THE LAY PANEL

- Annette Fløistrup 35 years old, physiotherapist on parent leave; Rødovre.
- Dorrit Jørgensen 45 years old, accountant; Rungsted.
- Gertrud Westerlund 61 years old, retired senior teacher; Rødekro.
- Helle Dam Hansen 21 years old, unemployed, preparatory school student; Brøndby.
- Kirsten Hansen 55 years old, primary school teacher; Odense.
- Marianne Karnøe Knudsen 31 years old, librarian, office clerk; Sindal.
- Marit Nielsen-Man 33 years old, MA, interpreter; Åbyhøj.
- Hans Sørensen 37 years old, quality product development consultant; Horsens.
- Henrik Berg 32 years old, student of law; Sønderborg.
- Jens Jensen 73 years old, retired dairy manager, factory worker; Ebberup.
- Jesper Bork 29 years old, unemployed, graduate in law; Århus.
- Tom Ringtved, 36 years old, unemployed B.Tech; Ålborg.
- Vagn Sohn 32 years old, continuation school teacher; Thorsø.

THE EXPERT PANEL

- Jens Peter Bonde Doctor of Medicine, The Clinic of Occupational Medicine; Århus.
- Olav Nørgård Veterinarian, Head of the National Association on Infertility.
- Aleksander Giwercman Doctor of Medicine, Dept. of Growth and Reproduction, the National Univ. Hospital
- Jens Dinesen Chief of Section, Ministry of Justice, Department of Civil Law.
- Katrine Sidenius MD, Head of the Ethical Committee under the Danish Medical Association.
- Kirsten Sandholt Priest at the Trinitatis Church; Copenhagen.
- Monica Tafdrup Notkin Clinical Psychologist at the PPR organisation; Solrød.
- Birgit Peterson MD, Senior Lecturer at the Institute of Social Medicine, University of Copenhagen.
- Lene Koch Research scholarship at the Institute of Social Medicine, University of Copenhagen.
- Linda Nielsen Doctor of Laws, Institute of Legal Science, University of Copenhagen.
- Anders Nyboe Andersen Doctor of Medicine, Herlev Hospital
- Bodil Nygård MD, Research scholarship at the Institute of Central Research of General Practice, University of Copenhagen
- Peter Lundström MD, The IVF Clinic; Ballerup.
- Anders Christensen Head of the Association for Adoption and Society.
- Peter Saugmann-Jensen MD, The National Board of Health

KEY QUESTION I

HOW COULD ADOPTION RULES AND PROCEDURES BE CHANGED SO THAT THE INTERESTS

OF BOTH THE CHILD AND THE PARENTS COULD BE TAKEN INTO CONSIDERATION?

a) How could a link between adoption and publicly financed treatment for infertility be created?

b) How could adoption be made more attractive compared to medical technological treatment for infertility?

Adoption rules ought to be changed in order to make adoption more attractive.

Subsequent to an application for adoption, the county should put more efforts into instructing the applicants and preparing them for receiving their adopted child. However, we realize that it is necessary that adoptants undergo an evaluation procedure with regard to their age and health status. In order to stress the importance of instruction and preparation, courses for the adoptants as well as conversations with families with adopted children should be arranged.

When a child is proposed for adoption, from a donor country to a particular couple, the adoptants´ own evaluation should be especially in focus. When in doubt, it should be possible for the adoptants to receive medical and psychological assistance.

On the first visit at the general practitioner`s office, an infertile couple should be offered information about treatment for infertility, information on possibilities for adoption and if necessary alternative counselling.

Adoption is not an offer for treatment but an active choice. Improved information could kill myths and ideas about procedures of approval, waiting time for adoption, the implementation of an adoption and living with an adopted child.

A partner in a so-called registered partnership should have the opportunity to adopt his or her child or children

In order to ensure economic equality between adoption and treatment for infertility, we suggest a grant-in-aid scheme to be regulated according to personal income.

KEY QUESTION II

HOW COULD THE GENERAL KNOWLEDGE REGARDING CAUSES OF INFERTILITY BE IMPROVED - E.G. WITHIN THE AREAS OF:

- MALE INFERTILITY

- THE ROLE OF THE ENVIRONMENT
- UNEXPLAINED INFERTILITY

a) How and on which background are priorities taken with regard to research in the causes of infertility?

As society may have a presumable interest in preventing a decrease in fertility, we find that research in causes of infertility is especially relevant in this context.

It is necessary that research in causes of infertility be accorded higher priority than research in the treatment of infertility. However, research should not be carried out at the cost of treatment.

In order to stimulate research in the causes of infertility, we recommend setting up a research programme which includes basic research, environmental research and epidemiological investigations.

A substantial problem is the reduced quality of male sperm. Since our present knowledge of the causes for this phenomenon is limited, initiatives should be taken to raise the status of andrology to an established medical speciality.

We suggest that diagnostic research of male sperm quality should be concentrated in a few, major centres, instead of the present situation where diagnostic practice is not organized. Such an arrangement could concentrate existing knowledge about the problem and make it possible to collect experience and create an attractive, centralized research and therapeutic environment.

Companies are responsible for the working environment and should, to a higher degree, be encouraged to improve working environment conditions.

KEY QUESTION III

COULD INFERTILITY BE PREVENTED VIA PRESENT KNOWLEDGE

a) Could infertility be reduced via preventive measures?

The lay panel estimates that according to both human as well as socioeconomic considerations it would be suitable to accord priority to the prevention of infertility to a higher extent than today.

On the basis of the experts' statements, we believe that special efforts should be taken in the following areas:

Chlamydia infection is a substantial cause of infertility in women and possibly in men. In order to limit the harmful effects of chlamydia infection we recommend that men and women between the ages of 15 and 25 be offered regular clinical examinations. These examinations should be followed up by tracing the sources of infection. Although this is a cost-demanding initiative we believe that the cost is outweighed by the positive effects.

Clinical examination and information are inseparable. Health hazards caused by chlamydia infection are largely unknown by the general population. For these reasons, massive public information should be provided. Since information should be given prior to sexual debut, it is recommended that young people be informed via existing health- and sex education programmes in the municipal primary and lower-secondary school.

The increase in age of women having their first baby is regarded as a problem when viewed in relationship with the fact that female fertility decreases with age. Today, young people stay within the educational system until the age of 25-30. Furthermore, women receiving an education often postpone their first pregnancy until they have finished their studies. We believe that improving e.g. child care facilities plus providing more flexible maternity leave- and leave of absence arrangements for students would provide a real possibility for students for having children at an earlier age.

Different lifestyles may have a decisive influence on fertility. More information should be provided about the fact that it is possible to prevent infertility through a healthy lifestyle. For example factors such as smoking, alcohol, overweight and eating habits may have an influence on fertility. A healthy lifestyle also includes a conscious and responsible sexual practice. People should take care of themselves and others.

KEY QUESTION IV

TO WHAT EXTENT IS TREATMENT FOR INFERTILITY COST- DEMANDING, COMPARED TO OTHER FORMS OF TREATMENT OFFERED BY THE PUBLIC HEALTH AUTHORITIES, AND HOW IS THE PRIORITY WITH REGARD TO TREATMENT OF INFERTILITY?

a) How much money is spent by the public authorities on:

1) - treatment for infertility?
2) - research in causes of infertility?
3) - prevention of infertility?

4) - adoption?

b) How are these figures related to the total expenditure in the health care system?

c) How should treatment against infertility be financed?

We do not consider infertility to be a societal problem insofar as society is not in lack of children. However, infertility may be a considerable personal problem. We do not consider infertility to be a disease.

We believe it to be a public task to upgrade research in the causes of infertility as well as to provide funds for prevention of infertility. However, it is our impression that there is more prestige in performing treatment and carrying out research in new methods for treating infertility than in performing basic research in causes and prevention of infertility.

The lay panel believes that both public authorities and experts are considerably in doubt about the total expenditure of treatment against infertility. According to the National Board of Health the cost of treating infertility is approximately 55 million Danish kroner a year out of a total public health budget amounting to approximately 45 billion Danish kroner a year.

Much of the information on expenditures related to infertility is not accessible. However, it should be possible - and it is necessary - to provide a more precise account of the relevant expenditures by taking into consideration all various aspects such as, for example, prematurely born children, effects of treatment performed on different clinics, multiple pregnancies, prenatal examinations at the practitioners and grant-in-aid to hormone therapy.

We recommend that a more thorough investigation of expenditures for infertility treatment be initiated by the Ministry of Health.

Treatment for infertility at the public expense should be partly financed via user payment - regulated according to income. User payment should be used to reduce waiting lists. Introduction of user payment must not result in a reduction of the present public expenditures for treatment for infertility.

Waiting lists for examination and treatment for infertility should be reduced. However, this presupposes a relatively long period of time before a person can be considered infertile and treatment initiated. The period of waiting prior to the first examination of the infertile should, on the basis of medical consideration, be considered in relation to the age etc. of the woman in question.

In order to ensure economic equality between adoption and treatment for infertility, we

suggest an income-regulated grant-in-aid for adoption purposes.

KEY QUESTION V

WHICH KIND OF PROBLEMS ARE RELATED TO THE DONATION OF HUMAN EGGS AND SPERM?

a) In light of the conflicting interests of the child - for knoving its genetic heritage and the interests of the donor for anonymity - it is requested that the following questions should be examined:

1) - which need does as child have for knowing its genetic origin?
2) - is this a human right?
3) - what is the justification for anonymity?
4) - what would a possible abolishment of anonymity involve?

b) What kind of legal ownership is involved in donation?

c) Who should donate eggs/sperm?

d) Who should receive donated eggs/sperm?

We find that regulations for donating eggs and sperm, and acceptance of individuals for therapy, should be identical for both the public health system and private clinics.

In the interest of the child, the lay panel recommends that the anonymity of donors should be lifted and the information made accessible to the child. In this way, the child later in life may obtain the chance to be informed about his or her genetic origin.

Openness and sincerity is a precondition for a safe and trusting relationship between parents and children. Therefore, as early as possible, a child should be able to obtain information about how it came into being.

With regard to acceptance of individuals for infertility therapy and donation of eggs and sperm, the lay panel finds it natural that a female has the ownership of her own eggs and a male of his sperm. A fertilized egg is owned by the couple in common. Furthermore, in a divorce situation or if one of the parties dies, it is important that present legislation with regard to destruction of fertilized eggs be maintained. The couple should give their permission if research is to be performed on additional fertilized eggs.

We recommend that all women of legal age, and not only women who are under IVF treatment, should have the opportunity to volunteer as egg donors. For this purpose, it would not be necessary that anyone other than the woman in question gave consent to the donation.

Prior to the removal of eggs the donor will have to undergo intensive hormone therapy. Consequently, the egg donors should receive thorough information about the risks of hormone therapy.

Donation should not be a business. It should be performed without payment in the same way as blood transfusion. The present payment system for donation of male sperm should be abolished.

Furthermore, any form of exchange transaction should be avoided; for example transactions where a woman under IVF treatment is offered an additional treatment at no cost if she agrees to be a donor.

Technology which makes it possible to remove eggs from aborted embryos is still at the research stage. In our opinion, removal and use of eggs from embryos should be prohibited even if further development of the technology would make it possible.

Receivers of donated eggs and sperm should be under forty years of age and should be of legal age.

At least one of the social parents should also be the genetic parent of a child.

Optimally, a child has both a father and a mother. We admit that gay and lesbians may be good parents and the panel therefore has no comment to the practices involved in the present form of treatment.

The panel strongly urges abolishing the present law which makes it possible to donate an egg which has already been used for research purposes. An egg used for research should be destroyed since we do not feel convinced whether it is possible to guarantee the quality of such an egg. This problem has also been recognized from the medical side.

KEY QUESTION VI

WITH REFERENCE TO TECHNOLOGIES FOR TREATING INFERTILITY - WHAT ARE THE CONSEQUENCES OF TREATMENT FOR THE PATIENT AND FOR THE CHILD?

THIS INCLUDES:

- PSYCHOLOGICAL EFFECTS?
- TO WHAT EXTENT IS THE LIFE QUALITY OF THE INFERTILE AFFECTED BY THE EXISTING POSSIBILITIES FOR TREATMENT?
- RISKS OF HORMONE THERAPY?
- REDUCTION OF THE FETUS?
- POSSIBLE DAMAGE TO THE GENETIC INHERITANCE VIA DEEP-FREEZING.

a) Why does present research in the consequences of treatment for infertility have low priority?

b) Why has it been decided to omit medical registration of women who have received treatment for infertility- and of their children?

There is no doubt that infertility as well as treatment for infertility is a cause of psycho-social problems for individuals as well as for couples. We recommend that research be carried out into the kind of problems which may arise before, during and after treatment for infertility. This research could reveal the nature of problems in order to estimate the need for psychological assistance or other forms of aid.

As a consequence of increasing possibilities for treatment of infertility, more and more stress will be put on the infertile, who will tend to focus on their own personal shortcomings rather than taking pleasure in existing life qualities. This aspect may contribute to reduced life quality of the infertile.

Infertility and especially male infertility is a taboo. It is our hope that more openness could be created with regard to infertility, since early recognition of the problem is essential for how people, may subsequently handle their own situation.

In our opinion, embryo reduction should be prohibited. Techniques for hormone treatment should be developed in order to avoid such a highly controversial situation.

A central registration system should be introduced in order to keep track of treated patients and their possible offspring. In this way, consequences of the treatment, e.g., long-term effects of hormone treatment, could be disclosed.

Specialists are of varying opinions as to the extent and importance of possible risks of very intensive hormone therapy of the women involved. Thus, we recommend that this research area receive high priority.

We find it to be in the interests of the infertile that research and treatment for infertility be concentrated in a few centres.

Prior to receiving donated eggs, a woman must undergo hormone treatment. In order to minimize the number of treatments, we find that the present legislation should be changed so that a donated egg could be frozen after the fertilization.

In case of reasonable suspicion of disease and as a free choice to the infertile, it is possible for women under IVF treatment to opt out of setting up of fertilized eggs. The criteria for this however, should only be based on existing criteria for performing amniocentesis. The justification for this view is that it is better to opt out the fertilized egg before it results in a pregnancy instead of, on the basis of amniocentesis, to abort the fetus when pregnant.

KEY QUESTION VII

HOW WILL THE NEW TECHNOLOGIES INFLUENCE THE WAY WE LOOK UPON OURSELVES AS HUMAN BEINGS?

a) Should everybody have equal access to have children of their own? and should each individual be allowed to draw his own ethical limits?

b) When dealing with the new technologies- should there be a unity in ethical attitudes between citizens, politicians and doctors?

c) Why is it legally possible for a doctor to have the liberty to determine which possibilities an individual may have for receiving treatment for infertility?

d) Is there a calculated political inertness against making laws for these difficult ethical questions?

The interests of a child is more important than the rights to have children.

Adults want children in order to live a fuller life and to have an opportunity to pass on their own life-experiences. Basically, there seems to be a biologically determined need to contribute to the continuation of ones family. Unfortunately, not everybody is able to have children, and we do not think that everybody should have equal rights to bear children.

In earlier times, people largely had to accept the natural conditions of reproduction. Today, with the help of technological development, we are able to manipulate nature. Thus we may get the feeling that it is technological standards which are setting the norm for our quality of life when the desirable situation would be that our own norms set the limits for technological development.

Ethics is a question of daring to set up limits even if it may be painful.

Individual ethical limits may fluctuate and cannot be dictated by others. This fact, combined with the advances in technological development, could imply an imminent danger of a possible uncontrolled slide in ethical norms. The borders may be moved little by little and suddenly we are far from the desired starting point. Therefore, it can neither be demanded nor expected that citizens, politicians and doctors share a common ethical attitude.

Yet, regarding the way the problem presents itself, it is important to point out that this is exactly why the Danish Parliament should try to establish ethical limits.

We cannot accept the present situation where it is left largely to medical practitioners to determine ethical norms. In reality, this is what happened recently in a private clinic where micro-injection was used for "treatment" even though, according to experts, the method was still on the research level.

This awkward form of ethics in which one practices first and then suspends ethical judgement until afterwards, is quite unacceptable.

The rules which have to be determined should include both the public as well as the private sector.

In relationship to treatment for infertility, it is our opinion that intervening in the genes should be prohibited and the existing prohibition against the cloning of human eggs should be maintained.

KEY QUESTION VIII

WHICH ADVANTAGES AND DISADVANTAGES ARE RELATED TO THE AUTHORIZATION OF THE PRIVATE CLINICS?

a) Which elements should be included in a possible authorization?

A set of regulations should be established which ensures minimum standards, for all infertility clinics. These standards should include specific demands for education, experience and routine with regard to personnel and especially with regard to laboratory personnel, since a major part of the work is carried out in the laboratory. The doctor who directs the infertility clinic should regularly be able to guarantee the standards of the clinic as well as the personnel. Present authorization regulations however, concern solely the doctor, as it is the

doctor who, as director of the clinic, is responsible for the clinic´s administration, therapy etc.

The infertility clinic should not compete solely on the basis of the price of the therapy. We want a transparent market, so that a couple can be ensured the same minimum standards, regardless of which clinic they may choose.

There should be an obligation to maintain central registration controls over the results of infertility treatment from private as well as public infertility clinics. Responsibility for registration should rest with the National Board of Health.

Registration should e.g. include the following kinds of data:
- number of treatments
- which methods have been used
- how many eggs have been collected
- what has been done with the eggs
- results of the treatment, i.e. number of pregnancies, number of liveborn children, number of abortions, number of pregnancies outside the uterus, delivery methods etc.

The rationale behind a central registration is a desire for greater openness. In this way, public authorities gain the opportunity to control the field and to ensure that childless couples, if they consider a treatment, only need go to one single office in order to obtain comparative information on infertility treatments.

We believe it is very important to register different methods of treatment in order to prevent methods still at the research level from being used for actual treatment. One such example was the newly developed method with micro- injection of sperm.