Informed Consent, Israel 2008 – is it Informed? The Case of In Vitro fertilization and Embryo Transfer

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ABSTRACT: **Background:** The rate of in vitro fertilization and embryo transfer procedures in Israel is the highest among industrialized countries. The procedure has the potential to make treated patients forever happy, should the desired result occur. It also entails, however, numerous potential complications. Patients who are candidates for the procedure should fully understand both potential desired and undesired results, and should give their consent based on this understanding. The question whether currently used informed consent forms for these procedures indeed serve this purpose is, however, open.

Objectives: To explore the usefulness of informed consent forms for IVF&ET that are currently used in Israel to represent the potential benefits and risks of the procedures to the patients.

Methods: Informed consent forms for IVF&ET were scrutinized for accuracy, clarity and relevance, by comparison to relevant medical literature. IVF&ET informed consent forms were also assessed whether they fulfill the requirements of the Israeli Law of Patient's Rights.

Results: Currently used "informed" consent forms for IVF&ET were found to be fundamentally inaccurate and outdated. In some cases (number of embryos to be transferred), the information is grossly obscure. In other cases (alternative management) there are glaring omissions.

Conclusions: Informed consent forms for IVF&ET that are currently used in Israel do not adequately serve their stated purpose. Potential risks and benefits are not presented clearly and alternative management strategies are also missing. Thus, they do not fulfill their social, ethical or legal goals. Updating these forms is urgently needed. New versions should clearly distinguish between common (controllable) and uncommon (uncontrollable) complications.

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Informed consent forms represent the technical tool to achieve a social process that shifts the autonomy to decide whether a medical procedure should be performed – from the doctor to the patient [1]. Studies on this subject have largely yielded non-satisfactory results. In the United States it has been argued that the federal government poses an actual barrier to informed consent concerning oral contraceptives and induced abortion [2]. In Israel, a recent study examining patients' comprehension of risks and benefits of amniocentesis [3] found that patients' understanding of the chances to deliver a baby with Down syndrome remained unchanged, in spite of specific efforts to convey the message.

For this study we chose in vitro fertilization and embryo transfer informed consent forms for the following reasons:

- Infertility is not a "disease": patients may elect to proceed with their lives – childless, or they may choose to adopt
- The procedure is elective, by definition. There is ample time to explore and define patients' wishes, fears and preferences
- Inadequate decisions may have life-long implications for both parents and babies [4]
- Finally, the Israeli rate of IVF procedures is the highest among industrialized countries, making this subject most important from the public health perspective [5].

Certainly, patients who are candidates for the procedure should fully understand potential desired and undesired results, and they should give their consent based on this understanding. The question whether currently used informed consent forms for these procedures indeed serve this purpose is still open.

The purpose of the present study was to explore the usefulness of informed consent forms for IVF&ET that are currently used in Israel to represent the potential benefits and risks of the procedures to the patients.

METHODS

Informed consent forms for IVF&ET were scrutinized for accuracy, clarity and relevance, by comparison to relevant medical literature. Information in the forms was examined for both content and form. The perspective of both a professional and a lay person was taken into account. For the sake of objectivity, and as a benchmark, IVF&ET informed consent forms were examined for fulfilling the requirements of the Israeli Law of Patient's Rights.

IVF&ET = in vitro fertilization and embryo transfer

RESULTS

In 1996, a specific informed consent form for in vitro fertilization was issued by the Israeli Medical Association, together with the Medical Risk Management Company, and the Israeli Association of Obstetrics and Gynecology [6]. In the introductory paragraph, labeled "Chances of Success," it is asserted that: "A child or children born of IVF may be physically, mentally or health-wise abnormal, including malformations or other defects, and genetic predisposition, or any other abnormality, just as in ordinary natural fertilization." However, in paragraph 9, "The Risks of Pregnancy and Multi-fetal Gestation," it is stated that: "The rate of multi-fetal gestations following fertility treatments is especially high (up to 30%)….Multi-fetal gestations entail complications such as premature or late miscarriage, premature rupture of membranes requiring termination of pregnancy, and delivery of premature babies. The risks of prematurity include, among others, motor impairment, brain and neural damage, and prolonged hospitalization." It is evident that a simple logical contradiction exists between the latter and the earlier paragraphs.

There is already considerable evidence for poor obstetric outcomes of IVF pregnancies, even in singletons, relative to naturally conceived babies. The medical literature suggests that "assisted reproductive technologies are associated with an elevated risk of congenital malformations….even in singleton infants" [7]. Making this information available to the couples seeking ART treatment is explicitly recommended [8]. Clearly, it is time to update the IVF informed consent form.

In chapter 6, "Micromanipulation," it is mentioned that "Men with extreme scarcity of sperm may transfer this trait to their sons."

The Israeli Law of Patient's Rights (1996), chapter D, dictates that:

- Medical treatment will not be imposed on a patient, unless informed consent is given in accordance with directives of this chapter
- For the purpose of accepting an informed consent, the attending staff will deliver to the patient the required clinical information, in a reasonable manner, in order to allow him to decide whether he or she should accept the suggested treatment.

For that matter, clinical information includes:

- The diagnosis and the prognosis of the medical condition
- Description of the proposed procedure, its goal, its effectiveness, and its prospects
- The risks involved with the proposed treatment, including side effects, pain and discomfort
- Prospects and risks of alternative treatments or avoiding treatment [9].

In the current informed consent form, the simplest alternative treatment, such as using a donor's sperm, is not mentioned. This omission is a violation of the law. Other obvious omissions are:

- **Expectant management (avoiding treatment)**. It is a well-documented fact that couples awaiting IVF treatments, or between treatment cycles, do get pregnant, especially in cases where the indication for treatment is "unexplained" infertility. Mol at al. [10], based on data from the Canadian Infertility Evaluation Study, estimated the cumulative pregnancy rate of subfertile couples suitable for IVF to be 23% after 3 years. Shimizu at al. [11] found similar results, with an 18% cumulative pregnancy rate at 60 months following delivery after IVF treatment, when the indications were endometriosis, mild male factor or unexplained infertility. Most conceptions occurred within 2 years of the delivery. In fact, in one case [12], it is explicitly recommended that, after a complete infertility evaluation, couples who believe there is no hope for spontaneous conception should be advised regarding their prognosis for pregnancy without treatment (often in the range of 1–3% per month for unexplained infertility).
- **Adoption.** Classical textbooks, especially from the pre-IVF era, mention this option as an alternative when conventional treatment is prolonged and without success. While cumulative success with higher numbers of IVF cycles is documented, many couples remain frustrated and exhausted mentally, physically and occasionally also financially. Reasonable and ethical management dictates that the option of adoption should be offered at a specified point. This is certainly a reasonable alternative for couples who undergo IVF treatments with both egg donation and sperm donation.
- **Natural cycle/Mild ovarian stimulation.** In the current IVF informed consent form, section 2 states that "…One of the goals of the treatment is to obtain a large number of eggs." This goal is achieved by the use of medications. More eggs enable attending staff to have more embryos to transfer into the uterus, upon which the chances of success depend. The risks of ovarian hyperstimulation syndrome are then discussed. Contemporary relevant literature is far less enthusiastic and presents "natural cycle" [13] and "mild stimulation" [14] as viable alternatives. Again, these omissions seem to be a violation of the law and a deviation from its spirit.

The second informed consent form that was examined was the one labeled: "Number of embryos implanted in the mother." In this form, a somewhat enigmatic statement is included: "The number of fetuses that will be implanted will

ART = assisted reproductive technologies

be subject to the directives of the Ministry of Health and in accordance with the recommendations of the Israeli Society of Gynecology and Obstetrics." This statement is problematic on several levels:

- Terminology inaccuracies:
  - Fetuses are usually referred to as the stage when fetal heart beats can be demonstrated. This is not the stage of "Embryo Transfer." Fertilized eggs are usually transferred back to the uterus, in the embryonic stage, before heart beats can be demonstrated.
  - Implantation is usually referred to as the stage of the embryo rooted in the endometrium. This is a later stage in the process, which is largely uncontrolled. The action of reintroducing embryo/s back into the uterus is generally referred to as "transfer."
  - Most Israeli IVF patients probably get their informed consent form in their native language, be it Hebrew, Arabic, or Russian. Nevertheless, The English version should be accurate.
- The statement document by the Israeli Society of Obstetrics and Gynecology in the Israeli Medical Association site is not updated, dating back to May 1997. Ministry of Health directives on the subject were updated in April 2004 and are materially different.
- Finally, and most important, contemporary literature does not support either recommendation: The statement document by the Israeli Society of Obstetrics and Gynecology dating back to 1997 will not be discussed here. The Ministry of Health directive from 2004, which is more conservative, recommends that the number of embryos transferred in the three initial cycles will not exceed two embryos per cycle. In the following circumstances transfer of more than two embryos can be considered:
  - From the fourth treatment on
  - Woman's age over 35 years, from the third treatment on
  - Woman's age over 41 years, from the first treatment on

  In any case, transfer of more than four embryos is prohibited. Current medical literature no longer discuses conditions when more than two embryos can be transferred. Current medical literature discusses the benefits of single embryo transfers over double embryo transfers [15-17].

DISCUSSION

IVF&ET, which lay in the realm of science fiction only a few decades ago, are currently commonplace. These and other related techniques that can bring everlasting joy for the expectant couple are not hazard free. Numerous potential complications are associated with these procedures. Patients should be presented with the realistic picture, including desired and undesired results alike. Contemporary scientific information should be presented in a fair manner. Informed consent forms should present complicated clinical and epidemiological data in a manner that will be meaningful to a lay person.

The results of this study demonstrate that this is not the case in Israel today. Significant omissions of alternative treatments (such as expectant management or adoption) do exist to begin with. In other cases (optimal ovarian stimulation, and number of embryos to be transferred) the presented information is either outdated and/or misleading.

With the current Israeli informed consent form for IVF&ET one cannot see the woods for the trees. Should informed consent forms for IVF&ET fulfill the requirements of the law, as well as ethical and practical requirements, major changes are urgently needed.

Potential complications of IVF & ET should be divided into two groups: Group I complications will include low probability, uncontrollable, accidental complications such as bleeding or infection. Group II complications will include high probability, semi-controllable, non-accidental complications, such as ovarian hyperstimulation syndrome and multifetal pregnancy. An open discussion with the couple or the woman should be a frank discussion about the link between the chances of pregnancy and the probability of complications, in order to explore her preferences, fears and hopes, rather than obscuring the few relevant issues by dozens of irrelevant ones.

Furthermore, It seems that the way "informed" consent forms for IVF&ET are formulated today is something new and quite removed from the original goal of developing informed consent forms. Whereas informed consent forms were developed originally with a social purpose in mind, to shift autonomy from the clinician to the patient, current informed consent forms represent a desperate effort to protect physicians from worrisome lawsuits, despite their best efforts to practice reasonable quality management. Why else would the Medical Risk Management Company be such an active partner in developing these forms? Indeed, physicians should be protected from unjustified lawsuits. It is argued, however, that intricate informed consent forms are not the appropriate tool to achieve this goal.

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