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Preimplantation genetic testing legislation and accessibility in the Nordic countries

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ABSTRACT

Introduction. Assisted Reproduction Technologies are in rapid development and implementation of preimplantation genetic testing (PGT) has allowed patients with genetic disorders to initiate pregnancies while minimizing or eliminating the risk of transmitting these disorders to their offspring. Testing for numeric chromosomal anomalies has been proposed as a way to increase efficacy in assisted reproduction, however this remains disputed. Legislation is lagging behind the rapid developments in this field. ***Material and methods.*** We conducted a structured online survey of legislation and accessibility to Preimplantation Genetic Testing in the Nordic countries to compare the regulation and uptake of this technique. The survey was designed and answered by the authors. ***Results.*** Key elements in regulation of preimplantation testing for monogenic disorders and structural rearrangements are similar in the Nordic countries although accessibility varies since only Denmark, Finland and Sweden have national clinics offering treatment. In addition, Denmark and Finland have private clinics offering PGT. Regulation is most stringent in Norway where a national board evaluates all couples seeking treatment. Treatment volumes vary between the Nordic countries with Norway and Finland having lowest treatment numbers. Preimplantation genetic testing for aneuploidy in the embryo varies between the Nordic countries where Finland and Iceland are allowed to offer this form of treatment, Denmark and Sweden only in the form of a research protocol while this form of testing is not allowed at all in Norway. Therefore the number of treatment cycles involving testing for embryo aneuploidy are lower in the Nordic countries compared to other countries where this treatment option is more common. ***Conclusions.*** Science needs to inform politics regarding the rapidly evolving field of reproductive medicine and we recommend harmonization of legislation and accessibility between the Nordic countries.

Keywords

Legislation in ART, preimplantation genetic testing, PGT legislation, Nordic, assisted reproductive technologies, aneuploidies, monogenic disorders, structural rearrangements

Abbreviations

PGT-A	preimplantation genetic testing for aneuploidies
PGT-M	preimplantation genetic testing for monogenic disorders
PGT-SR	preimplantation genetic testing for structural rearrangements
ART	assisted reproductive technologies
HLA	human leukocyte antigen

Key Message

We report the status of preimplantation genetic testing legislation and accessibility in the Nordic countries. The uptake of preimplantation genetic testing varies between the Nordic countries. Legislation should be accommodated to harmonize treatment availability for patients.

INTRODUCTION

A major breakthrough in the field of assisted reproduction was the introduction of preimplantation genetic testing (PGT) or preimplantation genetic diagnosis (PGD) as the technique was originally termed.[1] This involves removing one or more cells from a preimplantation embryo to test for a genetic disorder with the goal of establishing an unaffected pregnancy. Sex determination of embryos from couples at risk of transmitting X-linked disease was the first clinical PGT-application, but the technology soon evolved to include analysis for monogenic disorders (PGT-M) and structural rearrangements (PGT-SR). Further developments have allowed for simultaneous human leukocyte antigen (HLA) testing in order to identify unaffected embryos which could also be an HLA-compatible source for stem cell transplantation for a sibling.[2] PGT is also possible if an individual, who may be at-risk for a late onset disease such as Huntington's disease, wishes to prevent the birth of a carrier child without knowledge of their own carrier status. In these cases, it is possible to avoid alleles from the diseased family member, thus preserving the individual's right not to know.[3] The most recent development in the field involves non-invasive PGT (niPGT) where DNA fragments from the blastocyst fluid and culture media are analyzed in order to predict the chromosomal status of the embryo.[4]

Soon after the introduction of PGT for diagnosis of known genetic disorders, the use of the same technology to increase the efficacy of assisted reproductive technologies (ART) was suggested.[5] Aneuploidy, i.e. deviations in the numerical chromosome constitution of cells is found in a significant proportion of preimplantation embryos, occurring with an increasing frequency according to female age, reported from less than 30% in women < 30 years old to 80-90% in women above 40 years.[6,7] Selection of euploid embryos for transfer was thereby suggested as a possible way to improve clinical outcomes in ART especially for indications such as advanced maternal age, repeated implantation failure and recurrent miscarriage. The first pregnancies using PGT for this purpose (now termed PGT-A) were soon reported.[8] However, the first version of PGT-A based on biopsy of cleavage stage embryos using fluorescence in situ hybridization (FISH) for diagnosis was later shown to be inefficient or even to reduce live birth rates.[9] The concept of selecting euploid embryos for transfer is

an attractive proposition in light of the issues mentioned above. Recent implementation of diagnostic techniques allowing comprehensive chromosome screening combined with trophectoderm biopsy at the blastocyst stage is expected to increase the effectiveness of PGT-A, but still its routine use is not unanimously recommended.[10] Recent studies have shown that PGT-A may not improve overall pregnancy outcomes,[11] so the technique remains disputed. Nevertheless, despite the lack of conclusive evidence, and the technical and cost-effectiveness aspects, the use of this technique is increasing although the uptake of PGT-A varies greatly internationally. In the USA, around 40% of in vitro fertilization cycles include PGT-A.[12]

In summary, PGT is used either as a *diagnostic tool* to identify embryos with genetic errors as an alternative to prenatal diagnosis in families with a known risk of a child with a monogenic disorder (PGT-M) or a structural rearrangement (PGT-SR), or for *screening* of embryos for aneuploidy (PGT-A) in connection with infertility treatment to improve pregnancy rates and reduce the risk of miscarriage. In addition, the analytical genetic technology has evolved rapidly during the three decades since the introduction of PGT.

While technological advances improve our possibilities to offer new treatment modalities to our patients and improve outcome and efficacy, legislation often lags behind and new technology is often disputed. At the same time, PGT is subject to considerable variation in regulation between countries internationally.[13] This is also the case between the Nordic countries.

The aim of the current study was to show the current status of PGT in terms of legislation and accessibility in the Nordic countries, representing a region being seemingly homogeneous with respect to culture, economy and access to public health care.

MATERIAL AND METHODS

The study was performed as an on-line survey (SurveyMonkey) developed and approved by the authors in order to retrieve standardized information on legal aspects, reimbursement, accessibility, national treatment types and annual cycle numbers (see Supporting Information Table S1) in each of the Nordic countries. The authors represent each of the Nordic countries: Denmark, Finland, Island,

Norway, and Sweden and all either work in clinics performing PGT (Denmark, Sweden and Norway), or have specific knowledge and experience related to referral for treatment in other countries (Norway and Iceland). Considering that the authors represented the available expertise and that none of the authors had any conflicts of interest, as the information provided is objective, the survey questionnaire was distributed by e-mail to the authors.

Ethical approval

Ethical review board approval for the study was not relevant because of the nature of the study.

RESULTS

Legal aspects

PGT-M and PGT-SR are allowed in all the Nordic countries. The same applies for PGT with HLA testing, although in Norway, Sweden and Denmark this is allowed on a case by case basis only with each case to be approved separately by a national board of health and welfare (Table 1). PGT-A is allowed unconditionally in Iceland and Finland only, but within a research protocol approved by a local ethics' committee also in Denmark and Sweden. PGT-A is not allowed in Norway (Table 1). PGT is allowed also in privately funded clinics in all Nordic countries except in Norway. No clear distinction is made regarding the forms of PGT allowed in the privately funded clinics.

In Denmark, PGT-M/SR can be offered whenever prenatal diagnosis can be accepted, i.e. in couples with a high risk of transmitting a severe genetic disorder. The risk level is not clearly defined, but essentially greater than 25%. Severe disease is also not clearly defined. Initially, it was attempted to elaborate a "positive" list, but this was not possible due to many reasons such as variable expressivity of the disorder leading to variable phenotype and lack of agreement on the definition of what really is a severe disease.

In Finland, the situation is similar to Denmark in that PGT-M/SR can be offered where prenatal diagnosis can be accepted.

In Sweden PGT-M/SR is allowed if the male or female is carrying a mutation or a structural chromosomal aberration with a high risk of a child with of a serious disease

In Norway and Iceland, PGT-M/SR is allowed but not practised, and a low number of patients are referred each year for PGT-M/SR abroad (see below).

In Norway, all couples need to be approved by the National Office for Health Service Appeals, a government agency subject to the Norwegian Ministry of Health and Care Services. If the monogenic disorder is expected to lead to a "normal" life or if the disease is "treatable" the application will be rejected.

PGT-M and PGT-SR are publicly funded in all Nordic countries, and so is PGT for HLA matching, except in Iceland. In Norway and Iceland where PGT is not performed, PGT treatment in clinics abroad is publicly funded – except for the HLA analysis in PGT-HLA for Icelandic couples. Sex selection is allowed in Iceland, but not performed. Sex selection is allowed in case of X-linked disease in Denmark, Sweden and Finland, but not for family balancing.

Treatment is currently offered within the public health care system for two healthy children in Sweden, Norway, Finland and Denmark. However, this is not regulated by legislation. There are no limits for treatment in Iceland.

Treatment activity

PGT is not performed in Norway and Iceland. Three public clinics in Denmark, two in Sweden and one in Finland are performing PGT. One private clinic in Denmark and four in Finland offer PGT (Table 3). More than 300 PGT-M and PGT-SR cycles are performed yearly in Denmark and Sweden respectively, and 70-100 in Finland, whereas from Norway less than 50 and from Iceland 5-10 PGT-M and PGT-SR cases are sent abroad yearly (Table 4, data from 2018). From Norway, about 35 couples are referred to Sweden every year for PGT-M and PGT-SR. The number of patients from Norway is lower than in the other Nordic countries due to more strict criteria.

No PGT-A is offered to couples in Norway and Sweden, whereas 50-100 PGT-A cycles are offered to Danish couples and 100-200 to Finnish patients (Table 4), nearly all in private clinics. No data is

available on PGT-A cycles for Danish, Finnish, Icelandic and Swedish patients being performed in other countries.

DISCUSSION

The present survey shows some similarities between the Nordic countries, but also a striking diversity.

PGT for monogenic disorders and structural chromosomal aberrations are allowed in all countries, but not performed in Norway and Iceland, from where candidates are sent abroad. Currently however, preparations are ongoing in both countries to start offering PGT locally. Family balancing by sex selection is not performed in any of the Nordic countries and is not allowed in Denmark, Sweden, Norway or Finland. PGT-M and PGT-SR is publicly funded in all countries.

The number of PGT-M and -SR cycles offered to Danish patients seems to be double the number performed per inhabitant compared to Sweden and Iceland. Also, the numbers seem low in Finland, although increasing, and very low in Norway. The trend in all countries is that PGT is performed in very few centers, presumably because of the high technical demands and the requirements for extensive genetic counseling to patients. When performing PGT for genetic disorders, a clinical geneticist will in many cases need to study the penetrance of the disorder in the couple's immediate family and all patients require counseling regarding interpretation of outcome of the analysis and the chances of having a non-affected child. PGT-M/SR is also offered in private clinics in Denmark and Finland. Legal limitations do not seem to fully explain the rather low PGT-M and PGT-SR activity in Norway and Finland although the Norwegian legislation is more strict than in the other Nordic countries. Lack of availability and access to treatment may also explain lower numbers of PGT-M/SR in Norway and Iceland. Problems stemming from very restrictive legislation in PGT have been documented as it is considered to be at odds with both reproductive autonomy of patients, established international practice and also to treat different indications and varied penetrance of disorders unfairly.[14] Additionally, this appears illogical when compared to prenatal testing which may be more easily available.

The differences between countries regarding the number of PGT-M and PGT-SR cycles are difficult to explain but may not only be partly due to legal limitations but also to differences in awareness of this alternative to prenatal diagnosis as well as differences in resource allocations and reimbursement policies.

Most Western European countries have some restrictions on the use of PGT and regulate this activity through legislation. Typically PGT-M/SR is limited to cases of serious hereditary disease and in some countries, such as France, a case by case approval by a multidisciplinary committee is required. In other countries, such as the UK, general specifications are in force for the conditions under which PGT can be performed and each new disease has to be approved by the Human Fertilization and Embryology Authority (HFEA). PGT-A is allowed in many Western European countries whereas access to state funded treatment, which in general is high in the Nordic countries, might reduce patient pressure for performing PGT-A. The situation in Europe is very different from the US where no regulation on the application of PGT exists.[15] To a certain extent, variation in legislation between countries causes reproductive tourism, i.e. couples or individuals seeking treatment which is not permitted or accessible in their home country.[13] PGT-A is unconditionally allowed in Finland and Iceland only, but performed within research protocols in Denmark and Sweden. Overall PGT-A has very limited use in the Nordic countries seen as a proportion of the national ART activities: in 2014 the total number of in vitro fertilization and frozen/thawed embryo transfer cycles in these countries was 54 653.[16] This is in striking contrast to the situation in many other countries where a large proportion of in vitro fertilization cycles are performed with PGT-A.[17] The development of the diagnostic techniques such as complete genome sequencing, enables uncovering more genetic information than the specific genetic problem requiring PGT.[18] For example massive parallel sequencing allows complete genome sequencing. Presently massive parallel sequencing is used for PGT-A and also for PGT-SR where concomitant diagnosis of structural errors and chromosome number is delivered as extra information. In this respect, legislation which restricts the use of PGT-A is not in harmony with the technical advances of the last few years. In fact the arbitrary and technical distinction between these two PGT modalities is gradually vanishing as genome-wide single nucleotide and copy number variation (SNV and CNV) genetic laboratory testing is being carried out simultaneously as the analysis of structural variations from the technical point of view.[19] There is no

doubt that biologically, PGT-A should be efficient. However, the rather disappointing results of recent, larger prospective, randomized multicenter studies may be a reason to reconsider the implementation of large-scale PGT-A in ART, at least to selected patient groups.[20, 21] Nevertheless with the use of blastocyst culture often only a few blastocysts are usually available for transfer, and at the end of the day – after transfer of all blastocysts – the euploid embryo (if any) will be identified by implantation and establishment of a pregnancy. The balance between costs for PGT-A versus successive transfers has not been investigated in a public health care environment with a reimbursement system allowing for cumulative transfers of all embryos from one oocyte pick up. Beyond doubt, the cumulative pregnancy rate per initiated cycle will be little – if at all - improved. This may well contribute to the low use of PGT-A in the Nordic countries given the relatively easy access to state funded treatment. However, in certain patient groups it may be of value, for example PGT-A may allow identification of embryos with viable trisomies in selected couples. It may also function as a ranking of embryo potential, in addition to morphology and development, shortening time to pregnancy and live birth,[22] at least for patients with a high number of good quality embryos.

Massive parallel sequencing technology has increased the utilization possibilities of PGT together with promising developments in the use of non-invasive PGT on cell-free DNA from blastocyst fluid and spent media.[4, 23, 24]

The next big step in PGT will probably be the large scale introduction of non-invasive embryo analysis techniques, where the potential for improvements in outcome and reduction in costs is great.[23, 21] Additionally, preconception carrier screening for selected Mendelian recessive diseases is emerging,[25] and when implemented on a larger scale, this will increase the need for preimplantation genetic testing and prenatal diagnosis. Whether the strict legislation regarding PGT-A in some countries will change following implementation of non-invasive techniques remains to be seen.

CONCLUSION

We have shown the greatly varied uptake of PGT technology and its application in the Nordic countries. This is surprising considering the cultural and economic similarities between the countries.

We also see the need for science to inform politics since legislation in our swiftly developing field is lagging behind. To increase equality in access to this new technology, and to some extent counteract reproductive tourism, the authors recommend a harmonization of access to PGT in the Nordic countries.

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Supporting Information legend:

Table S1. The original survey is presented as supplementary material. Format of the survey was multiple choice questions as indicated here, with possibility for adding comments.

Tables

Table 1. Types of preimplantation genetic testing allowed in the Nordic countries.

	PGT-A	**PGT-M**	**PGT-SR**	**PGT with HLA testing**	**PGT for research**	**Minimally invasive PGT**	**PGT with exclusion testing**
Iceland	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sweden	Within an approved research protocol	Yes	Yes	Yes, after individual case approval	Yes	Not adressed in legislation	Yes
Norway	No	Yes	Yes	Yes, after individual case approval	No	Not adressed in legislation	No
Denmark	Within an approved research protocol	Yes	Yes	Yes, after individual case approval	Yes, within an approved research protocol	Not adressed in legislation	Yes
Finland	Yes	Yes	Yes	Yes, if together with PGT-M	Yes	Yes	Yes

The table specifies the types of preimplantation genetic testing (PGT) for aneuploidies (PGT-A), monogenic disorders (PGT-M), structural chromosomal rearrangements (PGT-SR) and PGT with tissue histocompatibility testing (human leukocyte antigen, HLA).

Table 2. Reimbursement for preimplantation genetic testing if performed in clinics in other countries?

Iceland	Yes, for PGT-M and PGT-SR
Sweden	No
Norway	Yes, for PGT-M, PGT-SR and PGD-HLA
Denmark	Some treatments have been publicly funded after special application
Finland	No

The table specifies if and to which extent treatments are funded for preimplantation genetic testing (PGT) internationally. M (monogenic disorders), SR (structural chromosomal rearrangements), HLA (human leukocyte antigen, i.e. tissue histocompatibility testing).

Table 3. Number of clinics performing preimplantation genetic testing.

	Public	Private
Iceland	0	0
Sweden	2	0
Norway	0	0
Denmark	3	1
Finland	1	4

The table shows the number of public and private clinics in the Nordic countries offering preimplantation genetic testing (PGT). In Finland four private clinics offer for aneuploidies (PGT-A), monogenic disorders (PGT-M), and structural chromosomal rearrangements (PGT-SR). In Denmark one public and one private clinic offer PGT-A.

Table 4. Number of preimplantation genetic testing cycles per year in each of the Nordic countries

Country and approximate number of inhabitants	PGT-A	PGT-M/SR	PGT-M/SR per year and million inhabitants (approximation)	Total number of fertility treatments per million inhabitants (2014)
Iceland 0.3 million	Not performed	5-10 (performed in Sweden)	33	2978
Sweden 10.1 million	0	>300	30	1897
Norway 5.3 million	0	35 (abroad)	6.6	2054
Denmark 5.6 million	50-100	>300	54	2884
Finland 5.5 million	100-200	70-100	18	1566

The table specifies the number of cycles of preimplantation genetic testing (PGT) cycles per year, M (Monogenetic disorder), SR (Structural Chromosomal Rearrangements). Data from 2018. Total number of fertility treatment cycles in these countries is included for comparison.[16]