

FAMILY LAW: WITNESS TO THE NEW PRENATAL PATERNITY TESTS

By

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SUMMARY

Current Family Law only requires and recognises results of paternity tests once a child is born. Paternity tests are therefore not considered until the moment after birth when DNA can be taken from the blood of the umbilical cord without any risk to the child. In theory, there should be no limitations to conducting the test in the prenatal stage as the biotechnology to do so has been developed. However, as a result of the development of new techniques, legislation has diversified between countries, specifically in relation to the collection of samples and the optimum method of obtaining genetic information from an unborn child.

The Human Genome Project has had a profound effect on the world of medicine and the study of human evolution far sooner than was anticipated, and its impact has been amplified by huge advances in biotechnology. As a result, genetic research is proving to be the discipline with the greatest potential to deliver considerable improvements in our quality of life. However, with this progress comes a growing social concern that the individual's legal rights need to be redefined in respect of these scientific advancements.

Predictive medicine and its clinical application may soon be a reality, with implications for Family Law. Like other disciplines, Family Law has the formidable task of having to predict the kinds of cases which will emerge in the future. Since the advancement of

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science is unstoppable, and new concepts are emerging all the time, ever more complex cases will appear within the framework of the law.

These cases will require continual assessment so that both their ethical and legal consequences are fully evaluated. In the specific case of the development of techniques which allow an individual's DNA to be analysed before birth, a new sphere of practice is being defined which could impact on certain cases in Family Law. The applications, usefulness, limitations and legality of this practice need to be debated in forums where members are appropriately multidisciplinary, professional and experienced.

KEY WORDS: paternity tests, prenatal period, parental rights, parental obligations, impact on Family Law.

CURRENT CLINICAL APPLICATION OF ANTENATAL DIAGNOSTICS

Despite the fact that Life (meaning the birth of a new individual) is still considered a positive, there has been an exponential increase in the development of antenatal diagnostic techniques driven by a demand to avoid certain pregnancies. These techniques are now being applied to the prediction of almost all genetically-based, congenital and/or hereditary diseases. This is fuelling a growing societal concern regarding the question of abortion, exacerbated by the emergence of extremely complex situations which necessitate the modification of current legislation, legislation which was designed for a bygone era.

Nowadays, prenatal diagnostic techniques allow a great number of diseases to be identified or ruled out with a high degree of certainty, with important consequences for the individual, their family and for society. Although the efficacy of these tests is not limited to type of pathology, the situations in which they are recommended remain: abnormal ranges from biochemical tests carried out on a pregnant woman; possible damage to the foetus from harmful substances or exposure to risk; the mother's age being over 35 years; suspicion or diagnosis in either parent of a chromosomal abnormality

capable of producing pathology or monogenic disease; cases where the mother is a carrier of a genetic disorder either with hereditary links to sex or found in mitochondrial DNA and/or previous birth of a child with congenital malformations or chromosomal abnormalities.

The primary objective of an analysis in the prenatal period is to produce a highly accurate study of the state of health and development of the foetus. It can be conducted at different levels:

Ecographic techniques are extremely useful throughout the whole gestation period and do not have any secondary effects for the mother or the foetus. They allow the development of the foetus to be monitored sensitively, detecting the majority of congenital defects and/or indirect signs of disease. However, it is possible for certain abnormalities to go undetected and for an important percentage of hereditary diseases to manifest themselves years after birth.

Chorionic villus sampling and amniocentesis (extraction of amniotic fluid) are the prenatal techniques most widely used in the third and fourth months of gestation, respectively. The degree of risk of miscarriage these techniques carry (0.8-1% and 0.5 respectively) and the ability to collect an adequate sample (avoiding contamination from maternal cells) depend directly on the skill of the medical team.

Amniotic fluid is extracted between weeks 14 and 20 of the pregnancy, via an abdominal puncture through the uterus. It allows for biochemical tests to be carried out, as well as for cells from the foetus, suspended in the fluid, to be collected for foetal chromosomal analysis and the extraction of foetal DNA for genetic analysis via molecular techniques. Another method of obtaining foetal DNA is via a biopsy of the chorionic villus, taken from tissues from the wall of the uterus which have genetic information identical to that of the foetus. Although it requires more experience and carries a greater risk of harm to the foetus, it allows the investigation to be brought forward to weeks 10 to 15 of the pregnancy.

The ability to apply genetic research to the prenatal period opens the way for the majority of congenital and/or hereditary diseases with an identified genetic defect, to be analysed with maximum precision, and in the first stages of the development of the foetus. With the range of techniques now available, very different and complex situations faced by families as a result of hereditary or congenital diseases can be addressed.

Applied biotechnology is also proving to be a very versatile tool in our society and extremely useful in very disparate disciplines, disciplines in which family law is already debated.

CURRENT FRAMEWORK REGARDING PRENATAL PATERNITY TESTS

The prenatal paternity test is a definitive method of determining if a man is, or is not, the father or an unborn child. It is an option for those who do not wish to wait until birth to establish the relationship. A person's genetic information, contained in DNA, is established at the moment of conception and henceforth never changes. For this reason, the results of a prenatal genetic test are as certain and conclusive as those from a post-natal test. With the exception of identical twins, DNA is unique to every individual, and we can refer to its genetic information not only to establish the existence of illness but also the many characteristics which can identify it. Of the sum total of this information, approximately half is received from each parent. On comparing a foetus's DNA with that of his mother, the part not inherited from her, corresponds with the biological father. It is currently possible to analyse any of the regions which are hypervariable between individuals, using foetal DNA in the same method as is used in newborns, allowing the profile of the foetus to be compared to that of the presumed father and paternity to be confirmed or ruled out quickly. If two or more of the regions analysed do not match, the presumed father is ruled out. The comparison of the three profiles obtained (mother, father and child) can determine the paternity with a degree of accuracy of over 99.9%.

Given that there is a potential risk to the mother and child in obtaining the necessary samples to conduct a DNA test, the majority of doctors who practice the technique discourage its use unless there are medical reasons which justify the procedure. If the pregnant woman is undergoing an amniocentesis for medical reasons, then a paternity test can be carried out as well. Otherwise, it is best to wait until birth before conducting the test. Chorionic villus sampling carries with it a significant increase in risk and should therefore never be used with the sole purpose of establishing paternity. Again, however, if the test is being carried out for medical reasons, the sample could at the same time be used for the purposes of a paternity test. As well as the sample required to collect foetal DNA, it is also necessary to collect a sample from the presumed father and the mother. These can be obtained from a sample of blood or from tissue and saliva from the inside of the cheek.

In order for the results of a paternity test to be considered admissible in a tribunal and legally exclusive or binding it is essential above all to guarantee the chain of custody of each sample used, as well as guaranteeing that it is not in any way manipulated or altered. The samples must be collected in a laboratory and each party has to undergo an identification process and give signed consent. The procedure should be conducted by experts specialising in human genetic testing in order to guarantee the quality of the testing and that the results are validated correctly and also to ensure that the chain of custody has not been broken.

Under current legislation a pregnant woman can undergo the procedure to collect a foetal DNA sample for the sole purpose of conducting a paternity test, providing she has been informed of the risks and has given signed consent beforehand. The results can be available in less than a week. There are certain situations in which this choice can be justified, such as in a case of rape, where the result may have an impact on the mother's decision to continue the pregnancy. However, the use of these new testing methods needs to be regulated by the law. This is especially true when considering that family law cases are becoming ever more complex, notable changes have been made to legislation on abortion and current trends in society demand that the interpretation of this legislation

should be sufficiently flexible to address the needs of the vast majority of modern women.

Whilst we consider regulating this new technology, we can already envisage the enormous upheaval that prenatal paternity tests carried out on samples of maternal blood will cause in the near future. The need to diagnose genetic disorders before birth is forcing the fine-tuning of techniques which already allow us determine the sex of the foetus and to diagnose some illnesses. In addition, we now have the ability to test a foetus's paternity simply via a sample of the mother's blood which contains her DNA, that of the foetus and that of the alleged father. This represents an enormous medical advance since it requires a sample of blood to be taken from the arm of the pregnant woman and is thus a non-invasive test. It carries no risk either to the mother or the foetus. The foetal DNA is used to determine a paternal match with the alleged father or fathers, who need only supply a sample from the inside of the cheek. DNA can be extracted accurately after the thirteenth week of gestation. In theory, this new technique, established in 2002, is a definitive alternative to the invasive tests, however, it requires fine-tuning to ensure its accuracy. In reality, the majority of laboratories do not offer this type of test and its results would be unlikely to be admissible in a paternity suit. Articles published in 2007 detail how scientists are continuing to perfect non-invasive methods, with success rates for their genetic analysis ranging between 66.7 and 98.2%. Interestingly, one of the principal problems with the test, other than the amount of foetal DNA present in the maternal blood, is remaining DNA from previous pregnancies. Previous pregnancies can therefore affect the test results as foetal cells can possibly remain in the mother's blood for over 20 years after the pregnancy.

Lastly, we need to bear in mind other implications of handling an individual's DNA before its birth. Genetic material is a combination of DNA from two parents and therefore by excluding the material which comes from the mother we can obtain genetic information about the biological father. This means that a pregnant woman, without obtaining any form of consent, can commission genetic tests on the individual with whom she has conceived. The legislation regarding the right to confidentiality and the right 'not

to know' is rigorously defined in the Law of Biomedical Investigation of July 2007, Ministry of Health of the Spanish Government.

CONCLUSIONS

Prenatal paternity tests which use invasive methods are currently only offered to a woman if her foetus is presumed to have a risk of chromosomal defect or other genetic anomaly which is greater than the risk of performing the test. The integrity of the results is exactly the same as tests performed post-natally.

The recent discovery of the presence of foetal cells and therefore foetal DNA in maternal blood has led to new, non-invasive diagnostics and paternity tests. Via genetic analysis of DNA markers which show a high degree of variation between individuals, special laboratories offer the potential to compare foetal DNA with the genetic profiles of the mother and of the alleged father/s. This procedure does not pose any risk to the mother or the foetus and is more cost effective than the invasive techniques. Analysis of foetal DNA via a sample of blood from the mother can take place with a higher degree of success after the fourteenth week of gestation. The results can be obtained in the following two to seven days. The alleged father can be excluded or not excluded as the biological father of the foetus on the basis of samples obtained from the mother and the alleged father, and the DNA extracted from the foetal cells present in the maternal blood. The sensitivity and specificity of detection of cells with foetal DNA free after fourteen weeks is over 99%. The integrity of the test is in its last stages of investigation, depending amongst other things, on the reproductive history of the woman being tested.

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