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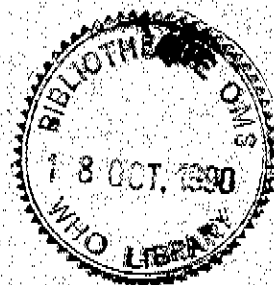
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ORIGINAL: ENGLISH

SUMMARY REPORT

Consultation on the Place of in vitro Fertilization in Infertility Care

Copenhagen
18-22 June 1990



1990

EUR/HFA target 38

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Health technology assessment

Before 1990, all Member States should have established a formal mechanism for the systematic assessment of the appropriate use of health technologies and of their effectiveness, efficiency, safety and acceptability, as well as reflecting national health policies and economic restraints.

Index:

INFERTILITY
FERTILIZATION IN VITRO ✓
REPRODUCTION TECHNICS ✓

Introduction

The meeting was attended by 15 participants from Europe, North America and Australia, representing gynaecologists offering in vitro fertilization (IVF), women's groups, epidemiologists, sociologists, economists, health administrators and journalists.

Infertility is a medical construct. The social consequence of infertility - involuntary childlessness - is the chief concern of infertile women and men, health planners and policy-makers. Involuntary childlessness may or may not be alleviated by the health services. Therefore, the starting point for the meeting was all infertility in the community and all care options, both social and medical.

IVF and related technologies have created many public health, legal and ethical problems, most of which remain unresolved. The participants agreed that certain principles would guide the discussion: (a) the principles of health care outlined in the targets for health for all by the year 2000 as approved by the Member States of the WHO European Region; and (b) the principles of human rights outlined in the Helsinki Declaration (as amended). The following recommendations were made.

I Assessment of infertility

The term "infertility" is defined by WHO as failure to conceive after at least two years of unprotected intercourse. Herein, the term "infertility" encompasses both sterility and subfertility; by this definition, the prevalence of infertility is estimated to be approximately 10% in industrialized countries. However, the prevalence of infertility at one point in time should not be misinterpreted as an estimate of the proportion of individuals who, at the end of their childbearing years, remain childless involuntarily or have fewer children than desired. Estimates of involuntary childlessness at the end of the childbearing years may be considerably lower than estimates of the overall prevalence of infertility at a given point in time. Accurate estimates of the prevalence of infertility, ascertainment of the current availability of resources (medical and social), and a determination of how they are used by infertile women and men are the foundations of rational planning.

1. Each country needs to determine the prevalence of primary and secondary infertility by gender and cause.
2. Each country needs to assess the availability of medical and social options for infertile women and men.
3. Each country needs to determine the proportion of the infertile population, choosing the various social (i.e. adoption, fostering, voluntary childlessness) and medical options (i.e. IVF, other medical treatments).

II Infertility services

A. Prevention programmes

Not enough is known about the causes of infertility or the effectiveness of infertility prevention programmes. The principles outlined in the health

for all targets make it clear that prevention is preferable to attempts to cure or circumvent a condition once it occurs.

4. There is a need for research on the preventable causes of infertility, including the role of environmental factors, workplace hazards, contraceptives, iatrogenic causes, sexually transmitted diseases and emotional factors.

5. The effectiveness of infertility prevention programmes needs careful evaluation.

B. Social options

For many people a social option (voluntary childlessness, foster parenting or adoption) may be the preferred solution to the problem of infertility. Yet, at least with regard to adoption, significant barriers exist in many countries. Those seeking adoption may be subject to more stringent definitions of infertility and longer waiting periods than those seeking IVF. Similarly, some or all of the costs of IVF or other medical treatment may be reimbursed by the health system, whereas the cost of an adoption is not. Therefore, countries should give equal consideration to both social options and medical options in the planning of services for infertile men and women.

6. Each country needs to assess the social options available to infertile people, including counselling services, barriers to these options, and inequities in access to these options.

7. Research is needed on the attitudes of the general public and of infertile women and men towards medical and social options. Such research should also assess the cultural and social meaning of infertility.

C. Medical options - IVF and related technologies

Because most countries have no mandatory licensing or reporting of clinical IVF data, information on IVF services is difficult to obtain. There is great variation in service availability among countries. The rapid proliferation of IVF services in nearly all industrialized countries is driven by the interests of providers, industry and other special interest groups, rather than by rational planning based on the needs of the population.

In many countries, as IVF services have become widely available, the indications for treatment have expanded, the criteria for admission to programmes have relaxed, and the number of treatments per individual woman have increased. This has implications for health care budgets and for the overall level of health of the population. IVF adds to the burden of low birth weight and infant mortality.

8. Further proliferation of new IVF centres and expansion of IVF services should not occur until countries have determined the need for infertility services, the priority for infertility services within all human services, and the priority for the various social and medical options for infertile women and men.

9. The role of industry and commercial interests in IVF should be documented, including industry's role in funding IVF research and its involvement in service provision. This information should be available to the public.

10. Governments should consider limiting the number of IVF treatment cycles per woman.

11. Governments should consider limiting the indications for IVF.

12. According to the European Society of Human Reproduction and Embryology, the hazards of pregnancy increase and success rates drop for women over the age of 40 who undergo IVF. Governments should consider limiting eligibility for IVF to women of 40 years of age and under.

D. Counselling and support

For many individuals, the inability to conceive a child can be a major source of stress and unhappiness. Infertility may place a significant strain on friendships and conjugal relationships, drain family economic resources and precipitate feelings of failure and mourning. Infertile people need information, support and, in some cases, counselling in order to resolve the crisis of infertility and actively participate in planning for their own care.

13. Infertile individuals must have full information on the availability, risks and effectiveness of all social and medical options for the management of infertility. They must then, in turn, have free choice of the use of these options.

14. Counselling should be available for infertile people. Interested individuals should be encouraged to seek help prior to contact with any type of infertility service. Infertile people may also be referred to mutual aid groups for support before, during and after pursuing social or medical options.

15. Counselling services and mutual aid groups must be independent of social and medical programmes for the management of infertility. Funding for these services should not come from clinics or industry.

III Technology assessment of IVF and related technologies

A. Evaluation of the new reproductive technologies

IVF and related technologies have not been adequately evaluated. Published results of randomized clinical trials to determine the true effectiveness of IVF are not yet available. Moreover, there has not been adequate research on the short-term and long-term risks associated with IVF and other medical treatments.

The bulk of the research on IVF has focused on perfecting clinical protocols and finding new and expanded uses for the technology. Research has not been oriented toward the priorities of health planners.

The best available epidemiological research indicates that IVF has limited effectiveness (fewer than 10 live births per 100 treatment cycles), that pregnancy rates independent of treatment are high, and that cumulative effectiveness rates diminish after 3-4 cycles of treatment.

Serious risks are associated with IVF. The ovarian hyperstimulation syndrome occurs in 1-2% of women treated with ovulation inducing drugs. Multiple gestation occurs in approximately 25% of IVF pregnancies. The perinatal mortality rate for IVF babies is four times and the neonatal mortality rate twice that of the general population. The rate of very low birth weight among IVF babies is over 11 times higher than in the general population.

16. There is a need for a standard definition of the effectiveness of IVF. The best definition for the purposes of evaluation and health planning is the number of live births per 100 treatment cycles.

17. The effectiveness, short-term safety and cost of IVF must be scientifically determined through multi-centred, randomized, clinical trials. As a treatment for a given cause of infertility, IVF should be compared with other medical options and with no treatment.

18. Case-control studies are needed to evaluate the short-term and long-term risks of ovulation induction and other IVF procedures.

19. Until there is an adequate appraisal of the risks of ovulation induction and other IVF procedures, countries should take steps to limit exposure of women and their offspring.

- More stringent guidelines on the indications for ovulation induction should be developed.
- Limits should be placed on the number of artificially stimulated cycles (both within and outside of IVF) that women undergo.
- Ovulation stimulation protocols should be as simple as possible.
- For selected women, natural cycle IVF may be a preferable option.
- The practice of ovulation induction for the purposes of timing pregnancy or regulating the menstrual cycle should be discontinued.
- The practice of ovulation induction in normally ovulating women for the sole purpose of oocyte donation should be discontinued.
- Social options can be promoted.
- Prevention programmes can be implemented.

20. All clinics should follow the guideline set out by the European Society of Human Reproduction and Embryology that limits the number of eggs or embryos transferred during an IVF treatment cycle to no more than three.

21. Governments should set priorities for infertility research and make available adequate funding and other support.

B. Costs

IVF is a very expensive procedure. The true costs of IVF have been underestimated by considering only the direct costs of one treatment cycle. In some countries, the proportion of IVF costs paid by governments and private

insurance has been hidden through separate billing for IVF procedures that cannot be distinguished from other gynaecological services, such as ultrasound, blood tests and laparoscopy.

22. Evaluation of the direct and indirect costs of IVF and related technologies is an essential part of rational planning. To calculate the costs of one IVF birth, one must include the costs of drugs, materials and human resources for all treatment cycles, successful and failed, for all women enrolled in the programme. IVF pregnancies require more high-risk obstetrical care and IVF babies more often require neonatal intensive care, so the costs of these services must be included as well. The proportion of the overall costs of IVF paid by government sources, private insurance sources and out-of-pocket payments by clients should also be determined. IVF costs then need to be compared with the costs of other forms of infertility care, both medical and social.

IV Planning and resource allocation

No country can afford to apply every health technology to every person it might benefit. Health needs must be assessed, priorities set, and resources allocated accordingly. For the purpose of rational planning, countries must bring together information on: the prevalence of infertility; the availability of all service options (medical and social); the effectiveness of infertility prevention programmes; the effectiveness, risks and benefits of all medical options including IVF; and the costs of medical and social services and prevention strategies.

23. Through surveys or other means, the priority that the public at large assigns to infertility management vis-à-vis other social and health services is determined so that the appropriate proportion of all health and social resources can be allocated to infertility.

24. Following this, the public and policy-makers decide on the priority to be given to each option, social and medical, for the management of infertility. This allows the appropriate proportion of the resources for infertility to be allocated to prevention (research and services), social options (research and services), conventional medical and surgical options (research and services), and IVF and related technologies (research and services).

V Quality assurance

Every country needs to develop an adequate system of quality assurance for all health care. This is especially true with a service like IVF, which is invasive, expensive and involves serious risks. Quality assurance includes: certification of all service providers; mandatory reporting of data; ongoing monitoring using selected indicators and independent audit; and enforceable sanctions for non-compliance.

25. As IVF and related technologies require knowledge and skill far beyond that of normal medical and gynaecological training, the certification of providers must be tied to thorough training and demonstrated skill. Each IVF centre must have at least one such certified provider who assumes direct responsibility for certain crucial steps such as dispensing ovulation inducing drugs, evaluating potential new clients, evaluating clients wishing to repeat cycles, and training and supervising other clinic personnel.

26. There should be mandatory reporting of all IVF cycles as a basis for quality assurance. Such population-based registries would also provide sampling frames for research and data for ongoing assessment of the costs and benefits of IVF. Additionally, record linkage of IVF registries with birth defects and cancer registries may provide useful data for monitoring adverse effects of treatment.

27. The monitoring and audit of IVF centres must be done by a team, the majority of members having no direct involvement in providing IVF. Sanctions for non-compliance with established standards should include closing the centre. The results of the monitoring and audit should be available to the public.

VI Ethics

Governments are under no obligation to ensure the availability of IVF to any person who might desire to have a child. Even if one acknowledges the individual's right to reproduce, this right cannot be extended automatically to those who do not have the capacity to reproduce. Nevertheless, IVF services have proliferated widely, often funded in part or wholly by governments. The existence and nature of these services has human rights and health care consequences, and it is these that are most relevant to countries intending to continue IVF.

While the recommendations herein are directed to IVF used to assist infertile people, countries must carefully monitor and assess recent experimental attempts to apply IVF to fertile people for other medical purposes - for example, to reduce the incidence of genetic diseases. This new application of IVF to fertile people can also be used inappropriately for social purposes - for example, gender selection. These new uses of IVF create new serious ethical, social and eugenic issues which governments must address and resolve before these new applications of IVF are allowed to proliferate.

28. Ethical considerations in infertility need to focus first on the services provided (including equity, screening procedures, honesty of information, and the rights of women and men), not just on the egg, embryo and fetus.

29. Service systems for infertility need mechanisms that provide for community participation in the planning and monitoring of these services including their ethical aspects. The mechanism must ensure that the nature of the services, including ethical issues, reflect the opinion of the entire community and are not dominated by service providers. Various models are available but generally include a local group of unbiased, well informed people, preferably having at least 50% women and a majority of lay people, whose selection is independent of the service providers. In addition, a similarly constituted group at national level is usually necessary. The mandates for these groups may be broader than infertility services, to include other types of health service. In some countries it is important for the mechanism to be given the full weight of the law, with regulatory powers given to the national group to monitor and enforce the law, with the assistance of the local groups. Whatever model is used, these groups must be accountable to the public and their deliberations should be available.

30. Because it is against international law to discriminate against individuals on the basis of personal, racial or social characteristics, countries should commit themselves, as an integral part of the provision of all infertility services, to a policy of non-discrimination:

- by ensuring that access to these services is not based on inappropriate use of irrelevant personal characteristics, such as race, sexual preference, or social economic or marital status;
- by providing appropriate mechanisms for the monitoring and review of access and screening decisions;
- by establishing an accessible and appropriate forum, with decision-making and enforcement powers, for individuals seeking review of access decisions.

31. In order to monitor the equity and ethical aspects of IVF services, centres should be required to report the demographic and social characteristics of clients. This information should be available to the public.

32. In every IVF centre, activities that are primarily for the purpose of developing or contributing to general knowledge need to be labelled as research and clearly differentiated from activities that are primarily for the purpose of enhancing the wellbeing of an individual client. There should be no incentives for clients to participate in research (for example, providing remuneration to clients who agree to participate in research or moving them to the top of the waiting list for treatment). Similarly, there should be no incentives for women seeking sterilization to agree to undergo ovulation induction for the purpose of ovum donation. Clients who participate in research must be fully informed as to its nature, purpose and conditions, and as to their rights as research subjects.

