Section 4

Social and psychological issues in infertility and ART

Consumer perspectives

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Introduction

Most people take for granted their ability to have a child. Some choose not to but most of those who try to have a child have no difficulty in achieving that goal. However, for between 13% and 24% of couples who would like to have a child but are not able to, it can be a very painful experience and one difficult to manage *(1–3)*.

Infertility is an extremely isolating experience. This is exacerbated because infertility and the death of a child are taboo subjects. As a society we have difficulty in dealing with these sad experiences. Infertile people need medical and social choices to help them deal with infertility. Some pursue adoption and for over 20 years, assisted reproductive technology (ART) has provided *in vitro* fertilization (IVF) and related treatments as another way of overcoming infertility and childlessness.

The limited recognition of infertility as a disease or medical condition

Governments worldwide have demonstrated a reluctance to acknowledge that infertility is a disability or medical condition (Appendix A). In most countries, infertility treatment is viewed as an elective procedure and therefore not worthy of reimbursement. In Bangladesh, despite the fact that infertility is considered a curse that brings couples bad luck, the majority is unaware of the possibility of treatment (Appendix A). The need to have access to health care is balanced against the need for governments to responsibly manage scarce resources and to distribute them justly and equitably for the good of the whole community. The challenge for consumers of infertility services is to persuade governments that infertility is a medical disability which causes suffering and, as such, is worthy of inclusion in their national health plan. This is one of the objectives of the International Consumer Support for Infertility (iCSi) network which brings patient leaders together to discuss common interests and concerns. There are also national patient associations in many countries which provide support for infertile people and advocate for access to affordable infertility treatment. The International Federation of Infertility Patient Associations (IFIPA) is another international group, whose membership is made up of national patient associations.

The emergence of patient support networks worldwide

Like any life crisis, infertility can be best understood by those who have experienced it. Therefore, infertility self-help groups play an invaluable role, as there is comfort in speaking with someone who really understands. It can ease the feeling of isolation. Many infertility self-help groups have been established around the world since the early 1980s (Appendix A). These groups seek to provide information to infertile people, their families and friends and also to government, media and the medical and scientific community. The iCSi network is a global family of patient leaders from support associations in more than 30 countries and strives to expand the number of countries reached each year, particularly to include developing countries. New contacts have been established recently with patient leaders in Bangladesh, India and Japan.

Equity of access to ART

The United Nations Declaration of Human Rights recognizes that, "Men and women of full age, without any limitation due to race, nationality or religion, have the right to marry and found a family" *(4)*. This is supported by the European Convention on Human Rights which guarantees respect for family life and the right to found a family *(5)*.

It can be argued that these provisions create a positive right to access ART to achieve this goal, one taken for granted by fertile people in the community. For those who need medical assistance to form their families, infertility causes immense suffering. For those who finally remain without a child, infertility can be a lifelong disability.

The objective of a health system is to deliver health care to all those in need. However, in some western countries, the limitless demand for health care can often not be met due to the scarcity of resources to service it (Appendix A). This has been exacerbated by an ageing population and costly advances in technology which have exceeded our ability to pay for them. Therefore, the need for rationing or micro allocation of health resources becomes apparent. No system of allocating limited resources at the level of the individual patient can work without resorting to notions of utility. While rationing is a necessity, it is important that the system used to decide who gets health care be one that promotes equity of access between people with health needs.

The question "*Who shall be eligible for assisted reproductive technologies?*" signals the onerous task of health professionals and governments to allocate scarce resources equitably. This raises the question of what criteria can be used to distribute resources fairly.

A utilitarian perspective, which argues that justice involves trade-offs to ensure that the greatest good can be delivered, can present a conflict for the medical practitioner who seeks to act in the best interests of the patient *(6)*. Notions of utility are inevitably resorted to when practitioners make decisions to ensure that the maximum benefit can be obtained for the greatest number of those in their care.

Many criteria are used in deciding which patient will receive health care. It has been argued, as in New Zealand, that determining an initial eligible pool of patients based on substantive standards and procedural rules is preferable to the decision-making process being left to the final selection of an individual for a particular procedure *(7)*. However, this process does not remove the possibility of value judgements impacting on selection. Governments in some countries that reimburse ART treatment, such as Austria, France and the United Kingdom, impose age criteria. Israel is currently debating this issue (Appendix A).

Methods of rationing that introduce notions of utility can use medical or social criteria. The use of social criteria is necessarily subjective, arguably immoral and is contrary to the principle of individual autonomy. However, it is difficult to see how those making decisions about rationing resources can avoid such judgements. Value judgements can be made based on an individual's past and potential contribution to society or, in the case of ART, on old-fashioned prejudices masquerading as new ethical dilemmas*(8)*.

For example, there has been discussion about whether it is ethical to allow single women, lesbian or homosexual couples access to ART. Many believe that this is morally wrong, arguing that it is preferable for a child to be raised within a stable, heterosexual relationship. Whatever our personal views, those who argue that the traditional concepts of family should be maintained, fail to recognize a different reality. An Australian government statistical report found that 69% of households had no children, 32% of households comprise two persons, 19% had two or more children and 13% of households had one child. Marriage rates continue to fall, divorce occurs in more than 40% of marriages and 27% of births were to single women *(9)*. These figures demonstrate the diversity of family arrangements that can exist.

It is important to distinguish public funding from legal access to health services in situations where people without a medical condition could pay for needed services, irrespective of the social choices that they have made.

Decisions about who will access health care resources can be complex and difficult. The scarcity of resources available to meet the needs of everyone seeking them compels health professionals and governments to make decisions about which individuals should have priority access to them and we are mindful that there is "very little distance between policy and politics" *(10)*. While this dilemma may be a practical necessity, it is important to be aware of the moral conflict and to aspire, wherever possible, to a deontological perspective such as the Kantian ideal or the biblical exhortation, of treating others as we would like to be treated if we were in their circumstances.

Success rates how can we be sure of treatment quality?

Success, like happiness, can be different things to different people. For some, success of IVF is a confirmed pregnancy, for others it is a healthy baby nine months later and some may suggest that success is a few years down the track when your child is enrolled in medical or law school.

In considering what success means to consumers of IVF services the familiar model of the Human Fertilisation and Embryology Authority (HFEA) in the UK provides a perspective. ISSUE, the National Fertility Association in the UK, has reported on the HFEA publication, *The patients' guide*, claiming that the practice of publishing success rates of identified clinics has impacted on the range of treatments available. An example cited was of one clinic that ceased to offer natural cycles because they impacted negatively on their success rates (personal communication with ISSUE, CEO, 1998). As a result, consumers are denied access to a less invasive treatment because of the commercial impact caused by the misleading way in which success rates have been reported. While explanations are given for the way statistics are reported, they have little meaning for most consumers trying to make a decision about where they should go for treatment.

When the patrons of ISSUE were asked about the *Patients' guide (11)*, Professor Ian Cooke from the Jessop Hospital for Women in Sheffield, UK found that there was very little information about the statistical data, making it vulnerable to the media to rank clinics, ignoring all statistical ranges. He found that the data from a very large number of clinics did not differ significantly.

Doctor Peter Brinsden from the Bourn Hall Clinic in Cambridge, UK said that while the *Guide* was a valuable source of information, he was not in favour of league tables. He noted that while the HFEA did not rank clinics, the press did, and this had had unfortunate consequences for some clinics whose effectiveness had been misrepresented.

Doctor Simon Fishel from CARE at the Park Hospital in Nottingham, UK commended the section with suggested questions for prospective patients to ask clinics but he also found a real problem with the data. He questioned the fairness of the adjusted live-birth rate as there was no information about the formula used to determine this. He also identified a significant disadvantage in the way clinics could manipulate these figures by driving a certain kind of practice that may be more "successful" rather than being concerned about specific treatment that could be tailored for the individual couple. He suggested that age divisions would provide more relevant information for couples considering treatment.

How then can success be determined?

The conflict of clinics to provide the best information for their patients while presenting their units in a positive light has been discussed, as has the problem of how best to present that information *(12)*. The inadequacies of the simplistic scenario of dividing the number of pregnancies by the number of patients who underwent treatment have been improved by a method of identifying a monthly pregnancy rate and cumulating the outcomes *(13)*. This has been further developed by expressing results as a "life table analysis" which has become an accepted method of reporting results for donor insemination *(14)*, ovulation induction *(15)*, and IVF *(16)*. This provides information to couples about the prospects of success over a specified number of treatment cycles. However, many variables remain including questions about what is a pregnancy. Should success be regarded as a positive beta-hCG test 14 days after treatment? Or it could be when a fetus is visible on ultrasound—but this includes ectopic pregnancies and early miscarriages. Is success determined when a normal fetal heartbeat can be detected? Is it more realistic to express success as a live birth, often referred to by consumers as the THB or "take home baby" rate?

Success rates can seem better if expressed "per transfer" rather than "per oocyte pick-up" (per OPU) or "per cycle commenced". Other variables include

- that the probability of success is higher in the first few cycles so programmes with new patients will have higher success rates;
- younger women are more fertile;
- multiple pregnancies increase reported success rates;
- cancellation rates have a negative impact on success rates; and
- the number of embryos transferred will also impact on reported results.

When reporting success rates should clinics be identified or anonymous?

An integral function of accrediting bodies and licensing authorities is to collect results for a specific group of patients, who have a similar likelihood of having a live-birth pregnancy, to compare success rates at different units *(17)*. The use of these data to measure performance for accreditation purposes is a useful means of identifying ways to improve practice, while maintaining confidentiality. However, publishing success rates that identify clinics in league tables can weaken the quality of the information available for consumers, as the UK examples have shown.

One strength of the annual Australian Institute for Health and Welfare (AIHW) report in Australia is, arguably, its anonymity *(18)*. There is no incentive to manipulate data so consumers can be confident of its reliability. Patient associations encourage consumers to approach individual clinics, perhaps more than one, to discuss the options available for their individual needs and the clinic's ability to meet them. Because there are wide differences between patients, specific information about an individual's chances of success should be obtained from the clinicians. This approach seems preferable to selecting a clinic based on statistics that do not reveal the full picture.

At the heart of a consumer's question about a clinic's success rates is the need to know where the best chance of success can be assured. This lies in the quality of the health care delivered by the clinic approached for help. If quality is effectively monitored through an accreditation process, where the data can be rigorously scrutinized, then consumers can be confident of having the best chance of realizing their dream of having a healthy baby.

It can be argued that the self-regulation model is weak as the locus of control lies with doctors. However, a strength of the Reproductive Technology Accreditation Committee (RTAC) model in Australia is that consumers participate as equal partners. This is unique in medicine in Australia and possibly in ART practice worldwide. Any successful attempt by a health professional to inappropriately manipulate the process would destroy the credibility and effectiveness of the RTAC.

What should the role of the law be in reporting success rates?

Emerson said over 100 years ago, "the less government we have, the better—the fewer laws and the less confided power" *(19)*. As consumers, we are careful not to be seduced by the assumption that the law will necessarily protect us from harm. The adoption experience in some countries is one historical example of this where, during a 30-day cooling-off period after the birth prescribed by law, many mothers who had changed their minds about relinquishing their children were told falsely by health professionals that their child had already been adopted.

In determining how success rates can best be reported, a model which delivers the most reliable data to assist informed decision-making is preferred by consumers to one which seeks by statute to make individual clinics accountable but fails to deliver meaningful data.

In working towards a model that meets the needs of all stakeholders, consumers seek a spirit of cooperation, which will ensure transparency and quality in the delivery of infertility services. Justice Hand of the US Supreme Court said that such a spirit is one "which is not too sure that it is right, which seeks to understand the minds of other men and women and weighs their interests alongside its own—without bias" *(20)*. Such a spirit of cooperation is crucial to achieving good outcomes and ensuring public confidence in the regulation and oversight of ART.

The impact of legislation on ART treatment

While some are proponents of restrictive legislation, others have argued that there is too much legislation for ART and cite existing legal choices for women in relation to human reproduction which respect individual autonomy. These include contraception, abortion, where it is permitted (the father has no say), tubal ligation and tubal reversals. There is only intervention when the child is at risk as in adoption *(21)*.

However, the Canadian Royal Commission took an opposing view, which claimed that, "Given rapidly expanding knowledge and rapid dissemination of technologies, immediate intervention and concerted leadership are required as citizens in provinces with insufficient regulation may suffer harm" *(22)*.

Fertile people have been free to determine their own meaning of family and to live their lives accordingly. Where there is no evidence of detriment to the child, there appears to be no need for society to interfere in these arrangements.

Adherence to the "best interests of the child" principle, while laudable, can be difficult to apply in practice. It would be difficult to argue that it would be in the best interests of a child not to be born at all. In South Australia, the Reproductive Technology Act requires that a couple seeking assisted conception must demonstrate that they have no outstanding criminal charges or a history of an offence that was sexual or violent in nature. It also states that a couple must have no disease or disability which could interfere with their capacity to parent a child. DeLacy argues that "while plausible, such requirements are extraordinary and unjust, and are likely to be both ineffective in protecting the welfare of children and harmful to individuals in the long term". She identified the assumptions on which these requirements rest. Firstly, that "a parental history of crime of violence will result in the child being exposed to violence" *(23)*. Secondly, that parents who have had a child removed from their care have been proven to be abusive or neglectful. This does not account for children removed from care for reasons other than poor parenting.

The requirement about a disability that could interfere with the capacity to parent offers no parameters with which to make that judgement. Given that reproductive medicine is called upon to intervene in situations of infertility caused by disease and disability, this presents a paradox for practitioners. This is supported by Douglas who argues that instituting a "fitness to parent" code is "difficult enough to apply in cases concerning children who are in existence, let alone those who are only a twinkle in the doctors' eye and it is open to many different assessments, depending on the person making the judgement" *(24)*. DeLacey asserts that judgements are being made about a child who does not exist when clients who do exist and to whom the practitioner owes a fiduciary duty, are being refused treatment, which may not be in their best interests, leaving a practitioner vulnerable to an accusation that she may have acted in an ethically questionable manner *(23)*.

Sometimes, specific treatments such as egg donation and surrogacy are prohibited. Surrogacy is not new. One of the earliest recorded instances of surrogacy appears in the Bible in the book of Genesis *(25)*. However, both these treatments are forbidden in some countries, such as Denmark, Germany, Norway and Switzerland, and in the state of Queensland in Australia (Appendix A).

Surrogacy is permitted under Buddhist law but questions may arise about family ties as well as legal and moral issues. While Jewish law does not forbid surrogacy, questions about the status of the child are raised when one of the women involved is not of the Jewish faith *(26)*. When traditional surrogacy is used, the resulting Jewish child belongs to the donor of the sperm but this question remains unresolved in the case of IVF surrogacy. In the case of Islam, the practice of surrogacy is not permitted. In New Zealand, the Maori culture of *whanau* (extended family) sanctions informal surrogacy arrangements. There is no evidence in the literature to suggest that in the vast majority of such arrangements there is any detrimental effect on the child or the other parties involved.

Current law in most countries recognizes the woman giving birth as the legal mother, even where she has no genetic link to the child. This leaves the genetic mother no option but to apply to adopt the child to secure legal parentage and leaves the woman who gestated the child in the position of needing to give up for adoption a child that she never intended to raise.

The Australian Capital Territory (ACT) introduced a fresh approach with the *Substitute Parent Agreements Act* 1994, making it the only jurisdiction where specific legislation has been enacted to allow noncommercial IVF surrogacy. The Act prohibits commercial surrogacy but does not prohibit the facilitation of pregnancy where there is a noncommercial agreement. Children have been born through IVF surrogacy in the ACT since 1994, with full knowledge and contact between the children and the women who gave birth to them. There has been no evidence of harm done to any party, except by inadequate legislation with unintended consequences, which left the children being raised by their biological parents but not recognized as such in law.

In 1996, the Chief Minister of the ACT introduced the *Artificial Conception (Amendments) Bill*. Its purpose was to allow biological parents to obtain legal parentage of a child born to another woman as the result of a surrogacy arrangement. The Bill imposed five conditions, including that at least six weeks and no more than six months must have elapsed since the birth and the birth parents were required to have agreed freely and with full understanding of what was involved. Both genetic and birth couples were required to have received assessment and counselling from a service other than that which carried out the IVF procedure and the biological parents were required to be residents of the ACT.

After lengthy public discussion, the Bill was passed in August, 2000 and provided for the ACT Supreme Court to issue a parentage order to allow the biological parents to be recognized as the legal parents of the child. The effect of the Act has been to ensure that the courts, known for their conservative approach, retain control of judging what are the best interests of the child. Primarily, it provides certainty to any children born as permitted under the Act, as to his/her parentage, thus allowing their best interests to be served. Importantly, it ensures that the wishes of the gestational mother are considered in any application for a parentage order. It has also, humanely, provided closure for the biological parents who may have undergone many years of medical treatment in order to have a child and who have lived with uncertainty from the outset.

The question is whether particular legislation will necessarily protect citizens from harm and, where it is considered necessary, what degree of protection should be imposed by the law in a society where most citizens are free to make a multitude of choices about their lives or health care, including reproduction. In Australian States free from restrictive legislation, there has been no evidence that consumers or society have been disadvantaged. It can be argued that where genuine informed decision-making occurs and there is a process for legitimate ethical review, restrictive laws make little sense and in some cases deny access to appropriate treatment for some couples who have no other means of forming their families. History has demonstrated that governments can often make ill-informed, politically expedient decisions, which are not necessarily in the best interests of their constituents. Furthermore, legislation is difficult to repeal. Even the most well-intended legislation in a high-tech, rapidly evolving area such as ART, can quickly prove obsolete.

Australia is the only country in the world with unrestricted access to public reimbursement for ART treatment. Crucial to securing this coverage has been the genuine involvement of consumers in all components of regulation, legislation, accreditation, and policy development. The inclusion of a consumer representative on the Federal Council of the Fertility Society of Australia (FSA) and on the RTAC, ensures that consumers have access to reliable information about treatment outcomes, possible drug side-effects and the quality of service provided by individual clinics. Despite the initial skepticism of the government, RTAC has demonstrated that self-regulation can work. Access to government funded drugs used in treatment in Australia is provided only to those clinics which have been accredited by RTAC. The availability of counselling is a requirement of accreditation, as is provision of detailed, written information on treatment, prior to its commencement. Clinics must demonstrate compliance with guidelines laid down by the National Health and Medical Research Council, the Australian Health Ethics Committee and a code of practice, together with relevant statutes in some States. To gain approval to conduct research or undertake new treatment with ethical considerations, individual clinics must apply to their local Institutional Ethics Committee. This ensures that the concerns of the community are addressed and that the interests of consumers are protected. In those states with regulatory authorities, their personnel accompany the RTAC team on clinic site visits in order to examine the clinic's state licence renewal. Benefits of self-regulation include its flexibility as it is more able to respond to emerging scientific advances and allow for a greater degree of autonomy for consumers in the decision-making process.

It also removes the need to rush to legislation every time a new procedure becomes available. In some countries, this has resulted in strange anomalies, such as:

- allowing sperm donation but not in an IVF cycle (Norway and Sweden), or
- allowing sperm donation but not oocyte donation (Denmark and Germany), or
- recommending that use of her frozen embryo by a woman if her husband dies be disallowed but allowing that same woman to receive donor sperm (Canada, France, Germany and UK).

Consumers of ART services seek politicians with integrity who have the courage to act fairly rather than expediently. In addition, almost one million ART children have been born worldwide. Some of them have reached voting age and will show great interest in how their elected officials value their existence.

Developing effective partnerships with providers

A significant factor in the success of negotiations with government in relation to regulation and reimbursement issues in Australia has been the commitment of consumers and providers to work in partnership to achieve common goals. This has proved to be a powerful tool in the political arena and has provided a model for similar representation in other countries. In the late 1980s, this coalition of consumers and physicians successfully lobbied the Australian federal government for recognition of infertility as a medical condition and reimbursement for ART treatment. In 1990 the Prime Minister announced the provision of reimbursement of ART procedures through Australia's national health plan. This has helped to provide equity of access to health care for infertile people in Australia. The continuing participation of consumers in public policy and the regulation of IVF clinics is a reassuring demonstration of openness by health ministers, physicians and bureaucrats in ensuring transparency and quality in the delivery of infertility services.

This paradigm shift from consumers as passive participants to partners has been difficult for IVF physicians in some countries but the political benefits for consumers and providers can be significant. These partnerships are also appropriate as they recognize that consumers of ART services must live with the consequences of policy and treatment decisions.

The challenge for consumers is to ensure that all stakeholders have confidence in our integrity, professionalism and our ability to work effectively with the medical profession, government ministers and senior public officials. This may not always be an easy task but the suffering of those who come to all of us for support, compels us to commit to nothing less.

Real costs of infertility: emotional, social, societal

Governments have argued that the costs of providing reimbursement for infertility treatment are too high but it can be argued that the financial costs are less significant than the real costs of infertility.

The Royal College of Obstetricians and Gynaecologists and the British Infertility Counselling Association found, based on papers by infertility specialists and interviews with medical, scientific and psychological experts, that infertility costs the nation in absenteeism, poor productivity and wasted resources *(27)*.

There are also social costs to consider such as marital relationships, taking time off from work, refusing promotions, strained family relationships, exclusion from inheritances or family mementos and isolation from friends. The quality of life for some infertile people can become marginal when they have difficulty coping with a friend's pregnancy, seeing babies and young children or watching television advertisements featuring babies. Events such as Christmas, Mother's Day and Father's Day can be painful reminders of other people's fertility and success and are times to be endured. Many couples do not participate in these family celebrations.

The emotional costs can be the most significant. Nicol, in examining the impact of maternal loss, found that—on average—10% of women suffered some form of reproductive loss each year. Furthermore, she found that the death of a child had an emotional and physical impact on a woman that was as significant as that caused by the death of a spouse and that with multiple losses the impact was exacerbated *(28)*. It is easy to see the implications for women who have undergone successive attempts at assisted conception.

In 1993, the London newspaper, the *Daily Mail* reported on the 15th birthday of "Bubbly Louise" (Brown), the world's first baby born through IVF *(29)*. A few pages away appeared a story headlined *Tragic teacher who longed for a baby*. Gillian Martine, a 34-year-old primary schoolteacher from Southampton and her husband Michael, after trying to conceive for some years, had been told by their doctors the heartbreaking news that they would never have a child. Depressed and discouraged, Gillian committed suicide *(30)*. On the same day, the joy of assisted parenthood and the desperation and despair of infertility were graphically contrasted. The question is not whether infertile people have a right to infertility treatment reimbursement but rather, why they should be discriminated against in being denied access to appropriate health care services.

The profound impact which infertility and involuntary childlessness has had on millions of people worldwide, means that the global family of infertility associations will continue to lobby and represent the needs of our constituents. We will not rest until all those we represent are treated with the dignity enjoyed by others in the community. Infertile people, as citizens and taxpayers of our respective countries, seek rather to claim our right to equity of access, with fellow citizens, to affordable quality health care and appropriate recognition of ART as a standard, proven treatment for infertility.

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