

Establishing Institutional Ethics Committees in Australia: Challenges and Operational Procedures with Particular Attention to the New Reproductive Technologies*

Irina Pollard**

Abstract

The ethical difficulties of modern health care are, for the most part, a result of new technologies – especially relevant are the New Reproductive Technologies. Increased costs, cultural emphasis on individual rights, uncertain or conflicting social values, and changing relationships among health care professionals all have dramatically changed hospital life and contributed toward modern predicaments. Recent changes in reproductive technology, for example, have altered control of fertility, childbearing, and child rearing. The newer aspects of reproduction such as contraception, abortion, fetal diagnosis, gamete and embryo donation, assisted conception, surrogacy and research on human embryos, all present major ethical challenges to individuals, governments and nations. However, it must be qualified that some of these topics such as contraception and abortion have been practiced since antiquity. Still, it is clear that medical questions require medical answers, but many of the most

* This paper was presented at the UNESCO International Conference on Bioethics Committees in Hospitals held in Zefat, Israel: 2009.

** Professor, Department of Biological Sciences, Macquarie University, Australia. irina.pollard@mq.edu.au

puzzling questions that health care workers currently face are not exclusively medical in nature. These questions are mostly about individual values, the personal meaning of life and death, and fairness or justice. Patients, doctors, nurses, social workers, religious advisers, hospital administrators, and society itself all need to take part in asking relevant questions and making decisions, which not only affect individual lives but, importantly, also shape social relations. Ethics committees represent an important response to that need for a broader range of thinking about critical health care decisions. Discussing ethical issues more openly and more frequently can lead not only to better decisions but also to better relationships among health care professionals. My experience of hospitals with ethics committees suggests that each institution will handle things a little differently; each will create a form that fits its own situation. In this publication, I am going to share my experiences on one of Sydney's largest Institutional Ethics Committee (IEC). As one of the founding members of the IEC servicing the Royal North Shore Hospital and allied Northern Sydney Health community in 1990, we had to start from scratch devising the composition and constitution of our Committee, which subsequently assisted other institutions also in the process of establishing their individual IECs.

Since space does not allow for a full discussion of the varied and diverse ethical dilemmas considered, I have concentrated on one implemented directive relating to the new reproductive technologies – a discipline I have some expertise in.

Keywords

Hospital and Institutional Ethics Committees (IECs), Bioethics, Bioscience Ethics, *In vitro* Fertilization, Assisted Reproductive Technology (ART), Infertility, Fertility Treatment Protocols, Sperm Micromanipulation, Intracytoplasmic Sperm Injection (ICSI)

1. Introduction

Human ethical thinking about the relationships between Nature, science, medicine and ethics began long before their written record. Accrued insights on topics such as truth, justice, freedom, mercy and compassion, have paved the way for the development of science-based medicine in surprisingly modern terms. For instance, the core of the Hippocratic tradition (the ethical standard for physicians effectively unchanged over two thousand years) primarily declares “do no harm.” Hippocrates understood that embedded within the physician’s healing powers, there is also the capacity to harm. In several versions of the Hippocratic Oath, it is clear that there are two ways to do harm: errors of commission and errors of omission. A physician can harm a patient with what he knows; but even more so, with what he does not.

While modern science is assisting in our understanding and treatment of ill health, full acceptance of the interrelationships between body, mind, spirit and community, is still limited. The ethical dimension of science, however, is essential because all of us will need to participate, as citizens, in making informed choices about its uses and abuses. Put simply, when contemporary science is applied, it automatically incorporates functions that expose value judgments and political forces. The human genome and human genome diversity projects, bioinformatics, ownership and patenting of genes, end-of-life care, organ transplantation, and new technologies for assisted human reproduction, are relevant real-life instances in this context. Thus, it seems obvious that our capacity to fully comprehend scientific advances depends on a willingness to view our physiological, emotional, cognitive, social, ecological and spiritual functions holistically. In essence, to adequately respond to the challenges that our technologically-based predicaments have created, a deeper

understanding of biological systems is essential. To this end, the new transdisciplinary field dubbed 'bioscience ethics' (Pollard 2009a) provides unique opportunities for advancing biological understanding within the scaffolding of ethics. Bioscience ethics provides a source of information that bridges the gap between applied science and applied ethics.

The principal terms of reference of Hospital Ethics Committees (HECs) and Institutional Ethics Committees (IECs), is to raise awareness about major new developments in the health field with significant bioethical implications, and to facilitate complex decision-making by doctors and hospital policy makers. To realize this, health care ethics committees consist of a variety of professionals, not established in law, who are charged with certain advisory responsibilities in the conduct of research or clinical practice at local, national and international levels. Typically, committee members include experts in medical research, research in public health and social science, clinical medical practice, nursing, disability, law, religion, ethics and philosophy. This array of experts in differing fields allows for an interdisciplinary perspective on common ethical issues. Briefly then, ethics committees have three varied objectives: a) to develop, recommend and record guidelines and policies to assist in patient care; b) to self-initiate bioscience-bioethics education for health care professionals and the general public; and c) to provide advice to clinicians on individual cases and medical research trials. Increasingly, the verdicts of established health care bioethics committees challenge the *status quo*, reform practice and guide change (UNESCO 2007). In this respect, the UNESCO Global Ethics Observatory (<http://www.unesco.org/shs/ethics.geobs>) might also be a helpful resource.

As alluded to above, the social dilemma that contributed toward the development of modern health care bioethics committees was the rapid innovation and use of medical technology. From the late 1970s, medical

innovations created ethical issues with very few precedents; thus, it became increasingly difficult for individual scientists and physicians to resolve increasingly complex ethical issues. When the question of ‘who’ had the responsibility to oversee possible use/misuse of technical innovations was raised, the fledgling HECs and IECs provided the solution. From small beginnings we now witness a wide-ranging array of certified, interdisciplinary health care committees systematically addressing the ethical dimensions of innovative science and deliberating the suitability of existing economic, legal and health care policies worldwide. Importantly, ethics committees are offering the general public a valuable forum to debate the ethics of long-standing values, norms and behaviour *vis-a-vie* new scientific and medical developments.

In Australia, the Australian Health Ethics Committee (AHEC) is one of the principle committees of the National Health and Medical Research Council or NHMRC (<http://www.nhmrc.gov.au/>). However, Australian ethics committees are not limited to the national level since most individual State and private hospitals and institutions have their own ethics committees, or access to an allied health committee in their locality. Each committee adapts to the priority demands of the community they are serving. For example, Aboriginal and Torres Strait Islander health research is one of the many areas that the NHMRC has considered and, in 2003, devised a document specifically addressing guidelines for ethical conduct in Aboriginal and Torres Strait Islander health research. The new guidelines were essential once it was acknowledged that Aboriginal and Torres Strait Islanders traditions, values, and customs varied significantly from the social order of the more Eurocentric Australians. The six values that lie at the heart of the guidelines are spirit and integrity, reciprocity, respect, equality, survival and protection, and responsibility (NHMRC 2003). Identifying and acknowledging the many different social values,

customs and traditions in a multi-cultural society, such as Australia, and attending to each with equity is one obligation faced by healthcare bioethics committees.

2. Establishing the Institutional Ethics Committee Servicing the Royal North Shore Hospital and Allied Northern Sydney Health Community Founded in 1990

Owing to space constraints the following is a curtailed overview of the composition and constitution of the Royal North Shore Hospital (RNSH) IEC and one implemented directive with particular reference to human reproductive biology.

Areas in which our IEC operated

1. Treatment or non-treatment of terminally ill or those unable to participate meaningfully in decision making.
2. Conflict between parental and fetal interests.
3. Abortions.
4. *In Vitro* Fertilization and the Assisted Reproductive Technologies (ART).
5. Surrogacy.
6. Children/ adults who are not legally competent but may be capable of making meaningful decisions.
7. Allocation of resources.
8. Health risks to staff by certain treatments.
9. The role of the patients' families in decision making.
10. End-of-life care, advanced directives and 'do not resuscitate'

orders.

Projects and Areas of Major Debate

1. Euthanasia, suicide and assisted suicide.
2. Withholding treatment and withdrawing treatment in intensive care.
3. Intended versus unintended but foreseeable consequences; e.g., administration of symptom-relieving drugs such as narcotic pain relievers.
4. Seriously ill newborns.
5. Balancing ART options; access of information – birth certificates and birth records of offspring born as a result of ART.
6. ART for unmarried singles and gay couples.
7. Posthumous conception and grieving for the dead.
8. Issues of law in Australia relating to surrogacy, stem cells and cloning technology.
9. Adoption and inheritance issues.

Terms of Reference

1. To undertake activities to promote increased awareness and discussion of bioethical issues amongst the hospital staff and in the community.
2. To develop, recommend and record guidelines and policies to assist staff to provide each patient with the appropriate level of care.
3. To provide a resource where staff and relatives may seek guidance on the ethical appropriateness of care in individual patients.

4. To provide guidance for the Hospital in which the ethical aspects of resource allocation may be discussed.
5. To self initiate discussion on matters that appear in the Committee's view to raise ethical concerns.

Composition

1. The minimum recommended membership should be:
 - One representative of the Management Committee
 - One representative of the Allied Medical Staff (e.g., social worker)
 - Two representatives of the active Nursing Staff
 - The IVF Social Worker
 - Two Medical Graduates in active clinical practice
 - One Lawyer
 - One Ethicist and/or Philosopher or Minister of Religion
 - One Academic (not associated with the Institution) and if decisions about assisted reproduction are made a gynecologist/obstetrician or reproductive biologist must be represented on the Committee
 - One representative of the Hospital Medical Administration
 - Two Lay Persons (ideally gender balanced) not associated with the Institution

Ideally, IECs should be composed of men and women reflecting different age groups where outsider people such as scientists, writers, professionals and any persons who can bring a fresh point of view would be welcomed.

2. The Committee should have power to co-opt members.
3. All members should be asked to consider the implications of joining the committee and consider their ability to devote the time needed and to attend regularly.
4. The Chairman should be elected annually and ideally should not serve as Chairman for more than 2 terms.
5. A regular and planned turnover in membership should be encouraged.

Rules of Operation

1. The Committee should meet monthly.
2. An Annual Report of the Committee should be produced to be used as a record of guidelines and policies and to form the basis of a history of the Committee.
3. In the event of urgent requests an attempt should be made to contact every committee member, but any decision made by those members available at the time may possibly constitute a decision of the Committee.
4. Minutes should be kept of all proceedings (full Committee and sub-committee). The minutes should record:
 - a. how the matter discussed was raised
 - b. brief details of the matter
 - c. key point raised in discussion
 - d. the view formed by the Committee with reference to ethical issues determining such view
 - e. where the view formed is not unanimous, the range of views

expressed should be recorded

5. Where individual patients/subjects are discussed these persons should not be identifiable in the minutes.
6. A quorum should be half the committee members plus one and must include a lay person and a clinical person.
7. The Committee should report to the Management Committee on the basis of policy and rules but where an individual problem is raised, response should be made direct and Management Committee notified of the Committee's response.
8. The Hospital should pay routine attendance expenses; such as parking fees, for those committee members not associated with the Hospital.

Education for the Committee

Since Committee members are increasingly required to respond to new scientific discoveries; there is also the need to undertake self-regulated continuing education. Our self-educational processes involved integrated, formalized focus sessions and informal information flows.

1. To invite speakers to talk on ethical principles in bioethical decision-making.
2. If we identified specific issues which our IEC would be required to consider in future we would then arrange proactive education on those particular issues.
3. Ensure that at least one representative (capable of acting at the required professional level) of the IEC attends conferences/seminars the Committee saw as relevant.

4. Following conference attendance participating member provides a synopsis for the Committee and for the IEC conference/seminar file.
 5. Taking note of the composition of the Committee, provide educational input for its members on their role and contributions when addressing practical health-related issues. It was acknowledged that not all members could be expected to be 'experts' in all issues under consideration.
 6. Individual Committee members bring to the Committee's attentions new developments published in the scientific literature or relevant bioethical journals so that all members were provided with reading materials, or on-line access to reading materials, prior to participating in committee discussions. A positive outcome was that each committee member effectively became an experienced 'peer educator'.
3. An Excellent Example of an Early Committee Initiative:
Monitoring of Babies Resulting from Certain ART Protocols as
Practiced at the Royal North Shore Hospital

Most of us understand counseling to be a therapeutic technique providing advice and guidance to a patient and significant others. Therefore, counseling is an important part of any fertility treatment and applies both to the doctor, who maybe motivated by a too enthusiastic desire to help the infertile couple, and the couple who maybe blinded to consider valid alternatives by their desperate desire for a child. When it comes to fertility treatment protocols, all known potential risks must be carefully explained

and received.

Accredited IVF clinics require couples to sign a general consent form acknowledging that they have understood and accepted the information provided. This information typically clarifies the various assisted reproductive technologies planned, includes a warning that there may be associated short, medium and long term health risks, that there is no guarantee of a successful pregnancy, and that they have been given fair opportunities to become better informed. The advantages of this practice to the couple are immeasurable from the point of view of increased understanding and in establishing mutual respect for each other and their unborn children.

Treatments that are collectively termed assisted reproductive technologies or ART have focused attention on the general problem of human infertility. Reproductive infertility is the inability of a couple to conceive or carry a baby to term. A couple is considered infertile if no conception has been achieved after 12 months, or more, of unprotected intercourse of average frequency. Because not all couples want to become pregnant, infertility is hard to assess accurately. However, several studies have reported that up to 15% of couples in developed countries are involuntarily infertile, with a much higher percentage in developing countries. The main causes of infertility in developing countries are sexually transmitted diseases and repeated pregnancies causing secondary infertility due to poor hygiene at the time of childbirth, abortion or miscarriage. Lifestyle also modulates fertility; for example, an association between cigarette-smoking and teratozoospermia (abnormal forms) has been documented (Zenzes 2000). According to WHO infertility figures (<http://www.who.int/topics/infertility/en/>), of the infertile couples 30-40% have an exclusively male factor, 25% have factors in both male and female, 40% have a predominantly female factor and in 2-15% (idiopathic

infertility) no diagnosis can be made after a complete investigation. It has also been reported that in as many as 35% of couples, the infertility may have multiple origins.

Important biological and ethical issues concern the application of assisted reproduction in all cases of infertility regardless of etiology. While ART has offered hope to those whose fertility is compromised, the technology itself may, in some cases, further compromise the reproductive outcome. Evidence is emerging that suggests that babies born as a result of the more invasive IVF procedures have an increased risk of low birth weight, genetic disorders, neurological abnormalities and maybe even cancer (Sutcliffe & Ludwig 2007). Fears about the safety of reproductive technologies, however, should be kept in perspective because in most cases the studies done were based on small sample size, while other studies on children conceived by assisted reproduction have found no evidence of any serious problems. Evidently more research is needed to assess the risks and care should be taken to refine as much as possible the ART techniques in order to reduce these risks.

Treatment protocols for male-mediated infertility have advanced rapidly but their long-term effects on the offspring are still uncertain. Patients with sperm defects such as low density, poor structure, abnormal or weak motility, immotility or biochemical dysfunction at the level of binding with the oocyte's (egg's) zona, can now father children through the techniques of sperm micromanipulation. Intracytoplasmic sperm injection (ICSI), in conjunction with IVF technology, is the most common assisted reproductive technology for severe male-mediated infertility. IVF is used if there are sufficient sperm available to add to oocytes in culture while ICSI is generally used when only a few sperm are seen in the ejaculate and they are perceived to be too weak or abnormal to penetrate the outer layers of an oocyte. With ICSI a single sperm is selected and

injected directly into the oocyte's cytoplasm. In patients with azoospermia (no sperm in the ejaculate), ICSI can be performed with sperm obtained by microsurgical epididymal aspiration or by fine-needle testicular extraction.

Increasingly researchers are questioning the safety of ICSI and other invasive techniques, claiming that they may be linked to increased rates of birth defects and rare genetic imprinting disorders (Pollard 2009b). Other researchers claim that infants conceived as a result of sperm micromanipulation compare favorably with the IVF group of babies, but there is considerable variability since pregnancy outcome depends closely on the overall semen quality used. Patients with severely defective semen have a high risk of siring babies leading to preterm deliveries, low birthweights and early perinatal mortality when compared with the children sired with 'better-quality' sperm and those resulting from natural conceptions (Zini & Sigman 2009). Recent research suggests that embryo quality and development in ICSI may be improved if the sperm cell selected for injection is based on its ability to bind to the hyaluronic acid that surrounds the oocyte (Parmegiani et al. 2009). Good binding capacity indicates reduced DNA fragmentation allowing for a more 'physiologic' ICSI procedure.

Lack of information, contradictions in the scientific literature, and fears about possible long-term negative health consequences in ICSI-assisted offspring, raised serious concern among the IEC members attached to the RNSH. We were of the opinion that at the core of developing ART guidelines and policies, our committee had to give priority to the health of the child born and ensure, as far as possible, that no part of the ART procedure seriously impeded the child from reaching its full genetic potential. We, therefore, determined that the ICSI protocol would be approved only on the condition that all babies conceived as a result of ICSI were enrolled in a follow-up program for initially one year

which was later extended to three years. Subsequently, monitoring for a period of three years was also introduced for all babies resulting from the use of freeze-thawed embryos. These conditions were not optional extras but an integral part of the treatment program which had to be agreed to by the couple prior to enrolment for infertility treatment. The patient consent form for IVF following ICSI and patient information sheet, as devised at the time, are attached for readers' attention (Figures 1 & 2).

Findings garnered from the initial follow-up program at one year of age revealed no significant differences in the incidence of major congenital malformations; however, on the Bayley Scales of Infant Mental Development Index the ICSI children (especially boys) scored significantly lower compared with standard IVF procedures and natural conceptions (Bowen et al. 1998). The cognitive tests assessed were memory retention, problem solving and language skills. Clearly, these adverse findings presented our Committee with an important ethical dilemma: to continue the study and assess long-term risk by defining the absolute risk of imprinting and other disorders after invasive ICSI procedures, or abort the study and recommend to the parents, retrospectively, special remedial education. The Committee disclosed the findings to the parents and recommended that special remedial education needed to be initiated. Vindication came a year later when a second follow-up study revealed no statistical differences between the ICSI and the control groups of children.

4. On Addressing the Ethical Dimensions of Health Care Science: Final Analysis

1. When science is applied in society it automatically incorporates functions that expose value judgments and political forces.

Therefore, the global community must agree on some bioethical consensus when applying the contributions from science – Hospital and Institutional Ethics Committees can assist.

2. The principal terms of reference of Institutional and Hospital Ethics Committees are to raise awareness about major new developments in the health field with significant bioethical implications and to facilitate complex decision-making by doctors and hospital policy makers.
3. Uncertain efficacy makes it imperative that all Ethics Committees incorporate flexible perspectives into decision-making when considering important health care advances such as infertility and new ART procedures. Thus, when addressing questions concerning procreative biology, the personal and the transgenerational have to be measured. Bioscience ethics supports a system of values gained from evolving scientific awareness and concerns itself with a better understanding of biological systems and using technology responsibly.
4. Self-evidently, bioscience ethics and bioethics (colloquially dubbed bioscience-bioethics) may seriously challenge traditional (human-centered) ethical and moral theory, but that can only be of advantage because challenge generates energy which fuels cultural evolution promoting resilience, flexibility and sustainable health-promoting skills.
5. The Bioscience-Bioethics Friendship Co-operative (BBFC) web portal at <http://www.bioscience-bioethics.org/>, provides free admittance to educational material in the area of stress physiology, reproduction, toxicology-teratology, environmental ethics, and access to other useful links for those interested in bioscience and bioethics.

Acknowledgment

I wish to acknowledge RNSH IEC's past and current members for freely providing their time and expertise in advancing research and applied health-care practice. I particularly wish to acknowledge the contributions and early recommendations of the founding RNSH IEC members who have sensitized Australian Ethics Committees to matters that may have been otherwise overlooked and have, consequently, improved scientific understanding and strengthened medical guidelines relating to a raft of concerns including new ART methodologies.

REFERENCES

- Bowen, J., F. Gibson, G. Leslie, and D. Saunders. 1998. Medical and Developmental Outcome at 1 Year for Children Conceived by Intracytoplasmic Sperm Injection. *Lancet* 351: 1529-34.
- NHMRC. 2003. *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. Diagram 1: Aboriginal and Torres Strait Islander Peoples values relevant to health research ethics*. Australian Government at <http://www.tripdatabase.com/search/656157>
- Parmegiani, L., G. Cognigni, S. Bernardi, et al. 2009. "Physiologic ICSI": Hyaluronic acid (HA) favors selection of spermatozoa without DNA fragmentation and with normal nucleus, resulting in improvement of embryo quality. *Fertility and Sterility*, Advance online publication.
- Pollard, I. 2009a. *Bioscience Ethics*. Cambridge (UK): Cambridge University Press.
- Pollard, I. 2009b. Current Reproductive Technologies: Achievements and Desired Goals. In *Bioscience Ethics*. Cambridge (UK): Cambridge University Press, pages 145-170.
- Sutcliffe, A. and M. Ludwig. 2007. Outcome of Assisted Reproduction. *Lancet* 70: 351-359.
- UNESCO. 2007. *Educating Bioethics Committees, Guide No 3* at

<http://unesdoc.unesco.org/images/0015/001509/15097e.pdf>

Zenzes, M. 2000. Smoking and Reproduction: Gene Damage to Human Gametes and Embryos. *Human Reproduction Update* 6: 122-31.

Zini, A. and M. Sigman. 2009. Are Tests of Sperm DNA Damage Clinically Useful? Pros and Cons. *Journal of Andrology* 30: 219-229.

Figure 1. Patient consent form for in vitro fertilization following ICSI.

ROYAL NORTH SHORE HOSPITAL AND COMMUNITY HEALTH SERVICES	Human Reproduction Unit ST LEONARDS NSW 2065 AUSTRALIA Phone: Clinic (02) 438 7420, 438 7684 Laboratory (02) 438 7326 Fax: (02) 906 6742
--	---

PATIENT CONSENT FORM FOR IN VITRO FERTILIZATION FOLLOWING ICSI
i.e. INJECTION OF A SINGLE SPERM DIRECTLY INTO THE OOCYTE (EGG)

We agree to the procedure and understand the following:

1. While pregnancies have been obtained using this technique at Royal North Shore Hospital and scientists have confirmed experimentally that it increases fertilisation rates, there is no guarantee of success.
2. The risks associated with oocyte pick-up.
3. The risks associated with intrauterine embryo transfer.
4. The risk that damage to the egg may result from the injection procedure.
5. The risk of foetal malformation.
6. The availability of, and the recommendation to undertake, tests to detect foetal malformation during pregnancy. It is our responsibility to discuss pregnancy monitoring with our obstetrician as soon as a pregnancy is confirmed.
7. The risks of multiple pregnancy.
8. Should all our eggs fail to fertilize following microinjection, they may be reinseminated with sperm from an anonymous donor of known fertility to test that the eggs are capable of fertilization.
9. Should fertilization occur with the anonymous donor sperm, the resulting embryos may be assessed for genetic normality. These embryos do not survive the test and will not be available for transfer.

We agree/do not agree with the request of the Royal North Shore Hospital to undertake long term follow up studies on the couples who use this microinjection procedure and their children conceived as a result of the procedure.

This procedure and risks have been fully explained to us by and we have read the ICSI information sheet (over page) and the brochure entitled "Enhancement of Fertilization by Micromanipulation".

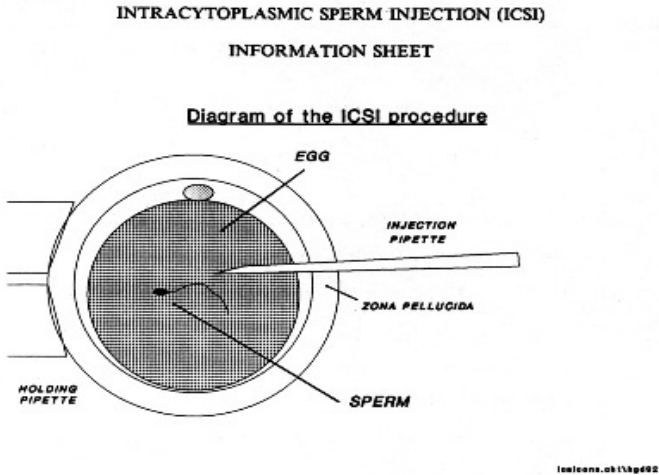
Signed:.....(female).....(male)

Witness:.....(date).....

WE ACKNOWLEDGE RECEIPT OF A COPY OF THIS CONSENT FORM:

Signed:.....(female).....(male)

Figure 2. Intracytoplasmic sperm injection (ICSI) information sheet.



Intracytoplasmic sperm injection, or ICSI, is the injection of a single sperm directly into the egg. A single sperm is picked up with the injection pipette and this is passed through the zona pellucida and the surface membrane of the egg. The sperm is then released from the injection pipette with a minimum amount of medium (see diagram above). This technique means that fewer sperm are required for injection, the possibility of multiple sperm penetration is overcome and the sperm do not have to undergo many of the usual changes before fertilization occurs.

Results from a Belgium group and groups within Australia, including the Human Reproduction Unit, show that the fertilization rate, even with very poor quality sperm samples, can be as high as 60%. The Belgium results indicate that the resultant embryos are normal and give rise to normal pregnancies.