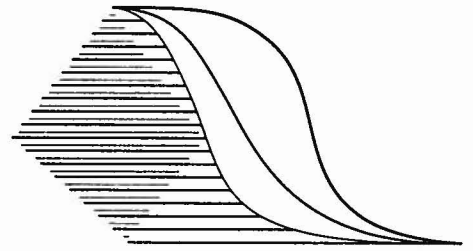


**Centre for Health Services
and Policy Research**



**The Role of Evidence in Policy
Development:
The Example of in vitro Fertilization**

Patricia A. Baird

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*Health Policy Research Unit
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THE UNIVERSITY OF BRITISH COLUMBIA

The Role of Evidence in Policy Development: The Example of in vitro Fertilization

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The role of evidence in policy development: The example of in vitro fertilization

Introduction

This paper discusses how in vitro fertilization provides a good example of the fact that research evidence is only part of a complexly interacting mix in policy development.

In vitro fertilization literally means "fertilization in glass". It involves obtaining eggs from a woman; in doing this she is usually injected with hormones to stimulate the production of eggs. Her hormone levels are monitored with blood tests and ultrasound, and just before ovulation occurs she is given a light anaesthetic, or a sedative and local anesthesia. An ultrasound-guided hollow needle is passed through the vaginal wall into her pelvic cavity to the ovary. Usually it is possible to aspirate and retrieve several eggs. They are put into a petri dish where either fresh sperm, or thawed sperm that has been frozen and stored, is added to them. The petri dish is kept in an incubator and on the third day, those eggs that have fertilized and produced dividing zygotes are available for transfer to a uterus. So as to increase the chances of pregnancy several zygotes are usually transferred.

From this description it is clear that the technology doesn't need the individuals themselves to have ever interacted or even to have met. Fertilization outside the body opens up the reproductive process to being manipulated in different ways, with the consequence that a child can be produced using IVF in many different scenarios. Four examples illustrate this. The most common scenario is where IVF is done using the sperm and eggs of a couple intending to carry the pregnancy and raise the child. Another not unusual category of use is for couples where the woman is older or even post menopausal. Because live births using older eggs in IVF are much less likely, the couple pay for IVF using the sperm of the man and the egg of a younger third party; his partner however carries the pregnancy and they raise the child. A third scenario occurs when IVF is done using the sperm and eggs of a couple who hire another woman to carry the pregnancy, but they intend to raise it - so called IVF surrogacy. IVF can also be done using the sperm and eggs of a couple who hand over the zygote to another couple who carry the child and raise it - embryo donation.

This brief list does not exhaust the possibilities of permutation and combination of how IVF may be used.

If we consider only situations where cohabiting couples wish to have IVF using their own gametes and intend to carry and raise the child, they are usually divided into several clinical categories. The most often used ones are:

- Fallopian tube blockage
- Endometriosis
- Ovulatory problems
- Sperm defects
- Unexplained infertility

Is IVF equally useful or indicated for each of these? Before going over what the evidence on this is, it is worth noting the difficulties of assessment in this area and why it is not easy or straight forward to answer the question.

Factors to be considered in assessing IVF

Even if nothing is done, couples who come for treatment have some chance of having a child. It is only possible to assess how many births are due to treatment if you know how many births would have occurred in that group of couples if they had just kept on trying without treatment. And how many would have occurred anyway depends not only on which of the above categories they fall into, but on how long they have been trying, and the age of the woman, because the longer they have been trying without success, and the older the woman is, the less likelihood of having a baby. The Royal Commission on New Reproductive Technologies found that many clinics take couples with a relatively short duration of trying to conceive, and pregnancies without any treatment would not be uncommon in these people.(1)

This is illustrated by some surveys of the general population done for the Royal Commission. If infertility is defined as the percentage of couples where the woman is between 18 to 44, who are

cohabiting for one year without contracepting, but who don't become pregnant, then 8.5% are infertile. If you change the definition, to require a time period of two years, then 7% are defined as infertile. This means that in the general population about 18% of those defined as infertile after one year of trying, become pregnant during the next year, simply by waiting longer.

Data on the background live birth rate in couples who come for treatment and are followed before treatment are rare, but a recent Canadian multi-centre study found the cumulative rate of conceptions leading to live birth in untreated infertile couples who came to them was 14.3% at 12 months.(2) We know that treatment-independent pregnancies occur in women who are put on waiting lists, therefore the number of births following treatment is not a direct measure of effectiveness of treatment. It is also necessary to know the baseline rate for the group untreated before you can assess how much, or if, the live birth rate has increased from baseline.

As background, it is worth knowing that the average monthly chance of conception for couples in the general population who are not using a contraceptive method is about 20-25% (There is a range in couples' ability to conceive, so the peak conception rate is 33% in the first month of trying, then it falls quickly).

What is the research evidence on results of IVF?

A meta analysis was done 8 years ago for the Royal Commission, looking at the effectiveness of IVF for each of the previously listed categories currently used to justify IVF in couples. A priori, the Commission decided that IVF would be considered effective for a given category if appropriately designed randomized clinical trials existed that allowed meta analysis of combined studies to give a total of at least 200 couples in the control and 200 couples in the treatment groups, and a greater chance of a liveborn infant was found in the treatment group.

Researchers for the Commission identified a total of 501 randomized trials in the literature. Relatively few were of sufficient quality for meta analysis - for example the method of randomization was unstated or pseudo randomized in 200 of the 501 trials. Many studies reported

only pregnancy rates, not live births, and since many IVF pregnancies are lost, it is not useful to use the pregnancy rate as a successful outcome.

The research showed that IVF gave a better chance than no treatment of having a liveborn child for bilaterally blocked tubes. This is the indication less than half the time it is used. IVF was found unproven for the other categories of indication. That is not to say it is ineffective - the evidence to judge simply was not available. There was not enough reliable evidence for the remaining categories to say whether the treatment was more likely to result in a livebirth than no treatment. One comment about the fourth category - sperm defects. The Commission examined classical IVF for sperm defects, but a technique in its infancy at that time, called intracytoplasmic sperm injection used in conjunction with IVF, has become widespread for male infertility. That constitutes another whole topic of its own, which is not addressed in this paper.

Perhaps the Commission's work is now out of date and there is better proof that IVF works? After all, IVF is very widely practiced - surely the data are better now? Because of the debate regarding funding of IVF services in Alberta, the Alberta Heritage Foundation commissioned a report in 1997 on the current status of IVF.

This was a very thorough review of all studies published in the 5-year period 1992-97.(3) It found that IVF has diffused widely without comprehensive assessment of its efficacy and safety. It found inadequate and insufficient data, with small uncontrolled studies with different designs, differing patient populations and differing definitions of outcome measures. It found that "reliable conclusions cannot be drawn on the effectiveness of IVF for most indications other than damaged, occluded and absent fallopian tubes. For other indications, the present evidence does not establish whether IVF is more effective than conventional treatment or no treatment".

So in a nutshell - IVF gives a better chance of a liveborn baby if there is bilateral tubal occlusion, for other indications we do not know yet if it is better than no treatment. Overall, the live birth rate per IVF treatment cycle is 15.5% currently in data from Britain based on about 27,000 cycles

in the year 1997, and about 14.0% if you base the rate on the more than 128,000 cycles done over the six years 1991-1997.(4)

Risks, costs and complications

There are risks and costs to both the women and children involved, as well as costs to the health care system and other social systems which have to deal with the complications and consequences of IVF. What are immediate risks to the woman from the treatment? The ovulation inducing hormones used may cause ovarian hyperstimulation syndrome - which can be mild, moderate or severe. (Severe occurs in 0.4 - 4.0% of cycles) Ovarian enlargement, nausea, vomiting, visual disturbances and fluid retention may occur. Severe cases occur in a small percentage of cycles and may have complications which on occasion are life threatening or fatal. Bleeding and infection in the pelvis do not occur often but as with any invasive procedure, they do occur.

With regard to the long term, a large review in 1993 raised the possibility that women who had received these hormones had a 2-3 times increased risk of ovarian cancer years later. Infertility itself may be a risk factor for ovarian cancer, and longer term follow-up of large cohorts of women who have been in IVF programs will be needed to clarify this.

There are other risks as well. A pregnancy after IVF is more likely to be multiple - to be twins, triplets or quadruplets. Counting the percentage of pregnancies that are multiple, which is usually done, understates the problem, because one pregnancy may give rise to several infants - and it is these as individuals who may have complications and ongoing problems. In the British IVF registry data, 47%, and in the Canadian data, 40%, of individual babies born after IVF come from a multiple pregnancy.(4)

For the mother, multiple pregnancy poses risks of toxemia, difficult delivery, caesarian section, post delivery haemorrhage etc. If she's carrying three or more, she usually spends several to many weeks in hospital. Miscarriage occurs in about 25% of women who test as pregnant after IVF.

Being multiple also poses risks for the fetuses. They are much more likely to be premature and low birth weight. The percentage of IVF babies that are low birth weight (<2500 gm.) is shown below:-

General Population	<6%
IVF singletons	12%
IVF twins	55%
IVF triplets	94%

Neonatal intensive care, which is very expensive, is more likely to be needed, and low birth weight infants after fertility treatment are becoming a significant cost for neonatal units. In fact a high proportion (262/328) of the triplet and quad pregnancies in Britain take place after IVF treatment. The cost consequences of prematurity and low birth weight do not stop at neonatal care. At every stage, multiple births entail higher costs to parents, and to health and social services and educational systems.(5) Developmental delays and cerebral palsy are more common, and low birth weight children have more hospitalizations and limitations of activity. And a substantial proportion of the very low birth weight children will require continuing care and special educational, vocational and support services for a good part of their lives. IVF babies have 3-4 times the population rate for still birth and for deaths in early life.

In Canada, and in fact in most countries, the long-term outcomes are presently not well documented. IVF clinics usually do not have data subsequent to the birth, and the Commission found that some do not even have birth outcome, but use pregnancy rates as their measures of success.

Another complication which requires resources is ectopic pregnancy, which is at least 25 times as common after IVF, and risks the life of the mother, so that the pregnancy has to be terminated. These occur in a few percent of women after IVF, possibly partly because women with tubal problems are selected for IVF.

Because of all the hazards of multiple pregnancy, selective reduction, where some fetuses are aborted to give the others a chance to survive, is frequently offered.

Another cost, which is not measured in dollars but which is real, is that women and their partners have to cope with the psychosocial and emotional effects of treatment failure, since in any cycle of treatment by far the most likely outcome is failure to have a baby.

And then lastly, there are the financial costs. The out-of-pocket cost to couples in the U.S. is between \$8-12,000 per cycle. A 1994 study in a Boston hospital showed the marginal costs incurred per successful delivery after IVF were about \$67,000 US for the first cycle of treatment to \$114,000 for the 6th cycle. For older couples in some diagnostic categories, the cost was \$800,000 per cycle because there were so few live births to this group.(6)

The current situation of IVF use in Canada

A 1996 survey of provincial and territorial medical insurance plans showed only Ontario pays for IVF, and it pays for 3 cycles of IVF treatment for patients with bilateral tubal occlusion.(7) PEI pays a part of physician charges for patients having IVF at a private clinic in Halifax. Currently, there are less than two dozen IVF facilities in Canada located in six provinces (11 of them in Ontario). Most are located within public facilities but are private clinics. IVF is a field where medical practice has developed outside the publicly supported system to a much greater extent than most other fields.

Although the IVF procedure itself is not funded publicly in most of Canada, most associated costs are billed to provincial medical plans. For example the diagnostic tests and consultations for diagnosis are usually covered, and in addition laparoscopies, ultrasound exams and blood tests for monitoring are probably billed to the medical plans. And of course, any complications that occur are a cost to the public medical care system - the miscarriages, ectopic pregnancies, premature births, neonatal intensive care and care for ongoing medical or educational problems.

The private IVF clinics are usually owned and operated physicians. Physician ownership of medical facilities providing services has been shown to increase the use of those services when the physician is in a position to recommend they are needed.(8) The publicly funded medical system unavoidably ends up bearing financial costs generated by the private clinics, with no means of recovering those costs from private clinics. The nature and number of privately provided IVF services are determined solely by the private providers, but they have unavoidable consequences for the public system - which has no way of controlling them in light of its own priorities. The existence of private clinics undercuts the system's ability to set priorities in allocating resources.

In essence, a large part of the cost of IVF is already being funded by provincial health plans, and the costs consequent to IVF that the public system has to pick up means that private services are very heavily subsidized by the taxpayer. If the amount charged to patients at private infertility clinics reflected all costs actually involved as it is now practiced in this country, fees would have to be set much higher and fewer prospective clients would be able to afford it.

Do we have reliable data on the way IVF is practiced and the outcomes in Canada?

The short answer is no. In a 1991 cross country survey of IVF facilities, the Commission found incomplete and unsatisfactory record keeping; for example a third of clinics didn't record multiple births, and a sixth of them didn't have information on outcome at all. It found that the informational material provided to patients was often unclear, and that consent forms varied enormously. In most material there was little mention of risks of multiple birth and its consequences. I think it is inexcusable that good information about multiple pregnancy is not a standard part of disclosure for consent to IVF. The Commission found that "success" rates were variously defined, so that whether consent to treatment was informed was questionable for some programs. Half of the programs had no limit on the number of treatment cycles. Half said they did not provide information to the Voluntary Registry which some practitioners had made valiant efforts to develop.

Some Canadian practitioners have made strenuous efforts to develop a voluntary registry, but there is still a dearth of data on outcome after IVF in Canada. For 1992 it recorded 524 live births after 4,154 treatment cycles started, or a live birth rate of 12%. This probably represents about 3,000 women, 70% of them in Ontario. There are no follow-up data on long term effects. The data collected are not specific to treatment cycles, they are incomplete, and data on the outcome of pregnancy are lacking or not well monitored. However, for the years 1987-92; it has the following data.(9)

Pregnancy outcome unknown 13.4%

For the remaining 86.6% of pregnancies:

22.5% spontaneous abortion

5.1% ectopic pregnancy

31.5% low birth weight

What would the research evidence suggest as policy?

This would be from the point of view of a policy maker trying to maximize the general good, using finite funds. I can tell you what policies the Royal Commission recommended. It recommended that IVF be offered as treatment only for indications where it has been shown to be effective - to date, this is bilaterally blocked fallopian tubes. It was judged to be misleading to patients and costly to the health care system to offer IVF as a treatment for indications where it has not been proven to be effective; it should be offered in those situations in the context of research trials in which women are fully informed participants. We recommended that multi-centre clinical trials and evaluation for other categories of indications for use of IVF be carried out, and on the basis of the resulting evidence be considered for coverage.

Because of the consequences I outlined earlier, the Commission believed that IVF should not be offered except in a regulated manner through the public system. To offer it only to those who can pay for the procedure is unjust, commercializes family formation, and puts serious burdens on the medical care system because of inappropriate use. We recommended that all facilities should be

required to have a licence from a regulatory body, and that to obtain a licence, certain standards should be complied with. These included such things as provision of clear information on success rates defined in a standard way; risks being disclosed to prospective participants in understandable and standard formats; and specified data being collected and reported to a central registry. Some decisions are not medical decisions, for example, whether post menopausal women should have access to young eggs, or whether other kinds of third party reproduction should be permitted. These are decisions society has a legitimate interest in, and not private decisions without any consequences for others. The Commission recommended a regulatory agency be put in place with legislation that made it mandatory for all IVF facilities to be licensed and it recommended that licensed facilities should not provide IVF in all situations requested. If research evidence or social attitudes change, it would be possible for the regulatory agency to adjust its policies, without going back to legislation.

What are the forces and interests at play in influencing policy development?

Why is IVF very widely disseminated and practiced in spite of being invasive, costly, with significant harmful side effects, and a lack of evidence that it works other than for blocked tubes? Obviously, there are some forces and interests at play here. There are numerous players in this arena; misinformation abounds and is actively, but not always knowingly, disseminated to the public and to prospective users, in the service of particular interests.

Some of the players and factors are:

- Service providers working in clinics, laboratories and supporting facilities have a vested interest in believing IVF works, and they actively promote the use of IVF. Many of them, even some medically trained IVF practitioners, do not have the relevant expertise to evaluate whether it is effective or not. Many assume all the births after IVF are because of IVF, and many strongly believe they are bringing a benefit to those they treat - and perhaps not completely unrelated, this belief aligns with their interests.
- Most infertile couples do not have the background to evaluate evidence on effectiveness, and they are told by IVF clinics and physicians, and indeed strongly believe, that IVF is their best

chance of having a baby. Having a family is central in most of our lives, and people are willing to go to great lengths if they think a certain course will enable them to have a child. Strong emotions are involved, motivating them to lobby for what they perceive as their chance to have a baby of their own. Those who can well afford IVF talk in the rhetoric of individual choice, and freedom to choose, and they emphatically do not want to see limits on their options.

These two groups have strong perceived interests in not wanting regulation or limits to their options. They are self identified and are strong and effective lobbyists not to have regulation.

- Women's groups are another advocacy source, but their positions have differed from one to another, with some advocating banning IVF, many others advocating accountability in how it is used and a few advocating free choice. There is no one single position by women's groups.
- The public in general is very aware of the importance to people's emotional lives of having a family. As a result, because most people think IVF works, they think couples who want to have it should be able to do so. "Miracle baby" stories with identifiable happy parents make much better news than the risks and failures, which are not newsworthy, and do not usually involve identifiable people. For example, the birth of quintuplets and pictures of their parents are a "news" story, but their on-going handicaps and developmental delays at age 2 or 3 years are not, so that most of the media coverage to date has not been balanced. The public is much more aware of the successes than aware of the failures and tragedies.
- Governments (both federal and provincial) have been reluctant to set limits in such an emotionally loaded area - in this context it is very easy for government to be portrayed in the media as harshly and tyrannically denying couples the chance at a family. As a result, private clinics have basically been without oversight or limits. The provincial medical plans have been reluctant to cover IVF, probably feeling that not covering it will save money. But leaving it outside accountability in the private clinics does not save their budgets money - in fact, it just means they subsidize IVF yet can't control policies in how it will be used. If IVF were covered and regulated, it likely would cost less because of more appropriate use.

- There are some macro "structural" factors at play as well. Canada is a federated nation and this makes it more complex to get coordinated policy across the country. We are also in an era when federal/provincial relationships are being redefined, with the provinces wanting more say. This makes national leadership on any front more complex and difficult.

The Commission proposed a National Regulatory Body at a time when the federal government was focused on the Referendum regarding separation of Quebec from Canada. The climate of intergovernmental authority clearly was not conducive to them taking a lead on policy implementation. The federal government was not able to act authoritatively - its leadership role was under threat. At that time any proposed national initiative could be used as a lightning rod to show that the Federal government was telling Quebecers what to do. That meant an "equivalent" way had to be developed for Quebec to look after its own provincial policy, in a way congruent with the other provinces. This takes time and is more complex.

The Commission proposed a new regulatory body at a time when all the federal thrust was on budgetary restraint to get the national debt under control. The government said that reducing the debt was its number one priority, and toward that end put a big emphasis on down-sizing in government. It proposed an initiative that no department had budgeted for, and there were no identified funds to set it up. So in order to become funded and implemented, it had to compete with other priorities and to displace something already funded. Doing anything new in a time of budgetary restraint and down-sizing is extremely difficult.

A last effect of the budgetary restraint was a government policy of decreasing staffing and restructuring the bureaucracy. As a result, individuals were moved around frequently, and so they did not get to know a portfolio in depth, or come to understand the implications of policy options in this area. The knowledge base and champions for appropriate policy initiation within the government bureaucracy for reproductive technologies was lacking.

A last aspect, one that is generalizable and affects many areas of policy making, is that the public in general have diffuse rather than concentrated interests, and this may be an impediment to getting policy in the public interest implemented. Groups such as medical professional groups, researchers, or infertility groups are well organized, have a large personal stake in policy decisions - their interest is concentrated - and they have a disproportionate influence on policy. They may be able to skew policy and it is in their interest to do so.

For example, our recommendations are seen as a threat to self regulation and autonomy by some medical professional groups, and they make strong representation against them to decision-makers. This is in spite of the fact that the preferences and priorities of individuals with concentrated interests may be quite different than those expressed by members of the general public. Those who would benefit from regulation are diffuse, not self identified, and without an organized voice or resources. It is all of us who have a stake in the effective use of medical resources and in the kind of community we live in. The opponents - medical professional groups; individuals who want the procedure and can pay for it - are well organized, and have a large personal stake in policy decisions.

So special interest groups are more likely to influence policy decisions than those holding diffuse public interests, even though the latter are far more numerous.

Significant policy change in this area will require that the federal government be seen to be and act as a legitimate policy broker with provinces in particular, and that it enact federal legislation. It is always easier for governments to do nothing than to act, so it may take a high profile harm in the field of reproductive technology use for the public to become concerned enough that politicians feel they have to regulate.

Although the window for policy implementation has not been open, it may now be opening. The issue of reproductive technology use, including IVF, seems to have come nearer the top of the political agenda. It has been announced there is to be legislation in the New Year. Publicly provided care for important medical services is part of Canadian public values. Currently in most facilities, the people able to have IVF are limited to those with either money or private insurance, or those willing to barter their eggs for the service. The Commission found the public consensus

in Canada is not to go the way of the market for forming families. Policy intervention to change the balance between state, health care professionals, and private financial interests in this area requires consolidation of political authority and the will. If that evolves, I think the Canadian public in general will be supportive of regulation and more evidence-based use.(10)

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