

Ethical regulation and the new reproductive technologies in Sri Lanka: perspectives of ethics committee members

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Abstract

Objective To report on part of a pilot study done to explore ethical responses to the new reproductive technologies in Sri Lanka.

Design Semi-structured interviews carried out with the members of three committees responsible for ethical review of medical research. Members were asked for their views on the ethical, social and legal implications of the new reproductive and genetic technologies. Members' responses were subject to a simple content analysis.

Conclusions There was broad acceptance of the new technologies among respondents, but anxieties about potential abuses. Respondents felt that a national committee should regulate practice and monitor future policy.

Introduction

Recent advances in embryology, molecular genetics and related clinical fields mean that there are novel possibilities for the transfer, donation, storage and selection of gametes. However, attempts to make sense of techniques such as *in-vitro* fertilisation (IVF), artificial insemination by husband (AIH) or by a donor (AID), egg donation and embryo donation create fundamental ethical, legal and social issues for society in general and clinicians in particular.

In recent decades, such issues have been addressed in Europe, Australia, New Zealand and North America (1), with networks of authorities, councils and committees now in place to monitor, regulate and advise on matters concerning the new reproductive and genetic technologies [NRGTs] (2, 3-7). The rapid growth and development of these technologies is not restricted to the industrialised world. The ease with which technology, information and practical expertise can now be transferred means that the application and development of NRGTs is a global phenomenon. Yet ease of transfer is often in stark contrast to the difficulties that are faced once attempts are made to assimilate these technologies into local systems of morality, belief and culture (8,9). Sri Lanka is no exception in this regard and, as in many parts of the developing world, new technologies are being put into place long before concerns have been debated, risks assessed and appropriate regulation agreed.

Methods

In July 2000 I carried out a pilot project to explore some of the issues posed by the appearance of NRGTs in Sri Lanka. I made contact with doctors and clinicians currently active in the field of medical ethics and, in particular, members of local ethics committees. My reasoning was that these people would in many respects be in the front-line as new developments entered into the teaching and practice of reproductive medicine. I focused on three committees: the Sri Lanka Medical Association Ethics Committee, the Research Ethics Committee of the Colombo Medical Faculty and the Research Ethics Committee of the Ruhunu Medical Faculty (Galle). In all I was able to interview 13 out of 31 of the members of these three committees. Here I report on the key issues to emerge from these interviews.

Results

Ethics committees and representation

Committee members were generally keen to dissociate their own religious views from their work on the committees. Mechanisms such as referral of projects to anonymous experts for evaluation ensured that a secular ideal was upheld. Nonetheless, most respondents were happy to reveal their religious persuasion (10 Buddhist, 2 Christian, 1 did not declare) and several acknowledged that it would be unrealistic to think that their religious views would not impinge on their attempts to evaluate issues arising from the NRGTs. In discussion with other members, despite their professed secularity, it was clear that religious convictions would be brought into their consideration of the ethics of NRGTs. Table 1 shows the broad range of medical expertise covered by committee members. Several respondents drew attention to the limited involvement of people from outside the medical profession, most notably lay people, lawyers and religious representatives. It was pointed out that there is very little tradition of debate and participation in Sri Lanka when it comes to managing issues in bio-medical ethics and much work has yet to be done to cultivate awareness, debate and trust among interested parties. Evidently, widening participation was easy in theory but proved rather more difficult in practice.

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Table 1. Respondent's area of medical expertise in relation to committee affiliation

Member's professional speciality	SLMA	Ethics committees	
		Colombo Medical Faculty	Ruhunu Medical Faculty
General practitioner	-		
General practitioner (rtd)	X		
Pharmacologist	X		X
Pharmacologist (rtd)	X	X	
Physician (rtd)	X		
Physiologist	-		
Medical administrator (rtd)	-		
School principal	-		
Anaesthetist			X
Psychiatrist			X
Ophthalmologist			X
Epidemiologist			X
Physiologist			-
Anatomist			-
Physician			-
Obstetrician/gynaecologist			-
Epidemiologist		X	
Psychiatrist		X	
Genito-urinary surgeon		X	
Pharmacologist		X	
Pathologist		X	
Obstetrician/gynaecologist	-		
Obstetrician/gynaecologist	-		
School principal	-		
Sociologist	-		
Pathologist	-		
Medical clinician	-		
Nursing tutor	-		
Director nursing education	-		

X = Members interviewed.

Rtd = retired

SLMA = Sri Lanka Medical Association

The views of committee members

Developments in the NRGTs have been recent and rapid, and although several respondents had worked in infertility clinics, family planning clinics and on community health projects dealing with reproductive health, none had any direct experience of NRGTs as practitioners or researchers. Consequently, respondents were often keen to point out the exploratory and speculative nature of their views. Nonetheless, there was a general feeling among

members that engagement with this area would be inevitable given the growing ethical concerns surrounding NRGTs in Sri Lanka.

NRGTs and infertility

In general terms, all those interviewed were broadly positive about the NRGTs. Some had general reservations about where such technologies might eventually lead and how they might be appropriately regulated, while others had specific concerns such as the problem of multiple conceptions arising from fertility drugs. There was a strong feeling that sub-fertility ought to be corrected if possible, and the ability to tackle disorders at their genetic origin was also seen as a positive development. Although there was broad consensus that treating infertility was a 'good thing' there was some disagreement as to where this figured in terms of national priorities. Eight respondents saw infertility as a high national priority but the remainder set the question against the broader issues of population control and resource allocation. It was pointed out that high-tech treatments are costly and less resource intensive solutions ought to be encouraged (for example, more efficient adoption agencies). For these five respondents, diverting government resources to the NRGTs was not seen as a priority, but it was recognised that demand 'cannot be stopped', and even if the government fails to invest in the technologies the private sector will.

Views on particular techniques

Committee members were asked for their views on the moral issues arising from a range of reproductive techniques involving the manipulation of eggs and sperm. In general, there was a high level of acceptance and approval of these techniques. Only one member was categorically opposed on religious grounds. When weighing up the ethical problems arising from gamete donation of surrogacy, most respondents identified the motivation of a childless couple to 'get a baby' as a factor likely to override ethical complications or subsequent social ambiguities.

Artificial insemination by husband: None of the respondents felt that this procedure raised any ethical concerns whatsoever. These statements were qualified to some extent by the assertion that partners needed to be fully informed of the procedures and should give consent. Several respondents pointed out that AIH had, in fact, been practised in Sri Lanka for a long time and was typically used where a man has a low sperm count and centrifuging is necessary, in cases where a man is impotent, and where successful intercourse cannot be achieved.

Artificial insemination by donor (AID): It was recognised that the introduction of another man's sperm into the reproductive process could create some social problems but, with one exception, all respondents thought that this technique was not ethically problematic providing both parties had consented. For the one who thought that it was problematic, the introduction of semen other than the

husband's into a woman was technically an adulterous act. A number of respondents drew parallels with adoption but pointed out that AID would also carry many of the same problems, such as how best to manage information about genetic origins and concerns about family dynamics in later life. For some respondents the source of the sperm was clearly an issue. For three respondents it was essential that sperm should originate from an anonymous donor *via* a sperm bank to avoid intra-family donation of sperm. Sperm banks do not yet exist in Sri Lanka and the systems for collecting, screening and monitoring sperm, and matching donors and recipients, are at a very early stage of development. For this reason there was a good deal of anxiety, not just over how confidentiality could be managed, but whether it could be managed at all in the short term. One informant felt that intra-familial donation was the ideal arrangement because it was most likely to minimise jealousy and anxiety on the part of the husband. Only one informant appeared comfortable with decision making by the couple, pointing out that it did not matter whether the sperm was from a bank or known donor, so long as all parties had freely consented. Respondents were unanimous in their view that the child born as a result of AID should be recognised as legally legitimate, and also that the donor of the sperm should remain anonymous with no rights on the child.

Egg donation: Respondents were for the most part happy to extrapolate from sperm donation to egg donation, although responses to questions about egg donation were characterised by a much greater caution and unease. Surprisingly, this was not linked by anyone to the medical and technical complexity of the operations involved but rather to cultural differences in the way that eggs and sperm are seen in reproductive processes. For at least one respondent, egg donation began to interfere with a fundamental notion of motherhood. For another, it evoked parallels with the first heart transplant and the questions that were asked then about the integrity of personhood and the body. Another felt that the manipulation of eggs was clearly the point where the expertise of clinicians ran out and questioned whether they, rather than religious and philosophical experts, were the best people to be addressing such issues. Two others confessed that they simply did not know where to begin with the ethics of egg donation.

Embryo donation: Of the 12 members who answered this question all felt that there were no particular problems attached to embryo donation. The reason for this appeared to be the ease with which the technique could be compared to adoption. The transfer of an embryo between parents was in effect no different than the transfer of a child between them; it was just happening at a much earlier stage. As such, embryo donation carried many of the same practical difficulties as contemporary adoption practice, for example, regarding consent, confidentiality and who within the receiving family should know about the arrangement.

Surrogacy: Consideration of surrogacy produced the widest range of responses. The general feeling appeared to be that there is a tradition of fluidity in family arrangements in Sri Lanka, and this is particularly evident when families face adversity (eg death of a child or a parent, or the experience of infertility). Hence, rearranging the biological imperatives of gametes, embryos and wombs to better fit with desired social outcomes did not, in theory, pose too great a problem for committee members. Only one respondent was against surrogacy on principle. Five respondents were concerned that surrogacy should not involve any kind of commercial transaction and pointed to the kinds of abuses that have already arisen in organ donation and adoption (eg exploitation of the poor, 'baby farms'). Three respondents did not see any problem with commercial surrogacy and felt that it might be the only way forward for some couples with infertility.

NRGTs and regulation

There was unanimous agreement that there should be a national committee for the regulation of NRGTs. This was not felt to be a task that could be tackled by local ethics committees and even less by individual doctors operating within codes of doctor-patient privacy. Three main reasons were identified. First, monitoring is essential in such a fast moving field. Without such monitoring there is a serious danger of exploitation, unregulated trials and experimentation. Second, a committee would be able to develop culturally appropriate practice and policy. Third, such a body would provide a national repository of expertise and advice, gathered locally and internationally. It was acknowledged that a national committee might impede research and development, but as one respondent described it, this is a 'dangerous field' and caution should be exercised.

There was a clear wish that a national committee should have 'teeth' but a good deal of scepticism whether this could ever be the case, given the public-private split in health provision. As one member reasoned, there is a need to regulate but most of the activity in the field of NRGTs takes place in the private sector which, for the most part, is self-regulating. Nonetheless it was felt that despite the difficulties a national committee was essential. Once set up it should strive to identify acceptable limits and boundaries for the NRGTs in Sri Lanka and aspire to achieve consistent regulation based on 'guiding principles'. One suggestion made for giving the committee 'teeth' was the inclusion of a member from the Medical Council of Sri Lanka so that, in the future, cases in which doctors and researchers failed to observe the regulations might be referred to existing disciplinary procedures.

Discussion

Respondents' comments suggest a high level of acceptance of the new technologies and general confidence about their use to combat subfertility. Respondents were less optimistic when it came to the question of monitoring

and regulation. There was strong agreement that a national committee was the appropriate place to start gathering information, planning and drawing up guidelines for regulation. Comments from interviewees reveal three major challenges when it comes to determining the scope and strategies for regulatory activity in the future.

1) The field of biomedical ethics, as distinct from medical ethics (10), is at an early stage of development in Sri Lanka. Ethics committees themselves only came into existence relatively recently and the voice of the patient is only just beginning to be heard when considering policy and practice. How can ethical debate about the NRGTs be fostered which is more participatory and inclusive?

2) Scope for abuse in the storage and use of human gametes is wide, with risks being generated not only from practitioners within Sri Lanka but also from those wishing to evade more rigorous regulatory practices in other countries. How can regulation of new technologies work in a mixed health economy?

3) Management of the new reproductive and genetic technologies involves highly sensitive personal information. Members of the committees were concerned that systems of record keeping needed to be robust when it comes to privacy and confidentiality. Anxieties were expressed by many respondents that the quality of record keeping in the health sector is currently very variable. What safeguards could be introduced to ensure that records would be accurately and properly maintained over long periods of time?

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