Ethical arguments for clinicians in favour of a patient-friendly approach to ART

Guido Pennings

ESHRE Campus Maribor 27-28 February 2009

Bioethics Institute Ghent

Looking from a distance at IVF

- 25 years: time for an evaluation.
- Two important conclusions can be drawn:
  1. The current practice is still too exclusively focused on effectiveness and success rate
  2. The multiple pregnancy rate is still too high.
- The first counter movement: single embryo transfer (SET)
  SET implies a major reversal of the value hierarchy to evaluate an IVF cycle. Safety became more important.

Bioethics Institute Ghent

Patient-friendly ART

- The future: patient-friendly ART:

1. cost-effectiveness	beneficence (doing well)
2. equity of access	justice
3. minimal risk for mother and child	non-maleficence (do not harm)
4. treatment choice for patient	autonomy

The 4 main principles in bioethics (Beauchamp & Childress)

One should simultaneously try to maximise all 4 criteria. There is no fixed ranking between the principles. The different values should be balanced depending on the specific circumstances.

Pennings, G. & Ombelet, W. (2007) Coming soon to your clinic: patient-friendly ART. Human Reproduction 22 (8): 2075-2079.

Bioethics Institute Ghent

1. Cost-effectiveness

NORMATIVE BASIS: BENEFICENCE

- The optimal use of scarce resources MAXIMISES WELL-BEING (utilitarianism)
- Three levels of distribution of scarce resources:
  - Between health care and other societal needs (education etc.)
  - Between infertility and other diseases (cancer etc.)
  - Between patients for infertility treatment.
- Money spend on cost-INeffective treatment deprives other patients of the treatment they need.

Bioethics Institute Ghent

Cost-effectiveness

- A health care system that offers equitable access to basic health care services is only viable when the interests of the individual patient and the social system are balanced. Patients have a right to the most cost-effective treatment but not to the most effective treatment (regardless of costs).
- There are numerous instances in which ART can be performed in a less costly way
  - Use of clomiphene citrate for ovarian stimulation in IUI cycles
  - Offer 6 IUI cycles in case of mild male factor infertility, unexplained infertility and mild endometriosis

Bioethics Institute Ghent

Cost-effectiveness

- Finding: 80% of the clinics are convinced of the cost-effectiveness of IUI but 30% offers IVF as first-line treatment
- Finding: less than half of the practitioners in the Netherlands follow the recommendations on IUI of the professional organisations
- Some explanations for the deviations from good clinical practice:
  - a strong tendency to stick to routine practice
  - financial incentives from pharmaceutical companies
  - fear of declining success rate ...

Bioethics Institute Ghent

2. Equity of access

NORMATIVE BASIS: JUSTICE

- Reproduction (family building) is an important part of many persons' life plan and infertility has a major impact on those persons' well-being.
- If the wish for a child is a basic need, then it is a duty of society to ensure equity of access. The 'ability to pay' should not be a criterion to obtain treatment.
- Equity of access can be improved through direct cost reduction or through public or private health insurance
- Access without excessive burden (USA, Canada: cost of IVF = 25% of annual household expenditure)

Bioethics Institute Ghent

Equity of access

- The allocation of public funds generates an obligation for practitioners to work cost-effectively and to minimise the costs.
- Balancing different criteria simultaneously: access (reimbursement) and cost-effectiveness. Reimbursement policy should avoid unwanted effects:
  - E.g., IVF being offered as first option
  - E.g., a patient opts for a treatment that costs her the least while it is the most expensive for society.

  In general, cost-effective treatment will increase equity

Bioethics Institute Ghent

3. Risk minimisation

NORMATIVE BASIS: DO NO HARM (non-maleficence)

- The main current risks are connected to the stimulation:
  - OHSS
  - multiple pregnancies (detrimental for both mother and children)
- New movement away from standard 'aggressive' stimulation towards 'soft', 'mild', 'minimal stimulation', 'natural' ... IVF. This indicates again a major change in the value hierarchy.
- Again, guidelines (about monitoring, embryo transfer etc.) are not followed by many clinics in practice. Coercive legislation is a necessity in many countries.

Bioethics Institute Ghent

4. Treatment choice for the patient

NORMATIVE BASIS: AUTONOMY

- The essence of patients rights: when there are different possible treatments, all options must be discussed with the patients in order to allow them to choose.
- Psychological, physical and social stress of IVF is high.
  - Psychological distress is the main reason why patients drop out (Olivius, 2004)
  - Mild stimulation has fewer side-effects and causes less stress (Verberg et al., 2008)

Bioethics Institute Ghent

Treatment choice for the patient

Stress is to a large extent explained by

- fear of the unknown,
- anxiety about hormone injections and
- concerns about side effects of the drugs (Hammarberg, 2003; Pistorius et al., 2006)

- Relevant aspects on which treatment may differ include not only success rate, but also stress, psychological burden and financial aspects. The patient should have a major say in weighing all these factors. She (they) should be able to choose for a less effective but considerably less burdensome treatment.

Bioethics Institute Ghent

Treatment choice for the patient

- Patients preferences are rarely studied or considered in reproductive medicine: they are often assumed.
- When patients are offered a choice between different treatments, they do not automatically opt for the most effective one.
  - The Netherlands: choice between one stimulated cycle and 3 natural cycles: 30% of patients (and physicians) were willing to trade off 6% success rate for unstimulated cycles (Braat & Kremer, 2004)
  - Hojgaard et al., 2001: patients preferred low stimulation cycle.

Bioethics Institute Ghent

Treatment choice for the patient

- More studies on the emotional, psychological and physical advantages and disadvantages of alternative stimulation protocols are needed.
  - Eijkemans et al., 2006: compares the effectiveness, health economics (costs) and patient discomfort (quality of life or psychological burden) of 2 treatment strategies that differ in ovarian stimulation protocol and embryo transfer policy.
- The comparison of treatment procedures requires a new measure of success which must be a cumulative success rate within a certain time period.

Bioethics Institute Ghent

Patient's preference and multiple pregnancies

SET has
- highest cost-effectiveness (taking into account all indirect costs)
- lowest risks for mother and children

Problem: all professional guidelines move in the direction of SET.
However, patients' wishes deviate from the guidelines.
Question: does more autonomy of the patient imply that the doctor should (within reasonable limits) replace the number of embryos that the patient wants?
Answer: no, since the approach demands the balancing of all 4 principles simultaneously.

Bioethics Institute Ghent

Conclusions

- A number of large steps (SET, minimal stimulation IVF) have been taken in the direction of patient-friendly ART and similar trends should be encouraged.
- Patient-friendly ART should include at least four components: cost-effectiveness (maximising well-being), equity of access (justice), minimal risk for mother and child (non-maleficence) and treatment choice for the patient (patient autonomy).
- The introduction of patient-friendly IVF demands major changes in the general way of looking at ART. It demands a relatively complex balancing of multiple criteria that should be introduced step by step.
- Much more effort should be invested to find out what the non-medical effects of different protocols are and patients should be offered the choice among these.

Bioethics Institute Ghent