

Technological assessment of intracytoplasmic sperm injection: an analysis of the value context

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Since the introduction of intracytoplasmic sperm injection (ICSI) in 1992, the new technology has raised a series of basic moral issues. In this article, I present a brief review of this moral debate. I argue that even if we solve the moral problems of the debate, there is a residue of value issues. These value issues are crucial for the understanding of the dynamics of the health policy and the legislative process concerning ICSI. That is, values analyses are crucial to make viable moral judgments about new technologies such as ICSI. (*Fertil Steril*® 2003;80:930–5. ©2003 by American Society for Reproductive Medicine.)

Key Words: Ethics, ICSI, value analysis, health policy

Intracytoplasmic sperm injection (ICSI) was introduced in 1992. Since then, many countries have implemented the method, and thousands of babies have been conceived worldwide through this in vitro fertilization method (IVF). In spite of severely compromised semen characteristics ICSI enables fertilization to take place, and its use usually has been restricted to men with poor sperm quality. There has been concern regarding the safety of the ICSI procedure. In the absence of natural selection of the fertilizing sperm and the oocyte to be fertilized, any structural damage caused by the operation, or transfer of genes that would not normally have been passed on to the child, could increase the risk of developmental abnormalities and health problems in the children.

In connection with these issues the ethical aspects of ICSI have been debated. I briefly review some of the arguments and present a values analysis of the ethics of ICSI. I argue that, to take into account the moral issues related to the implementation of a new technology such as ICSI, an analysis of the values context is crucial for making viable political decisions concerning a new technology.

ETHICAL CHALLENGES WITH ASSISTED REPRODUCTIVE TECHNOLOGIES

In many ways the ethical debate on ICSI revives the arguments about assisted reproductive

technologies (ART) in general (1–21). This is not the place to reopen the heated moral debate on ART. For the sake of argument, let me only briefly present some of the main issues.

1. Does ART alter the conception of humans? Do we become self-manipulating machines?
2. Does ART change human rights in the direction of biological needs such as the right to reproduce (22, 23)?
3. Does ART make children a means to our ends (24)?
4. Is ART a kind of medicalization of conditions that traditionally have not been conceived of as medical issues? Is ART an “offer we cannot refuse,” “a solution to a problem we did not know we had” (25–28)?
5. How does ART influence the biological conditions, traditional ideas, and social and legal roles of what it is to be a father or a mother? What does it mean when conception, pregnancy, bearing a child, and being a mother are separate events (26, 29–33)?
6. How does the potential of manipulation affect our definitions of a person, parenthood, and a family (26, 34)?
7. Does ART lead us one step closer to babies on demand and cloning (35)?
8. Is ART technology a measure to treat social conditions such as pro-natalism?
9. In terms of prioritization, what is the severity of infertility compared with other relevant health conditions?

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These issues must be taken into serious account when discussing ICSI, because of what has been called the “the slippery slope” argument. That is, if we take small steps without relating them to the moral context, we can end in very awkward situations. For instance, we accept IVF; therefore, one could argue that to be morally consistent we should also allow research on fertilized ova, a practice not accepted in many countries.

Correspondingly, if we allow ICSI in general, there seems to be no morally relevant difference in using sperm from ejaculate, the testicles, or the epididymis. Furthermore, if we accept the methods that use sperm derived from the testicles and epididymis, why should we also not allow methods that use pre-stages of sperm? And if we allow such types of ICSI, why should we not accept techniques based on other body cells and parts of body cells?

The consistency argument might force us in a direction we do not want to go, so it is important to investigate the moral context of the technology involved. To make sure that this particular step does not make us lose foothold and slide down the slippery slope, we have to look into all the relevant moral issues related to a technology, even though they have been debated before. Not only does ICSI revive—and potentially shed new light on—old controversies and ethical issues, the new technology introduces some specific issues.

ETHICAL ASPECTS OF ICSI

At least four concerns appear to be morally unique with respect to ICSI: gender justice; health risk to parents and children; risk of passing what is conceived of as a problem on to the next generation; and treating one person (the woman) for another person’s condition (male factor infertility).

Gender Justice

In some countries such as Norway, IVF was allowed for female infertility only (36). In the absence of established assisted reproductive methods for male infertility, such legal measures represented no major moral dilemma. However, with the introduction of methods such as ICSI, the differentiation between male and female infertility has become a moral problem: ICSI removes the discrimination between infertile men and women, and establishes a moral balance between the genders with respect to artificial reproductive methods. Even more, it can be argued that if we approve of IVF, we must approve of ICSI to be morally consistent.

Health Risks to Parents and Children

Concern over the safety of the ICSI procedure has posed the question of whether ICSI represents a health risk for the parents (mothers) and the children. In the absence of natural selection of the fertilizing sperm and the oocyte to be fertilized, any structural damage inflicted by the operation or by the transfer of genes that would not normally have been

passed on to the child could increase the risk of developmental abnormalities and health problems in the children.

This raises a series of moral issues. Can we accept an increase in the risk of birth defects? If we can accept the increased risk, on what grounds can we accept it? Moreover, do we accept the increased risk relative to the risks associated with normal birth, oocyte donation (OD), or adoption? Where do we set the limit for acceptable risk? What kind of birth defects can we accept—congenital malformations, growth disturbances, neurologic developmental disturbances, chromosomal abnormalities, or transmission of subfertility to male offspring? If we are risk averse, what do we then implicitly say about the value and/or worth of people that have these birth defects? What relevance does the precaution principle have? If we do not know enough about the risk of birth defects, should we then be restrictive? Moreover, what moral responsibility do we have for the children born with birth defects, and who has responsibility for taking care of them and paying the extra costs involved?

The point here is not to answer all these questions but rather to highlight the variety of moral issues related to the risks associated with ICSI. The answers to the questions depend on whether we are asking them to an infertile person, the couple, the child, the professional, or the public in general.

Risk of Passing Infertility on to the Next Generation

Men with genetically caused infertility are at risk of passing this condition on to their children. Although this is not a prevalent problem, passing on a condition that the parents themselves find undesirable is of principal moral interest. This raises the question of whether children are only a means to the parent’s end and not an end in themselves.

One can argue that the child will have access to the same treatment as the parents, thereby making this not a practical problem. However, this does not solve the main problem relevant to all assisted reproductive technologies.

Furthermore, as with all reproductive technologies, there is a question of resources and priorities. Should we give priority to a method that perpetuates a problem? One could argue that technologies that reduce the genetic quality of the population should be avoided, but this is a controversial argument with eugenic implications.

Treating One Person for Another Person’s Condition

In contrast to traditional IVF, ICSI is in essence treating one person for another person’s condition: the woman is treated for the man’s infertility. Thus, ICSI raises the same kind of moral questions as transplantation from living donors.

One could argue that it is not infertility per se that is the problem but rather not having children. As childlessness is a

condition the couple has in common, treatment that involves both partners is legitimate. This argument is controversial because single women and men, as well as homosexual couples, may also suffer from childlessness, and thus *ceteris paribus* should be treated. However, societies often draw moral distinctions among these groups.

VALUES INVOLVED WITH ICSI

What if we took as a given that all the general moral challenges revived by ICSI were satisfied, and that all the moral challenges specific to ICSI had been addressed? What if we were sure that ICSI does not involve any slide down the slippery slope, and that it does not offend any moral principles or theories? Would we then have solved all the value problems relevant to an assessment of ICSI? The obvious answer to the latter question would seem to be yes. However, even when the moral issues relevant to a technology have been addressed, such assessments of technology still do not impact actual practice, because admonitions not to implement technologies are overridden and recommendations for certain technologies are not followed. Within technology assessment in health care (TAHC), this is called the “dissemination problem.”

Simply including in the assessment an evaluation of the social and ethical consequences does not solve the dissemination problem. This failure may be related to other value issues that were not addressed by an analysis that only pertained to consequences. Thus, discussion of those other potential value issues is important.

Social Values

The ART debate has highlighted many social values, most prominently the deeply rooted value of respect for human life, whether it is expressed as respect for God’s creation, or for nature, or for scientific laws. Regarding ICSI, such values are expressed in questions such as whether ICSI crosses the line of acceptable medical manipulation. Such thinking underlies statements such as “we should not tinker with nature,” “we should not play God,” and “there should be limits to manipulation”—and it is even implied in the term “artificial insemination” itself.

Moreover, as with ART in general, basic values are at stake in the debate on ICSI because it involves the issue of whether having children is a human right. And if having children is a basic value to us, what kind of value is it? Is it a social or a biological value (22, 23)? Infertile persons and their interest groups strongly support the idea that having a child is a basic biological value. Likewise, advocates of ICSI emphasize the biological values involved, arguing that it is every person’s right to have his or her own genetic child.

Additionally, ART in general and ICSI in particular have challenged our ideas related to embryos, fetuses, and children. What a person is and what value we assign to the family are questions that have arisen. Related issues also

arise: what rights do the embryo, the fetus, and the child have (37)? Is the value of the child to be weighed as the child being an end in itself, or as a means to satisfy the need to have one’s own children (24)? Moreover, is there a right not to have been born (38, 39); if yes, how do we apply this to the risk of birth defects? In other words, the parents, who are acting as agents for the unborn children, may have interests that are not compatible with the interests of the future child. This issue challenges the traditional autonomy principle in bioethics, and illustrates the viability of a value analysis.

Scientific Values

Coherence, consistency, completeness, simplicity, transparency, reproducibility, fruitfulness, and explainability are scientific values. The hierarchy of knowledge in health care has been based on such values, as has the evaluation of ICSI. And thus, “the ideal study to evaluate possible adverse effects on the offsprings following treatment for male infertility by ICSI would be to randomize couples that are candidates for ICSI to either ICSI or traditional IVF” (40, p. 50). Randomized clinical trials are considered to achieve a higher standard scientific validity than other types of studies, such as cohort or case-control studies.

In some instances, scientific values may coincide with moral values. Because there is a moral impetus to be able to give a rational account of medical activity, much attention has been given to designing and performing good studies that give reliable results with respect to the efficacy and effectiveness of ICSI and whether it increases the risk of birth defects. However, some scientific values conflict with moral values. Moral values dictate that people should not be harmed unnecessarily, and that medical methods only should be applied to persons who potentially can gain from them. Thus, some argue that a study that randomizes couples to ICSI or traditional IVF “would be regarded as unethical, since candidates for ICSI usually have severely compromised sperm quality which cannot be expected to fertilize ova by standard IVF” (40).

Another example of scientific values being at odds with moral values is including chromosome and DNA analyses for all children conceived by ICSI and IVF, as well as for their parents, as a crucial part of a scientifically good study design. The information obtained from such analyses may present a moral challenge to the patient, the physician, and the researcher.

In many cases, scientific values can be reconciled with moral values. There is a moral basis for all medical knowledge: to help individuals with conditions that are believed to have bodily or mental origins and that are found to be undesirable by that person. However, in practice many other values intervene in the interplay between scientific values and moral values. Researchers and scientists seek prestige and funding, the industry is preoccupied with economics, and interest groups promote their particular agendas. This

interaction of values is particularly applicable to ART in general, and ICSI in particular, and ignoring it may be treacherous. Because, in health care, every argument and every value can be hidden behind generalizations such as “in patient’s best interest,” it is important to look underneath and to identify the underlying values.

The conflict of interests in science can be identified by the ways in which scientific results are presented. For example, the result from a meta-analysis comparing ICSI and traditional IVF was as follows: “Overall, the risk of birth defects was 1.13 (95% confidence interval: 1.00–1.29, $p = 0.06$)” (40). This result has been presented to the public in a variety of ways: ICSI compared with traditional IVF [1] has no increased risk of birth defects; [2] shows no evidence of an increased risk of birth defects; [3] has a small, but insignificant, increased risk of birth defects; [4] has an increased risk of birth defects. The confidence interval is thus another aspect of the conflict of scientific and moral values. If we were to choose a confidence interval of 94%, the conclusion would be different. So why do we choose a confidence interval of 95%? What is magic about 95%? Or, more precisely, which values are involved in the setting of “scientific” limits?

The point here is not to enter into the debate on the philosophy of science, but rather to point out that scientific values play an important role in the debate on ICSI. Scientific values interact with other values, and this interaction of values must be taken into account in the assessment.

Assessment Values

As technology assessment is based on scientific methods, the basic values in such assessments are closely related to scientific values. Thus, the selection of studies to be included in a meta-analysis or an assessment is an issue of value.

Moreover, technology assessment in health care (TAHC) is believed to be of worth, even though its effectiveness and efficiency as a tool in health policy has never been evaluated. Some TAHC agencies explicitly state that they do not draw conclusions, but only present and assess the available facts, laying the foundation for decisions and leaving the conclusion open. Yet it is difficult to see how such an evaluation could be value-free and without evaluative constraints. The selection process of TAHC is value-laden. Which technologies to assess is a value issue. Methodological difficulties, such as with randomized controlled trials for surgical procedures, pose many constraints. Thus, pharmaceutical products are assessed more stringently than medical methods and devices, and therapeutic technologies are more often assessed than diagnostic technologies. Furthermore, the technologies most often selected for assessment tend to be controversial or very expensive.

Technological Values

Additionally there are values related to technology in itself (27, 41). Technology is the symbol of progress, hope,

and power. In particular, ART and ICSI are technologies that represent our power over life and death, and as such are viewed by many as imperative (26, 42–44). As emerges quite clearly in the ART and ICSI debates, these values are in opposition to the values of respect for natural limitations and the values of self-restriction. Hence, ICSI promotes the values of human control and power but threatens the values related to the ancient virtues of temperance and sobriety (*sofrosune*).

As the purpose of ICSI is to conceive life artificially by sperm selection and injection, its use promotes the value of such artificial life conception (45); again, this actualizes general value issues related to whether assisted reproduction is right or wrong.

Medical Values

Among what we may call “medical values,” we find the ability to explain suffering; the aptitude to analyze undesirable conditions in terms of bodily and mental events, states, and processes; and the desire to help and actively intervene. Medical values are closely related to scientific and technological values, and have been intrinsic to the development, diffusion, and use of ICSI.

Medical values can be controversial. For example, analyzing undesirable conditions in terms of bodily and mental events, states, and processes has generally proven successful for conditions such as cancer and pneumonia, but has been less successful for conditions such as chronic fatigue syndrome. The debate on this value has been termed the medicalization debate (46). It is closely related to the discussion on the concept of disease (25): What are we to conceive of as disease? In particular, is male factor infertility a disease? As indicated, ICSI and ART are part of the debate about what conditions we should handle as medical problems.

Hence, ICSI promotes medical values, and challenges values that oppose medicalization. Until recently, infertility was conceived of by society as being a natural condition or fate, a condition one had to accept and to live with. Assisted reproduction techniques, and ICSI in particular, have changed and challenged this view.

Religious and Biological Values

Religious explanations and values are part of the traditional conception of infertility as fate and punishment. Although they are not as prominent in thinking today as in the past, religious values are still present in the current debate. For example, it is frequently held that Rachel’s words to Jacob, “Give me sons, or I shall die.” (Genesis 30:1), give legitimacy to any necessary measures to have children. Correspondingly, it is claimed that to reproduce is a genuine need and a basic instinct, and as such it is a fundamental value. On the other hand, it also can be argued that a religious conception forbids us to tinker with nature. Accordingly, it is not natural for everyone to have children, and it is unnatural to intervene in the process of life. One may

contend that reproduction has been conceived of as something subject to human manipulation and intervention as far back as antiquity; *technogonia*, the ancient conception of childbirth, has the same origin as art or technique, *techné*.

The point here is not to fully explore the religious and biological values that have been and are involved in the ICSI debate, but rather to emphasize that such values are still relevant; ignoring them can result in difficult decisions.

Moral Values of Rationing

The rapid expansion of medical possibilities and the escalation of the corresponding costs, as well as limited available resources, have forced us to ration medical care. We try to ration according to the basic moral value of medicine: to give the best possible treatment to as many individual persons as possible. To do this, we must consider criteria such as severity of the disease or condition, and the outcome and cost of the available treatments. Hence, every profound debate about ICSI includes a debate of the issues of how severe male factor infertility is when compared with other undesirable conditions, and how effective and efficient this treatment method is compared with other methods.

CONCLUSIONS

In this article I have investigated the evaluative issues related to ICSI. The technique has consequences for impacting the relationship between the genders with respect to infertility treatment, poses the challenge of how to handle a possible increased risk of birth defects, and raises the principle questions of whether it is right to pass on to the next generation a condition that is viewed as being undesirable and whether it is right to treat one person (the woman) for a condition in another person (the man).

Additionally, ICSI revives the evaluative challenges pertaining to ART in general, which are relevant in avoiding the dangers of the slippery slope. Intracytoplasmic sperm injection raises general issues, such as what a person is, which rights belong to embryos, fetuses, and children, whether children are merely a means to provide for the parents' satisfaction, whether single persons and homosexual couples should have access to ICSI, and whether ICSI leads us closer to cloning.

However, this broader context of the relevant moral issues related to ICSI appears to be insufficient for making viable moral decisions. Analyzing only the consequences of ICSI misses moral aspects that are important in the moral dynamics of the health policy process. A values analysis provides insight into not only the relevant moral consequences but also the values that are involved.

The values analysis has revealed a wide range of issues relevant to the debate on ICSI. In particular, the values analysis is a fruitful framework to display the interplay of interests. The values of infertile men and their partners who demand ICSI are quite obvious. However, the values of

health care professionals can be much more complex. Many health care professionals are compelled by scientific values. In principle, almost all of us accept the need to ration and to document the efficacy, effectiveness, and efficiency of the technology we want to develop or use. However, when we are confronted with suffering patients who have strong interests and needs, we turn to medical values such as the ability to act, intervene, and help. This makes many professionals argue for the immediate application of a new technology such as ICSI even before it has been thoroughly assessed. Personal and professional interests, such as the ability to develop and use a new technology such as ICSI and to contribute to progress, are also present. This leads to arguments that good assessments are unnecessary when the usefulness of the new technology is self-evident. Or we may argue that to perform advanced studies and extensive assessments is unethical. Hence, health care professionals are swayed by scientific, technological, and medical values. Moreover, we have social and religious convictions as well as beliefs about the basis of the reproductive desires and needs of humans.

Thus, there is a complex interplay of values. The point of this article has not been to perform an overall, objective, and everlasting values analysis, but to emphasize the importance of such an analysis. We cannot conclude from this study that ICSI is a good or a bad technology as such. That conclusion would be inconsistent with a values analysis, which is meant to point out the values of the different agents.

Decisions vary among nations. I have tried to highlight some of the aspects that should be included in the decision-making process to make it viable. An assessment of a particular technology should investigate the relevant moral consequences and the moral context of the technology, and should include a values analysis (axiology). The wide range of relevant moral challenges and the complexity of the interplay between values makes ICSI an interesting case.

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