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Title **Preimplantation Genetic Diagnosis – An HTA**

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Aim

The overall purpose was to contribute with information and input for decision making by analyzing the literature on preimplantation genetic diagnosis (PGD) and evaluating the experience obtained during a 2-year project at a Danish university hospital offering PGD to couples with selected hereditary diseases. Another issue concerns the ethical questions derived from PGD and attitudes toward PGD among potential consumers of the technique compared to prenatal diagnosis (PND). Furthermore, it was decided to analyze the present organization of PGD in Denmark and in the Nordic countries in an attempt to outline a future organization of PGD in Denmark. Finally, using a model-based, health economic analysis, it was intended to evaluate the economic implications for the public healthcare system of introducing PGD to couples at risk of offspring with a particular hereditary disease – cystic fibrosis.

Conclusions and results

Using PGD, members of families with hereditary diseases can reduce their risk of having an affected child from 25%–50% to 1% or lower. Technologically, preimplantation diagnosis can be introduced in Denmark, but not without increasing costs for the healthcare sector. However, these extra costs are moderate, especially when compared with the costs of many new pharmaceuticals.

The PGD technique is very much demanded by potential users (families at risk of having a diseased child), but presumably the method will be employed by a limited group of people at risk of having a child with relatively severe disease. From a gradualistic perspective (ie, human life has a gradually increasing moral value from fertilization to birth) the method is ethically preferable. A minor uncertainty concerning the possible long-term risk associated with PGD does not justify a reservation. PGD can be introduced in the public healthcare sector at a relatively moderate extra cost, which must be balanced against the advantages of the method, eg, avoided legal abortions.

Methods

A systematic HTA approach was used covering the following aspects of PGD, ie, technology, patient, organization, and economics. The technology analysis was based on a literature review covering existing knowledge and experience with prenatal and preimplantation diagnosis. Ethical analyses focused on: *ethically relevant characteristics* of PGD as a technology, ethical *problems* related to the ethically relevant characteristics, and *ethical assessment*. Attitudes and preferences to PGD and PND among potential users were investigated by a survey. The health economic analysis (a cost-minimization analysis and two cost effectiveness analyses) included experiences with PGD from Denmark and Europe. Furthermore, PGD-related organizational aspects and the influence on processes and structure in health care were analyzed.

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