

INTRODUCTION

An ad hoc Group on Genetic Paternity Testing Services was brought together for the express purpose of considering genetic paternity testing services provided in the United Kingdom.

The Group's membership included representatives from commissioners of genetic paternity testing services, providers of such services, patient groups, clinicians, academics and scientists. The Code has been considered by the Genetic Testing Sub-group of the Human Genetics Commission, who have absorbed the former Advisory Committee on Genetic Testing (ACGT).

Paternity Testing

Modern paternity testing often involves comparing the DNA of individuals to determine their biological relationship. Tests are undertaken to determine, with a high level of accuracy, whether a man is the biological father of the child in question. The scientific testing methods used to perform DNA based paternity testing are constantly evolving and improving. Until recently it was necessary to take blood samples from the child and parents using venepuncture. This required the assistance of a medical practitioner.

Advances in modern genetics now mean that it is possible to produce accurate results from cells taken from inside the mouth using buccal swabs, hair follicle samples or from finger prick blood samples. Such sampling methods are welcomed as they may be less invasive. However, these developments offer the possibility of paternity testing taking place without any professional medical involvement. Indeed it offers the possibility of testing being offered direct to the public (i.e. "over the counter") using sampling "kits" distributed and samples returned through the post without the involvement of medical practitioners.

A related development comes from the increased availability of paternity testing services via the Internet. A recent survey found at least twenty such companies –

mainly based in the USA. Most of these companies appear to be reputable bodies who participate in the appropriate accreditation and quality assurance schemes of the countries in which they are based but this cannot be guaranteed.

Additionally, although routine paternity testing is carried out with samples taken from the mother, putative father and the child, increasingly tests are being undertaken using samples provided by the child and putative father alone ("motherless testing").

As a result of these and other issues, Ministers asked the ACGT to consider paternity testing.

A subcommittee of the ACGT reported back in 1998 and recommended that:

- Those providing testing services should be accredited to recognised European standards and participate in appropriate quality assurance schemes;
- That the mother, or third party with parental responsibility, should give written consent to testing before a "motherless" test is performed; and
- That these principles should be incorporated into a code of practice.

Ad Hoc Group on Paternity Testing Services

The Group was established, under the Chairmanship of Dr Jeremy Metters CB expressly to consider developments in genetic - particularly DNA - paternity testing services provided to the public and to develop a Code of Practice that complements that produced by the ACGT in respect of other genetic testing. A full list of the Group's members is at Annex A.. The Terms of Reference were:

- i. To produce a voluntary code of practice on paternity testing services that is acceptable to all interests; and
- ii. To consider how best to achieve compliance with the Code.

The Code of Practice

The Code of Practice is based upon ACGT's "Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public" published in 1997. The earlier Code specifically excluded genetic tests offered for paternity testing. The ACGT recognised that such tests are of a specialised nature not easily covered by its Code and that the majority of such tests are not medically motivated but are carried out to resolve issues related to parentage frequently involving legal proceedings.

The ad hoc Group considered the developments in paternity testing services described above. They recognised that these raise a number of ethical and procedural issues. For example, a mouth swab or hair sample can be obtained from a child without the knowledge of the mother and without the intervention of a medical practitioner. This raises questions about ethical and legal issues such as to the nature of the consent required to take the sample. Appropriate information or counselling about the implications of the test results also needs to be considered.

Similarly, there are issues surrounding the authenticity of samples and the steps that need to be taken to verify that sample results can be reliably traced back to the appropriate donor.

Finally, the public would need to be reassured that quality standards amongst the providers of genetic paternity testing services are being maintained, that all providers achieve the requisite standards and that these standards are regularly monitored and reviewed.

Principles

The Code of Practice should be read with the following principles in mind:

- The best interests of the child should be taken into account when commissioning genetic paternity tests.
- Paternity tests should not be commissioned by people under 16 years of age.
- Samples should only be taken if the sampler or the organisation providing the test is satisfied that those consenting to the taking of a sample from the child or to the test being undertaken are authorised to do so.
- That those consenting to testing have had an opportunity to consider the possible implications raised by knowledge of the results of the test.
- That the Code of Practice will not necessarily apply to tests and investigations conducted in connection with criminal proceedings.
- The results of tests undertaken by organisations that do not meet the requirements of the Code may not be recognised by government departments, government agencies or in any proceedings instituted in a court of law.
- The Code is intended to apply in England, Scotland, Wales and Northern Ireland. The main differences in legislation in Scotland are noted. However, if detailed advice on the provision of paternity testing services in Scotland and Northern Ireland is needed, then the Scottish Executive or the Department of Health and Social Services in Northern Ireland should be contacted.

Who does the Code apply to?

The Code of Practice is aimed at organisations that provide, and advertise that they provide, genetic paternity testing services direct to the public.

It will also be of interest to those who commission such services, to general medical practitioners and other clinicians whose advice may be sought by members of the public and organisations and members of the public with an interest in this area.

Other Paternity Testing Methods

Although DNA paternity testing is widely used and recognised by, for instance, Government Departments and the law courts, there are alternative methods that may still be usefully employed. These involve testing for non-DNA genetic markers found in blood. In order to answer questions of paternity, it is generally necessary to use a larger number of these non-DNA markers compared with the number of DNA markers. The principles of this Code should be seen as also applying to these tests and their providers.

Conclusion

The Government has an interest, through its responsibility for consumer protection, in setting out the framework for protecting the welfare of those subjected to genetic paternity testing, especially children.

The Code therefore sets out the standards to be expected of organisations that seek to deliver genetic paternity services direct to the public. All Government and public bodies commissioning services are expected to, so far as is practicable, ensure that those supplying services comply with the Code.

Definitions used in this Code of Practice and Guidance

Commissioner – An organisation or member of the public that contracts with a supplier for the provision of a genetic paternity test.

Deoxyribonucleic Acid (DNA) is found in almost all of the cells that make up the human body. DNA contains a code that determines the characteristics of a person. No two people in the world have exactly the same DNA except for identical twins. Samples of DNA can be used to establish whether individuals are related.

Parties to the Test – a person or people being tested or providing samples for a scientific test.

Paternity Testing – Modern paternity testing compares the genetic patterns (commonly, these days, the DNA) of the mother, a man and the child to predict with a high level of accuracy whether or not the man is the biological father of the child in question.

Sampler - A person who takes a sample, on behalf of a supplier, for testing purposes.

Supplier - The provider of a genetic paternity testing service.

UKAS - United Kingdom Accreditation Service.

CODE OF PRACTICE

AND

GUIDANCE

The Ad Hoc Advisory Group encourages those offering genetic paternity testing services to abide by this Code of Practice and Guidance, thereby enabling such services to continue without the need for statutory controls.

In this document the Guidance (to be found in the right column) is provided to give additional detail and information in support of the Code of Practice (to be found in the left column).

This Code of Practice and Guidance does not amend or limit any existing law.

1. Information to be provided to Parties giving consent to the Test.

Suppliers should have mechanisms in place to ensure that, before the test is performed, those giving consent for a test are fully informed. They should understand the nature of the test, the purpose of the test and the potential consequences of the test result.

They should be informed of the normal degree of accuracy that can be expected from the testing technique employed.

The result of the test should include a clear statement that indicates the level of confidence with the result of the actual test undertaken having regard to both the technique employed and the type of the samples examined.

Advertising

Providers of paternity testing services are, under current legislation, prohibited from broadcasting advertisements on the radio, TV or cinema.

Written advertising material and advertising on the Internet must accord with any relevant advertising codes that are currently in force for written material. Currently, Suppliers must apply the British Codes of Advertising and Sales Promotion to their advertising and sales promotion material intended for the press, to be put on posters, shown in the cinema or made available on the Internet and to the content of any direct mailings.

Information to individual parties to the Test.

Suppliers should provide as much information to the parties to the test as is reasonable in a form that is easy to understand by a lay person of average intelligence. Sources of help and advice should also be identified to the parties to the test (see Annex B).

Suppliers should provide sufficient, unambiguous, information to enable the customer to understand the testing techniques to be employed, the scope and limitations and the use to which the results may be put.

Those consenting to the test (including those consenting on behalf of a child) should be aware of the significance and possible irrevocable consequences that knowledge of the results of the test may bring. If they appear uncertain of the implications of test results for them, it is recommended that they should seek independent advice or counselling. Some organisations able to provide such help are at Annex B.

It is recommended that suppliers should work with appropriate professional and voluntary bodies when developing advertising and customer information materials

Material must be provided in a suitable format for visually impaired people and, where appropriate, it is good practice to provide for those whose first language is not English.

2. CONSENT

Testing must not take place unless written consent has been obtained.

Where all the persons to be tested are adults capable of giving consent, the consent of each to the test should be obtained (in Scotland it is immaterial whether the person is an adult or not).

Samplers must be satisfied that consent to testing has been given before a sample is taken.

Persons under 16 years

In **England, Wales & Northern Ireland**, only a person with parental responsibility for a person under 16 years can give consent for that child to be tested. However, where a court has directed a test and the person with parental responsibility for a child under 16 has refused consent for the test to be carried out, the court may waive the requirement for consent where it is satisfied that this is in the best interests of the child.

Where possible, after taking into account the age and ability of the young person, the sampler should obtain and take into consideration the views of the young person in reaching a decision on whether to undertake a test.

A sample should not be obtained or a test undertaken if the sampler or the provider of the testing service has reason to believe that this would not be in the best interests of the child.

It is recommended that providers of genetic testing services should provide their samplers with protocols. These should cover areas such as the need to take into account the views of the child (when mature or old enough), ensuring that only those with parental responsibility give consent for a sample to be taken from a child.

Genetic paternity testing services should not be supplied solely at the request of those under the age of 16, or to those not competent to act on their own behalf.

Children and Young People.

In the case of children, it is generally accepted that it is probably best for a child to grow up knowing who their biological father is – but this may not always be the case. Factors which may be relevant include the possible impact on a child's sense of identity, on the possible relationship between the child and the putative father, the child's relationship with those presently perceived as siblings and with those undertaking the care of the child

“Motherless Tests” (i.e. those that do not include the mother) should only be undertaken where the mother consents to the child being tested or where the putative father has care and control and is able to give consent for the child. It may be necessary, in some cases, for a solicitor to provide confirmation, in writing, that this is the case.

The Child Support Agency requires genetic testing of all three parties - the child, the mother and the alleged father. It is unlikely that the CSA will accept motherless testing as a method of resolving a paternity dispute for the foreseeable future.

Disputed Consent

In England, Wales & Northern Ireland, in cases where consent is disputed and more than one person has parental responsibility, no one person with parental responsibility has any priority right to give consent for the particular child. Section 2(7) of the Children Act 1989 provides that “each of them may act alone...”. Nor is there any requirement that they should act jointly when giving consent

It should be borne in mind that others who are not parents may have parental responsibility.

Those being tested and those giving consent in respect of a child, may wish to seek independent advice – perhaps from a lawyer, a CAB or an advice agency – before consenting to the provision of a sample for testing. A number of advice agencies are listed in Annex B.

In **Scotland**, the law on consent differs:

Although in general children under 16 years do not have legal capacity, the Age of Legal Capacity (Scotland) Act 1991 sets out exceptions to this general rule. Children under 16 can themselves consent to a 'medical procedure if, in the opinion of a qualified medical practitioner attending them, they are capable of understanding the nature and possible consequences of the procedure'. 'Medical procedure' is not defined, but would include the taking of a blood or other intimate body sample. If such a child has the necessary legal capacity, the child's decision cannot be overruled by a parent or a local authority responsible for him.

The position in Scotland

Where the child concerned does not have legal capacity to consent to the testing, consent can be sought from a person who has parental responsibilities and rights in relation to the child. These are set out in sections 1 and 2 of the Children (Scotland) Act 1995. In particular, section 2(2) of the 1995 Act provides that, where 2 or more persons have a parental right in relation to the child, each of them may exercise rights without the consent of the other(s). Because each person with parental rights can exercise them independently of the others, only one such person needs to consent to the testing.

It should be borne in mind that others who are not parents may have parental responsibilities and rights.

Those being tested, and those giving consent in respect of a child may wish to seek independent advice – perhaps from a lawyer, a CAB or and advice agency before consenting to the provision of a sample for testing. A number of advice agencies are listed in Annex B.

Where it is necessary to obtain evidence in civil proceedings to determine parentage, a sample of blood, other body fluid or body tissue may be sought. Where such a sample is sought from a child under the age of 16 years, consent to the taking of the sample may be obtained from:

- i) Any person having parental responsibilities (within the meaning of section 1 (3) of the Children (Scotland) Act 1995) in relation to the child, or having care and control of the child.*
- ii) Where the subject of the test is incapable of giving consent, the court may consent where:-*
 - a) There is no person who is entitled to give consent.*
 - b) It is not reasonably practicable to obtain the person's consent in the circumstances, or the person is unwilling to accept the responsibility of giving or withholding consent.*

Consent by the court may only be given if the taking of the sample would not be detrimental to the person's health.

Adults

In general, no one is able to give consent on behalf of an adult not capable of giving consent. It will be reasonable to proceed with the test if this is in the best interests of the person.

Adults

It may be appropriate for legal advice to be obtained on whether an adult can give consent. It may be necessary for guidance to be obtained – possibly through the courts - on whether a test would be in the best interests of the person. It would not normally be the responsibility of the sampler or the supplier to obtain the guidance but they may trigger the procedure for the guidance to be obtained.

Nevertheless, with the exception of certain tests ordered by courts in connection with the investigation of criminal offences, those providing or agreeing to the provision of samples, should be aware that they have an absolute right to withhold consent to a test. However, they should also be made aware that in some circumstances the law may allow inferences to be drawn from any failure to consent to a test and this may be detrimental to the party concerned, for example a benefit penalty may be applied under child support law.

The position in Scotland

The position in Scotland is at present that no person has an automatic right to consent on behalf of an adult with incapacity. But it is possible to Petition the Court of Session to have a tutor dativo appointed by the court. The tutor dativo can give consent on behalf of the incapable person. If the person already has a tutor dativo, that person can give consent without going back to court. Another situation in which consent to a test for an incapable adult can be given is for civil court proceedings under Section 6 of the Law Reform (Parent and Child) (Scotland) Act 1986 as amended.

A court may consent to a sample being taken from any person incapable of giving consent for the purpose of obtaining evidence of paternity by a party to a civil proceedings. A court may give consent if a) there is no person who is entitled to give such consent; b) there is such a person but it is not reasonably practicable to obtain his consent in the circumstances or he is unwilling to accept the responsibility of giving or withholding consent. The court shall consent to the sample being taken only if to do so would not be detrimental to the incapable person's health.

When Part 6 of the Adults with Incapacity (Scotland) Act 2000 comes into force in April 2002, guardianship orders and intervention orders can be obtained from the sheriff court. Persons authorised under such orders will be able to take decisions, provided that they are within the scope of the powers that they have been given, on behalf of an adult with impaired capacity. In any case of doubt, legal advice should be sought. The new provisions for guardianship which will come into force in April 2002 will replace the office of tutor dativo (after a transitional period).

3. Authentication

In accordance with protocols agreed between samplers and testing organisations and subject to Regulations related to court directed tests, all samples to be tested must be supported by a reliable mechanism to establish and maintain the authenticity and integrity of the sample.

Required levels of training and competence for those taking samples should be incorporated into the standard operating procedures or operating requirements of the supplier.

Whenever possible, it is recommended that samplers use materials or kits supplied by organisations conducting tests. This may be important for a number of reasons including for validation and quality assurance purposes.

It is essential that for each sample that is tested, there are robust measures to ensure that the identity of the provider of the sample can be established and maintained.

Any method used to verify that samples relate to donors must be clear, robust and capable of being maintained.

The sampler should not be related to the sample giver, nor have any financial or personal interest in the outcome of the paternity test.

One common method requires each person being tested (including all children of whatever age) to provide two passport-sized photographs for identification purposes. These photographs should be surrendered to the sampler and retained for identification purposes with the samples. The sampler must sign that the photographs are a true likeness to the donor of the sample.

The photographs may form an integral part of a reliable “audit trail” linking the sample with the donor. In any dispute, it will be essential to be able to show that specific samples were taken from the person in the photograph.

It should be noted that additional measures may be required for criminal cases, for example to meet the requirements of the Police and Criminal Evidence Act 1984. Such measures are beyond the scope of this document.

4. Validation & Accreditation.

Organisations offering genetic paternity testing services to the public should use appropriate testing techniques and provide assured levels of accuracy and reliability.

They should carry out an internal quality assurance programme and be accredited to ISO / IEC 17025 standard by an accreditation body that meets the requirements of ISO Guide 58.

A reliable system should exist to validate the whole process including the selection and training of samplers, laboratory staff and support staff. The system should encompass the whole process from the provision of information to the public (whether written, oral or electronic), sampling procedures, laboratory techniques, equipment and materials through to the delivery of results.

It is recommended that all organisations offering genetic testing services should:-

Carry out an internal quality assurance programme and be accredited to ISO / IEC 17025 standard by an accreditation body that meets the requirements of ISO Guide 58. Continued registration with such a body will be dependent upon satisfactory audits being performed at regular intervals by the accreditation body to ensure continued compliance with the appropriate standards.

Ensure that a senior officer or manager is responsible for verifying staff competence and that, where appropriate, these standards are maintained by continuing training or experience.

Take part in a recognised external quality assurance scheme, such as that organised by the International Society of Forensic Genetics

Organisations offering genetic testing services should provide those taking samples on their behalf with protocols covering matters such as consent, confidentiality, the authentication of samples, information to be provided to donors etc.

To ensure that sampling techniques are universally applied and maintained, it is recommended that, those taking samples use testing kits provided by testing organisations and adhere to agreed protocols covering topics such as the provision of information to the parties to the test as well as the actual taking of the sample.

Suppliers must ensure that all reagents and materials used in their testing processes comply with statutory requirements.

Manufacturers must ensure that reagents and materials used in their testing processes comply with statutory requirements. The 'In Vitro Diagnostic Medical Devices Directive' may apply. Further information on the Directive is available from the Medical Devices Agency (see annex for details).

Where a Public Body or its agency commission tests, they will normally provide testing organisations with any particular requirements that they may have. These may cover such matters as: the authentication of samples, advice to be provided to the public, those providing consent for a sample to be taken, disclosure to a third party etc.

5 Confidentiality and Storage of Samples and Records.

Suppliers have a common law duty of confidence in respect of all the parties to the test. Storage and security of samples and data should be such as to ensure confidentiality.

Suppliers should inform the parties giving consent to the test of their procedures for ensuring that data remains confidential. Disclosure of test results will only be made to parties to the test and authorised third parties - for example the Child Support Agency in the case of tests arranged through that Agency. For further information see Annex B.

Before obtaining samples and personal information from those being tested, suppliers should inform the customer of their procedures for the secure storage and disposal of samples and records.

Suppliers should test samples and use identifiable data only for those purposes for which consent has been given.

All staff (including subcontractors) with access to samples or data should be bound by a code of confidentiality.

Samples and records should be retained for periods consistent with the nature of the test and the purposes to which the results are likely to be put.

Data Protection Act 1998

Organisations have a responsibility to ensure that any databases containing information related to individuals whether processed or stored on computer or in a manual filing system, are kept and processed in accordance with the data protection principles. This applies whether the database is structured either by reference to individuals or by reference to criteria related to individuals. There are many valuable and important judgements embedded in many areas of these principles and organisations will need to be confident that their processing or storage of personal information can be justified and defended.

An introduction to the Data Protection Act 1998 can be obtained from the office of the Data Protection Registrar.

Specimens and records should be retained for a reasonable period of time. The ability to recheck in cases where the test result is challenged is the only valid reason for suppliers to retain samples/data in an individually identifiable form. In the interests of security and of reducing the risk of unintended disclosure of confidential information, organisations should have in place protocols to regularly review the retention of samples and supporting data. Samples and data should not be retained indefinitely without good cause. As a guide, suppliers should retain test samples for a minimum of three months, and individually identifiable customer data for a minimum of twelve months from the notification of the test result to the customer.

NB. All parties to the test should note that this guidance may not apply in respect of tests that are undertaken as a part of investigations into alleged criminal offences.

Annex A

Members of the Ad Hoc Group on Genetic Paternity Testing Services

| | |
|--------------------------------------|--|
| Dr Jeremy Metters CB | (Chairman) |
| Dr R Bramley Dr A D Butler | Forensic Science Service Committee of Advertising Practice /Advertising Standards Authority |
| Mr N Carlton | Department of Social Security |
| Miss Karen Wynne | National Assembly for Wales |
| Mr J Creer Mr C Pipe | Lord Chancellor's Department |
| Dr Paul Debenham Ms Linda Hassell | University Diagnostics Ltd, |
| Ms Alison Garnham | National Council for One Parent Families |
| Dr Rosalind Skinner | Scottish Executive |
| Rev Dr John Polkinghorne KBE FRS | ex - ACGT, HGC Member. |
| Mr M Killen | Child Support Agency |
| Dr D Syndercombe Court, | St. Bartholomew's and the Royal London School of Medicine and Dentistry |
| Dr J Tann | Home Office |
| Mr Philip Webb | Retired General Manager, AstraZeneca Diagnostics and ex - ACGT, HGC member. |
| The Secretariat may be contacted at: | Department of Health 652C, Skipton House 80, London Road LONDON SE1 6LW Tel: 020 7972 1518 Fax: 020 7972 1717 E-mail: genetics-policy@doh.gov.uk |

Annex B. Organisations for further information, advice, personal and family support.

Citizen Advice Bureau

There is a local CAB in most towns. Details can be found in the telephone directory.

Child Support Agency
National Enquiry Line 0345 133 133
Monday to Friday 08.30am to 6.00pm.
:

Useful guidance may be found in
CSA 2001 - "For parents who live apart".
CSA 2090 - "GENETIC testing"
Obtainable from any Child Support Office.

Data Protection Registrar

Wilmslow, Cheshire.

www.dataprotection.gov.uk

Medical Devices Agency
Enquiry Line: 020 7972 8300

www.medical-devices.gov.uk

National Council for One Parent Families
Helpline. 0800 018 5026

255 Kentish Town Road,
London, NW5 2LX.

Relate - National Marriage Guidance Counselling line: 0870 601 2121.

The National Family and Parenting Institute

Parentline

Gingerbread

In Scotland

Scottish Law Centre
Tel 0131 667 6333

23 Buccleuch Place
Edinburgh, EH8 9LN

One Parent Families Scotland
Tel 0131 556 3899/4563

13 Gayfield Square
Edinburgh, EH1 3NX

Scottish Executive Justice Department
(For Family Law)
Tel 0131 244 2206
E-mail: paul.parr@scotland.gsi.gov.uk

Paul Parr
Civil Law Policy Branch
Spur V1, Saughton House
Edinburgh, EH11 3DX

Scottish Executive Health Department
(for policy on genetic paternity testing)
E-mail: nigel.lindsay@scotland.gsi.gov.uk

Nigel Lindsay
Public Health Division
3ES St Andrew's House
Regent Road
Edinburgh, EH1 3DG