Council, 10 December 2009

Application for the regulation of genetic counsellors by the Association of Genetic Nurses and Counsellors

Executive summary and recommendations

Introduction

At its meeting on 10 September 2009, the Council discussed an application for the regulation of genetic counsellors submitted by the Association of Genetic Nurses and Counsellors (AGNC).

The Executive scored the application as meeting the new professions criteria in all but two areas which were scored partly met:

7. Independently assessed entry qualifications: There is some independent assessment of entry qualifications and internal mechanisms in place for quality assuring the qualifications which are not independently assessed.

9. Disciplinary procedures to enforce standards of conduct, performance and ethics: There is a proposed disciplinary procedure but it has not been used.

The Council invited the AGNC to present at this Council meeting on its application.

The following are attached:

- Criteria for aspirant professions, reproduced from the guidance notes.
- Application by the Association of Genetic Nurses and Counsellors. (appendices are separately circulated)
- Presentation by the Association of Genetic Nurses and Counsellors.

Decision

The Council is invited, in light of the AGNC's presentation at this meeting and their written application, to consider whether it should recommend the regulation of the aspirant profession to the Secretary of State for Health under Article 3 (17) (a) of the Health Professions Order 2001.

Background information

None

Resource implications

None at this time

Financial implications

None at this time

Appendices
See previous page

Date of paper
30 November 2009

Each criteria to be addressed (taken from the Guidance Notes)

Part A of the assessment

The Council will first assess whether an occupation is eligible for regulation. Only those occupations involving at least one of the following activities are eligible:

- Invasive procedures
- Clinical intervention with the potential for harm
- Exercise of judgment by unsupervised professionals which can substantially impact on patient health or welfare.

Additionally, occupations where these activities are already regulated by other means will be ineligible. This includes occupations that already have a regulator (such as nurses and medical practitioners) or do not make independent clinical judgments. In general, the Council regulates health workers who are not otherwise supervised, practising autonomously, making professional and independent judgments on treatment, and taking full responsibility for their actions.

Part B of the assessment

The criteria that the Council will apply in Part B of the assessment were settled following a public consultation in the summer of 2002. The criteria will each have equal weight. Each occupation wishing to be regulated will be required to:

1) Cover a discrete area of activity displaying some homogeneity
2) Apply a defined body of knowledge
3) Practise based on evidence of efficacy
4) Have at least one established professional body which accounts for a significant proportion of that occupational group
5) Operate a voluntary register
6) Have defined routes of entry to the profession
7) Have independently assessed entry qualifications
8) Have standards in relation to conduct, performance and ethics
9) Have fitness to practise procedures to enforce those standards
10) Be committed to continuous professional development (CPD)

1. The occupation must cover a discrete area of activity displaying some homogeneity

This criterion covers **what a profession's scope of practice is**. The Council will assess applications for evidence that demonstrates that the applicant occupation practises activities that:

- Are distinctly its own
- Are common across the occupation
- Are distinct from the scope of practice of other occupations, although there may be some overlap.

2. The occupation must apply a defined body of knowledge

The *body of knowledge* criterion covers **what a profession does**. Frequently, the *body of knowledge* of a health profession will overlap those of other professions. However, each profession that the Council regulates has its own distinct *body of knowledge* and applications will not be successful if the Council considers that the applicant occupation has not provided sufficient evidence to demonstrate that it, too, has a distinct *body of knowledge*.

3. The occupation must practise based on evidence of efficacy

This criterion covers **how a profession practises**. The Council recognizes the centrality of evidence-based practice to modern health care and will assess applicant occupations for evidence that demonstrates that:

- Their practice is subject to research into its effectiveness. Suitable evidence would include publication in journals that are accepted as learned by the health sciences and/or social care communities
- There is an established scientific and measurable basis for measuring outcomes of their practice. This is a minimum—the Council welcomes evidence of there being a scientific basis for other aspects of practice and the *body of knowledge* of an applicant occupation
- It subscribes to the ethos of evidence-based practice, including being open to changing treatment strategies when the evidence is in favour of doing so.

4. The occupation must have at least one established professional body which accounts for a significant proportion of that occupational group

This criterion covers **how a profession has established itself**. The Council will assess applications for evidence that there is at least one established professional body. The Council will assess the application for evidence that membership of the body or bodies accounts for a significant proportion—at least 25%—of the occupation’s practitioners. Suitable evidence for the existence of established professional body or bodies would include:

- A constitution or rules
- Minutes
- Standing Orders for the body or bodies and committees
- Election Rules and results

Where there is more than one professional body or representative organization for an applicant occupation, the Council will additionally seek evidence that all the bodies are involved in, and supportive of, the application process. The Council would welcome evidence of the existence of a steering group with representatives from all the bodies, and that a fair and effective decision-making process is in place. The Council would expect to work primarily with such a steering group and would also expect evidence that the steering group, and not an individual professional body, was involved in drawing up the application for regulation.

The Council will require an attestation from the applicant that there are no professional bodies or other representative organizations in existence for the profession that have not been informed of the application.

The Council will also seek evidence that practitioners who do not belong to the professional body or bodies or representative organization(s) are also supportive of the application. If any of these practitioners are likely not to have followed the applicant occupation's entry routes as described in sections 6 and 7 below, then the Council will require information about likely grandparenting requirements.

5. The occupation must operate a voluntary register(s)

This criterion covers **how a profession accounts for its members**. The Council's Register is its primary mechanism for protecting the public. The Council will seek to assess whether workers in an applicant occupation have accepted the principles, benefits and obligations of registration, by enrolling on a voluntary register or registers. The Council will require evidence that the voluntary register(s) cover at least 25% of an applicant occupation's workforce. These requirements are a minimum and the Council would consider very favourably evidence of plans to inform an applicant occupation's practitioners of the consequences of regulation by the Council. Such plans should cover issues that will be of particular importance to those members, particularly:

- Regulation of the practice of the profession's members. As explained in the introduction, members of the profession will be subject to the Council's regulatory authority, which it will exercise to protect the public.
- Arrangements for applying for entry to the Council's Register
- Protection of title
- Fees and other potential financial implications

The Council has published leaflets on these topics.

6. The occupation must have defined routes of entry

This criterion covers **how a profession ensures its practitioners have the requisite knowledge and skills on entry**. The Council will assess evidence of how entry to the applicant occupation is controlled. The Council will seek evidence that only individuals who have chosen defined routes of entry are recognized as being practitioners of the profession, in the eyes of educational institutions, employers, professional bodies and (where appropriate) the public at large. The Council will also assess evidence that the applicant occupation either already has a Subject Benchmark from the Quality Assurance Agency or equivalent body, or intends to work towards one as part of the process of becoming a regulated profession.

7. The occupation must have independently assessed entry qualifications

This criterion covers **how a profession ensures its recognized qualifications are valid**. The Council will require evidence that there are qualifications that are recognized as being a necessity for entry to the profession, awarded by recognized educational institutions and independently assessed and monitored through a system of quality control.

8. The occupation must have standards of conduct, performance and ethics

This criterion covers **how a profession ensures high standards**. The Council will assess evidence that an applicant occupation has written standards of conduct, performance and ethics, covering the behaviour it expects of practitioners. The standards should cover similar ground to the Council's standards, and include health, character and competence, among other topics.

9. The occupation must have fitness to practise procedures to enforce those standards

This criterion covers **how a profession polices the behaviour of its practitioners**. The Council will assess evidence that an applicant occupation has a system for disciplining practitioners on its voluntary register (including striking-off) when it is determined that they are unfit to practice by reason of:

- Incompetence
- Misconduct
- Health

The Council will also assess evidence that breaches of the applicant occupation's code of ethics are taken into account when deciding whether a practitioner is unfit to practise. The Council will assess evidence of written procedures covering the administration of the system, and requires applicant occupations to submit anonymised information regarding cases that have been dealt with through the system.

10. The occupation must require commitment to continuous professional development (CPD)

This criterion covers **how a profession ensures its practitioners engage in life-long learning**. The Council is committed to the principles underpinning CPD, and will be requiring all registrants to undertake CPD from August 2005. Many of the currently regulated professions run CPD schemes at present. The Council will therefore be seeking evidence from applicant occupations that they are also committed to the principles of CPD. Suitable evidence would include written details of planned or existing CPD schemes.

ACKNOWLEDGEMENTS

This draft application for the regulation of the Genetic Counselling profession by the Health Professions Council has been assembled by members of the Genetic Counsellor Statutory Regulation Steering Group (GCSRSG), a Working Group of the UK Association of Genetic Nurses and Counsellors (AGNC).

The group have received help and advice from a number of colleagues. In particular, we would like to offer our special thanks to the following for their important and invaluable contributions:

Anna Middleton
Pat Finnemore
Marion McAllister
Kathy Barnes
Gilly Bromilow
Heather Skirton

We would also like to acknowledge the helpful advice and ongoing support received from Michael Guthrie and Rachel Tripp at the HPC, to whom we offer our grateful thanks.

GCSRSG members:
Georgina Hall (Manchester) (Chair)
Jan Birch (Liverpool)
Sarah Durell (Oxford)
Chris Jacobs (London)
Chris Patch (London)
Lesley Snadden (Glasgow)
Chris Barnes (London)

Address for correspondence:
Georgina Hall
GCSRSG Chairperson and Principal Genetic Counsellor
Genetic Medicine
Manchester Academic Health Science Centre
Central Manchester University Hospitals NHS Foundation Trust
St Mary's Hospital
Oxford Road
Manchester M13 9WL
Georgina.Hall@cmft.nhs.uk

Glossary of terms frequently used in the application

Genetic counsellor: Genetic counsellor is the title given to practitioners of the genetic counselling profession. The term ‘genetic counselling’ was first coined by Sheldon Reed in 1947, who sought to emphasise a non-directive rather than eugenic approach to Human Genetics (Reed 1955, Reed 1974, Anderson 2003). In the UK, genetic counselling was first established in 1951 at The Hospital for Sick Children, Great Ormond Street, London, and now plays an important role in many aspects of health care. Genetic counsellors work alongside medical geneticists in Regional Genetics Units with patients and families at high risk of genetic disease. The title ‘genetic counsellor’ has been recognised within the NHS as a distinct profession with its own Agenda for Change job profile.

Important note:
The professional title “Genetic Counsellor” is recognised internationally (for example by the National Society for Genetic Counselors in the USA, the Canadian Association of Genetic Counsellors and the Human Genetics Society of Australasia). The Transnational Alliance of Genetic Counselling is attended by genetic counsellors from across the world (e.g. Chile, China, Japan, South Africa, Europe) and meets annually to discuss training and professional issues.

Although genetic counselling is an international profession, only a small number of countries provide formal courses in genetic counselling (Begleiter, 2002). In the UK, formal training with a Masters Degree in Genetic Counselling was first established in 1992 and formal registration (accreditation) of genetic counsellors began in 2002.

As the professional title ‘genetic counsellor’ has been in practice since the 1950’s, is internationally recognised and is distinct within the NHS, we consider it appropriate for this to become a protected professional title.

Trainee Genetic Counsellor: Prior to registration, a trainee genetic counsellor must complete at least two years of clinical experience and training. Trainee genetic counsellors must fulfil the minimum entry-level qualifications as described in Section 9.

AGNC: **The Association of Genetic Nurses and Counsellors**
This is the professional organisation for genetic counsellors in the UK. Section 4 gives more details of the history of the Association. *(See Appendix G1 for general information and Appendix G2 for the Constitution).* Membership is open to clinical and research workers and educators in genetic counselling as well as other professionals with an interest in the field. At the time of writing, the AGNC had 315 members.

GCRB: **The Genetic Counsellor Registration Board**
Formed in 2001, this elected Board is responsible for the Voluntary Register of Genetic Counsellors. To become registered, genetic counsellors must complete an assessment process involving a Masters level portfolio and interview (see Sections 9 and 10). The GCRB has recently become a Registered Company (Company House Registration No. 06963771).

GCRB Certificate of Registration: Award of successful registration by the GCRB.

GCSRSG: **The Genetic Counsellor Statutory Regulation Steering Group**
An independent working group set up on behalf of genetic counsellors by the AGNC. The aim of the group is to put together an application to the Health Professions Council. The group comprises experienced genetic counsellors and includes representatives from both the GCRB and AGNC Committee.

References used in Glossary

Anderson VE (2003). Obituary: Sheldon C Reed, Ph. D (November 7, 1910 – February 1, 2003) Genetic Counseling, Behavioral Genetics. *Am J Hum Genet* 73: 1-4

Begleiter, ML (2002). Training for genetic counsellors. *Nat Rev Genet 3*: 557-61.

Reed, SC (1955) Counseling in Medical Genetics. W.B. Saunders Company, Philadelphia

Reed, SC (1974) A short history of genetic counselling *Soc. Biol*. 21: 332-339

Websites

Canadian Association of Genetic Counsellors: www.cagc-accg.ca

Human Genetics Society of Australasia: www.hgsa.com.au

National Society for Genetic Counselors: www.nsgc.org

Transnational Alliance of Genetic Counselling: http://tagc.med.sc.edu/

Appendices to Glossary

Appendix G1: General information about AGNC (*www.agnc.org.uk/About%20us/aboutagnc.htm*)

Appendix G2: AGNC Constitution (revised 2004) (*www.agnc.org.uk/About%20us/constitution.htm*)

Part A: Assessment of whether an occupation is eligible for regulation.

INTRODUCTORY COMMENTS TO APPLICATION

Potential for harm

Genetic counsellors are responsible for interpreting family history, calculating genetic risk, organising genetic tests and interpreting complex test results. At the minimum, genetic counsellors are working with individuals and families at vulnerable and emotional times. Many families attending genetic services have bereavements and loss in their family, such as:

- early deaths from cancer
- diagnosis of a disability or a progressive genetic condition in themselves or their family or
- loss of a child or pregnancy.

Individuals, couples and families attend the genetic service for accurate information and support around decision-making. The skills of a genetic counsellor include:

- decision making around reproduction, pre-natal testing and continuing with or terminating an affected pregnancy
- breaking bad news
- facilitating adjustment to the risk of a genetic condition (such as sudden cardiac death, progressive neurological conditions, muscular dystrophy)
- making appropriate referrals on the basis of genetic risk, such as cancer screening or cardiology investigations for women who carry a muscular dystrophy gene.
- predictive genetic testing in which individuals chose to have a genetic test revealing significant health risks in the future such as hereditary breast cancer or Huntington's Disease

Genetic counsellors must keep up to date with rapidly advancing molecular research and medical screening and management that requires the ability to critically analyse research at a Masters level (see *Appendix 5.2* in genetic counsellor competencies)**.** Lack of information or misinterpretation of information can have significant implications for couples and families. Examples might include misinterpretation of a prenatal test result leading to unnecessary termination of pregnancy, misinterpretation of cancer risks leading to unnecessary prophylactic surgery (e.g. mastectomy to remove healthy breasts to prevent breast cancer) or false reassurance without screening and management for an individual at high risk. Ethical issues also play a very important role in genetics including confidentiality amongst family members, non-paternity, adoption, responsibility to support families in sharing genetic risk information and informed consent for genetic testing.

Expansion of genetics into wider public health care

The profession of genetic counselling is rapidly expanding. Clinical genetics now plays a role in many areas of health care. Indeed, many health professionals use discrete aspects of genetics in their role. Examples would include screening midwives who discuss amniocentesis and testing for Down syndrome, cancer nurses who offer low and moderate risk screening for women with a family history of breast cancer. Most of these services act as triage for appropriate referral of high risk / complex genetic families to the regional genetic counselling services. Antenatal screening midwives do not have the expertise to interpret complex chromosome results and couples require accurate genetic counselling before deciding whether to continue with a pregnancy. However, there are concerns that if the title of genetic counsellor is not protected, other health care providers could use the title to describe the discrete area of their work. The public would not be able to distinguish the specialist skills of the genetic counsellor from other health professionals with limited areas of knowledge.

Private genetic services

Private genetic testing laboratories are increasing within the UK. Concerns have been raised about private testing for genetic predisposition direct to the public (see *Appendix A1* **and** *Appendix A2***)**.

One option that might be considered to make the provision of genetic tests in this way more acceptable is to provide appropriate genetic counselling with the tests. Private laboratories are likely to expand particularly in areas such as pharmacogenetics and susceptibility testing. Many of these private laboratories offer support and information and we believe some offer the services of a genetic counsellor. Anecdotally a number of genetic counsellors in the UK have been approached recently to work in a private health screening company offering susceptibility testing for genetic markers associated with breast cancer. If genetic counsellors do move to work in the private sector, they will be isolated from the NHS multidisciplinary genetic services and employment and practice will be unregulated. If the profession remains unregulated there remains the possibility of individuals without appropriate training and expertise being employed as genetic counsellors, which has implications for the protection of the public.

The need for statutory regulation of genetic counsellors

Genetic counsellors are taking an increasingly autonomous role in genetic services. Whilst good practice and regional services support multidisciplinary "team-based" regulation, increased training and competency of the genetic counselling profession alongside increasing referral and patient demand for genetic services has lead to more independent working, in not only large centres, but in community settings and potentially private practice.

The GCSRSG have considered alternative regulation. Having achieved 8 years of voluntary registration, this has the disadvantage that competent practitioners take pride in achieving registration, whereas those with incomplete training or lacking skills may avoid registration, putting the public more at risk. A voluntary register does not hold the statutory, legal strengths that can be enforced by the HPC. A GCRB disciplinary procedure holds no legal statute. Professionals investigated and deemed incompetent could remain in employment. Registration becomes an academic achievement but individual trusts would have no obligation to recognise or enforce this level of competency achievement.

Employer-led regulation would involve the statutory requirement of employers to ensure staff are registered and appropriately trained. Our experience to date has been that many NHS Trusts have a very poor understanding of the value and purpose of voluntary registration and many have tried to fill vacant posts with less qualified staff. If a comprehensive system of employer-led regulation was brought into the NHS, it could not be enforced in the private sector.

Neither of these forms of regulation protects the title "genetic counsellor." Other professional groups could choose to use the title causing confusion and risk to the public.

Our voluntary register has given our profession the opportunity to structure training, skills and competencies for genetic counsellors entering the profession from different backgrounds. Statutory recognition of this process will allow the register to be fully operational with disciplinary procedures. Without statutory regulation and employer recognition of the competencies demonstrated by registration, our voluntary register is likely to be unsustainable in the long-term. A voluntary register may not be expensive to the tax payer, but is extremely costly in terms of professional time and relies heavily on the good will of individuals running the registration process. In a small profession such as genetic counselling, this is a particular challenge.

Unregulated Genetic Counsellors in practice in the UK

The importance of regulation for genetic counsellors is highlighted by a reducing proportion of genetic counsellors in the UK who are regulated practitioners. Historically, genetic counsellors were either 'genetic nurses' or 'genetic social workers' but the introduction of formal training (MSc Genetic Counselling) has lead to increasing numbers of unregulated genetic counsellors. To date (June 2009), only 37% of trainee genetic counsellors within the current Department of Health funded scheme have a prior professional qualification and current registration. The remaining 63% of trainees had an academic (unregulated) background (see Section 7). This trend predicts an increasing proportion of unregulated genetic counsellors in the future. In addition, of the 11% of genetic counsellors due to retire in the next 5 years (AGNC census), 93% have a nursing background.

In this way, the demographics of the genetic counselling profession are changing, with increasing numbers of unregulated genetic counsellors practising in the UK.

Success of Genetic Counsellor Voluntary Registration

The assessment portfolio for registration of genetic counsellors has been highly supported, with nearly half of all genetic counsellors in the UK opting to complete their portfolio as a voluntary demonstration of competency. Section 8 demonstrates the high proportion of regulated nurses/midwives now practising as genetic counsellors completing the written and interview assessment to become registered genetic counsellors. There is widespread recognition of the unique set of competencies and a commitment to further the training of genetic counsellors with the GCRB Certificate of Registration.

Appendices to Part A

Appendix A1: HGC statement on private genetic testing services

Appendix A2: European ethical guidelines weigh in against mail order genetic tests 25 October 2007

Appendix 5.2: Competency base for current registration system for genetic counsellors

SECTION 1: Contact details

Name of main contact	Georgina Hall **(Registered Genetic Counsellor and Chair of Genetic Counsellor Statutory Regulation Steering Group, Association of Genetic Nurses and Counsellors)**
Address	Genetic Medicine Manchester Academic Health Science Centre Central Manchester University Hospitals NHS Foundation Trust St Mary's Hospital Oxford Road Manchester
Postcode	M13 9WL
Country	UK
Main telephone number	0161 276 4150
Fax number	0161 276 6145
Email address	Georgina.Hall@cmft.nhs.uk
Website address	www.agnc.org.uk
Name of applicant occupation/ title for protection	Genetic Counsellor

SECTION 2: Previous applications

Please indicate if this is the first time that the occupation has applied to be regulated by the predecessor, the CPSM.

Yes.

As an emerging profession, genetic counselling has not yet been considered for statutory regulation. Two decades ago, all professionals practising in the field were nurses and therefore regulated. However, the scope of practice and emerging skills mix means that genetic counsellors are now a discrete autonomous group that require separate regulation. The White Paper Trust Assurance and Safety (*Department of Health 2007)* names genetic counsellors as an emerging professional group that may be eligible for regulation by the HPC.

Reference to Section 2

Department of Health (2007). Trust, Assurance and Safety – The Regulation of Health Professionals in the 21st Century (Cm 7013).

SECTION 3: Consideration of alternative routes to regulation

Has the applicant occupation considered seeking explored regulation as a distinct subsection within a profession already being regulated and if so have you rejected this route?

Yes.

If so, what were the reason(s) for rejection of alternative route?

Unlike counsellors and psychotherapists, genetic counsellors are not fully trained in therapeutic counselling although they use counselling skills in their practice. All genetic counsellors have training in counselling skills and theory and some have also completed a diploma in counselling. Genetic counsellors use counselling skills and interventions for the effective delivery of appropriate, sensitive information and to support decision-making and facilitate adjustment. However, they do not work therapeutically with clients, in the sense of a humanistic approach of changing a client's "way of being". Genetic counsellors do not contract for sessions but will refer patients for psychological therapy if issues arise such as the need for bereavement counselling. In this way, the education and training of genetic counsellors and the nature of the work is very different to counsellors and psychotherapists.

We have explored other groups of health related counsellors such as the infertility counsellors. However, we understand the core nature of their work is grounded around therapeutic counselling and although they have a specific patient group, their education and training aligns with counsellors and psychotherapists.

We have not been able to find any other groups of clinical or scientific professionals who use counselling as their intervention to provide scientific and clinical management for patients who are currently seeking regulation.

Has the applicant occupation considered joining other unregulated occupations in a similar field who are currently seeking HPC regulation or may do so?

Yes (please see answer to above question in Section 3).

SECTION 4: The occupation must cover a discrete area of activity displaying some homogeneity

Please define the applicant occupation's scope of practice in terms of activities practised.

Clinical genetics can be defined as a specialist area of healthcare aimed at addressing the physical, psychological, cognitive, emotional or social needs of an individual or family affected by or at risk of a genetic condition (*Skirton & Patch 2002, Skirton, Patch & Williams 2005, Skirton & Patch 2009).* In the UK, clinical genetics is now well established and delivered by the NHS through specialist Regional Genetics Centres. Each centre employs a multidisciplinary team involving doctors (clinical geneticists), genetic counsellors, administrative staff and scientists and covers a population of between 3 and 5 million people. The clinical component is an outpatient-based specialty although patients are also seen on wards, in other locations including GP surgeries, and in the family home *(Temple & Westwood 2006).*

The first non-medical genetic counsellor in the UK was appointed in 1959. By 1980, about 20 genetic counsellors (mostly experienced nurses with no genetics training) were in post. At that point, an informal professional group was formed, which aimed to help genetic counsellors improve genetic healthcare care of families through the exchange of ideas and information and to establish appropriate education for members in clinical genetics departments. Two years later, the Genetic Nurses and Social Workers Association (GNSWA) was formed, the name reflecting the professional backgrounds of the practitioners of the time. In 1983, when closer links between medical geneticists and genetic counsellors were being established in many centres, the GNSWA was invited by the Clinical Genetics Society (CGS) to become an affiliated body with representation on the CGS Council.

In 1996, the British Society for Human Genetics (BSHG) became the umbrella organisation for the various professionals groups involved in the provision of clinical genetics services, including the GNSWA. However, by this time, graduates from the first UK MSc Course in Genetic Counselling (established in 1992 at the University of Manchester) were joining clinical genetic teams. Most of these graduates had a scientific background instead of health professional training and, in 1998, the GNSWA changed its name to the Association of Genetic Nurses and Counsellors (AGNC) in recognition of the different entry roots into the profession.

Currently (October 2008), the AGNC has 300 members. A survey of Regional Genetic Services undertaken in August 2008 identified 253 individuals practising under the title Genetic Counsellor. Of these, 91% were members of the AGNC, 62% had a health professional background and 38% had an academic non-health professional background. At the time of writing, 109 genetic counsellors have undertaken voluntary registration, now a well-established and unifying process. The 2003 White Paper (*Department of Health 2003)* on genetic services acknowledged UK genetic counselling as an "emerging profession…. (with a)… strong professional identity", and recognised the need to increase training capacity by funding of a national Scheme for new clinical training posts in genetic counselling.

In recent years, most Genetic Centres have experienced a substantial increase in the number of genetic counsellors employed and in the number of patients seen by genetic counsellors working as autonomous practitioners. For example:

- Guy's and St Thomas' NHS Foundation Trust Genetics Centre reported an increase of 184% in the number of genetic counsellor appointments between 2003/2004 (n=1328) and 2007/2008 (n=2522), during a period when there was only an 8% rise in genetic counsellors employed (7.7 FTEs in 2003/4 to 8.3 FTEs in 2007/8) *(Patch 2008, personal communication).*

- There has been an increase of 162% in the number of WTE trained genetic counsellors in the Regional Genetics Service in Manchester over the last 10 years, with genetic counsellors providing the majority of the post-diagnosis genetic counselling (see *Appendix 4.1*).

- Liverpool Women's NHS Foundation Trust reported an increase of 276% in the number of WTE trained genetic counsellors between 1998 and 2008 (see *Appendix 4.2*).

The **scope of practice** of genetic counsellors can be described as thus:

- ❑ Collect and interpret comprehensive client information, including medical, psychological and genetic family history.
- ❑ Make appropriate and accurate genetic risk assessments.
- ❑ Use therapeutic counselling and communication skills with clients to help them*:
    - comprehend medical facts about a genetic disorder.
    - appreciate the way heredity contributes to the disorder, and the risk of recurrence in specified relatives.
    - understand options for dealing with the risk of recurrence.
    - choose the course of action that seems to them appropriate.
    - make the best possible adjustment to the disorder in an affected family member and/or the risk of recurrence of that disorder.
- ❑ Make psychosocial assessments of client need, providing support and referral to other agencies as appropriate.
- ❑ Plan, organise and deliver professional and public education in genetic healthcare.
- ❑ Serve as a genetic healthcare resource for professionals and the general public.
- ❑ Liaise with other members of the genetics multidisciplinary team to provide optimum services for clients.

(based upon 1975 American Society of Human Genetics statement, which remains the most commonly accepted and used definition of genetic counselling)*

The professional roles of UK genetics clinicians (Clinical Geneticists and Genetic Counsellors) were the focus of a Working Party of the Clinical Genetics Society and the Association of Genetic Nurses and Counsellors, which reported in April 2006. Some overlap between the respective scopes of practice of geneticists and genetic counsellors were noted and commended, in an attempt to clarify care pathways in clinical genetics practice. The limitations of the genetic counsellor role in situations where medical input might be considered to be critical (e.g. where a genetic diagnosis is unknown or unclear) are discussed in the Working Party's report (*Appendix 4.3*). However, the skills of a genetic counsellor are described as "particularly appropriate when the need for medical input is small, previously met or met elsewhere …. when the primary requirement is for counselling intervention such as facilitating decision making in pregnancy or around genetic testing …. (and) ….in the follow up of patients, particularly those with genetic disease *(CGS/AGNC 2006).*

Are there professions we currently regulate with whom the scope of practice overlaps?

YES. Certain parts of the genetic counsellor scope of practice overlap with some clinical scientists (see below).

If yes, please provide evidence showing how the applicant occupation's scope of practice is distinct.

One of the Clinical Scientists modalities is Clinical Genetics. Clinical Scientists in this modality include Cytogeneticists, Molecular Geneticists and Genetic Biochemists. As part of the genetics multidisciplinary team, Clinical Scientists perform laboratory tests that enhance genetic risk assessment and liaise closely with the clinicians who counsel families. They also deliver professional (and occasionally public) education in genetic healthcare and serve as a genetic health resource for professionals.

However, the central difference between the scopes of practice of genetic counsellors and clinical scientists is that genetic counsellors have **direct contact** with clients and their families.

References to Section 4

American Society of Human Genetics Ad Hoc Committee on Genetic Counseling (1975) Genetic Counseling. *Am J Human Genet* 27: 240-242

Department of Health (2003) Our Inheritance, Our Future. Realising the potential of genetics in the NHS (Cm 5791-II)

Skirton H and Patch C (2002) Genetics for Healthcare Professionals. Oxford, Bios.

Skirton H and Patch C (2009) Genetics for the Health Sciences: A Handbook for Clinical Healthcare. Oxford, Scion.

Skirton H, Patch C and Williams J (2005) Applied Genetics in Healthcare. New York & London, Taylor & Francis.

Temple I.K and Westwood G (2006) Do Once and Share: Clinical Genetics. Department of Health Connecting for Health Programme *(www.bshg.org.uk/documents/official_docs/DOAS_final_printed_report[1].pdf)*

Working Party of the Clinical Genetics Society and the Association of Genetic Nurses and Counsellors (2006) Professional Roles in the Multidisciplinary Team in Genetics: A Framework for Practice.*(www.clingensoc.org/Docs/WP_AGNC_CGS.pdf)*

Appendices to Section 4

Appendix 4.1: 18.08.08 Letter from Bronwyn Kerr, Consultant Clinical Geneticist, Central Manchester and Manchester Children's University Hospitals NHS Trust

Appendix 4.2: 31.07.08 Letter from Gail Mannion, Principal Genetic Counsellor/ Team Leader, Liverpool Women's NHS Foundation Trust, Central Manchester and Manchester Children's University Hospitals NHS Trust

Appendix 4.3: Clinical Genetics Society and the Association of Genetic Nurses and Counsellors. (2006) Professional Roles in the Multidisciplinary Team in Genetics: A Framework for Practice. *Report of a Working Party.(www.clingensoc.org/Docs/WP_AGNC_CGS.pdf)*

SECTION 5: The occupation must apply a defined body of knowledge.

Please attach evidence of applicant occupation's body of knowledge

The past two decades have seen an exponential increase in the demand for genetic counselling services alongside the enormous advances in genetic science. Although accurate genetic counselling relies on a firm medical diagnosis, accepted definitions of genetic counselling also emphasise the educative and counselling components.

Genetic counselling is a communication process which deals with the occurrence, or risk of occurrence, of a genetic disorder in a family. There are recognised programmes of genetic counselling training which develop the knowledge and skills necessary to fulfil these roles. These include modules in the medical and scientific aspects of human genetics, genetic risk assessment, communication and counselling skills and consideration of the ethical legal and social aspects of genetics as applied to health.

Genetic counsellors particularly contribute to the educative and psychosocial aspects of genetic counselling. Masters level genetic counselling training programmes have existed in North America for over 25 years, and there are two programmes within the UK at Manchester and Cardiff that equip individuals with the skills and knowledge that together with clinical experience provide the basis for registration. The course content is outlined in *Appendix 5.1*. For full details of the course content, please see:

- www.medicine.manchester.ac.uk/postgraduate/taught/geneticcounselling
- http://coursefinder.cf.ac.uk:80/postgraduate/course/detail/875.html

Genetic counselling can act as a bridge between the science of genetics and the understanding and feelings of its clients. It can help clients to choose the course of action that they regard as most appropriate in the light of their objective situation while taking account of their personal and family goals. It can help clients make the best possible adjustment to the disorder in an affected family member and/or to the risk of recurrence of the disorder. This requires a body of knowledge that is specific to the practice of genetic counselling. There is international recognition of genetic counsellors as a separate profession combing the scientific knowledge of genetics and health with risk assessment and counselling and education [*Begleiter (2002), Saharr et al (2005), and Weil (2000)*].

The current registration system for genetic counsellors is competency based and the competencies are summarised below. Full details are available in *Appendix 5.2.*

- THE CLIENT/COUNSELLOR RELATIONSHIP

Establish and maintain a relationship with clients through effective communication, which promotes clients' goodwill, trust and confidentiality and shows particular concern for their personal beliefs and values.

Take a flexible and client centred approach to identifying and responding to emerging needs, working with the client to facilitate and support decision making

- MANAGEMENT AND ORGANISATION OF CARE

Maintain comprehensive, accurate and objective records of all client contact in a systematic manner that facilitates best practice and manage care to maximise the use of local, regional and national resources.

- PROFESSIONAL AND ETHICAL PRACTICE

Promote knowledge and understanding of the impact of genetics on health and facilitate access to genetics services through effective communication and education.

Recognise the duty of care by maintaining professional behaviour and boundaries, in keeping with accepted codes of ethical practice.

- PROFESSIONAL AND PERSONAL DEVELOPMENT

Seek at all times to maintain and improve service delivery and professional standards by promoting evidence-based practice for oneself and others through continual professional development.

Genetic counsellors are increasingly holding their own caseload of clients and are working alongside their medical colleagues applying their particular skills and knowledge *(Temple and Westwood 2006)*. The separate and defined body of knowledge that is used in genetic counselling is recognised by the Department of Health, which has funded training programmes based on the voluntary competency based registration system.

Are there professions currently regulated by the HPC with whom the applicant occupation's body of knowledge overlaps?

YES

If yes, please provide evidence showing how the applicant occupation's body of knowledge is distinct.

Clinical scientists (molecular genetic scientists and cytogeneticists) perform and interpret laboratory analyses however they do not see patients.

Although nurses are not regulated through the HPC some genetic counsellors working in the UK are registered nurses. The Nursing and Midwifery Council (NMC) would not be an appropriate route for registration for the non-nurse genetic counsellors as they would have to meet the standards required of the NMC, necessitating education and training as a nurse. Nurses need to have knowledge of genetics as applied to their practice, but it is well recognised that they do not have the advanced level scientific knowledge or counselling skills relevant to genetic counselling (*Kirk et al 2008)*. The competencies and skills that are set out in the voluntary registration process would not be met through current nurse training.

References to Section 5

Begleiter, ML (2002). Training for Genetic Counsellors. *Nat Rev Genet 3*: 557-61.

Kirk M, Tonkin E, Burke S. (2008) Engaging nurses in genetics: the strategic approach of the NHS National Education and Development Centre. *J Genet Counsel 17***:** 180-8.

Saharr MA et al (2005). Educating Genetic Counsellors in Australia: Developing an International perspective. *J Genet Counsel 14*: 283-294.

Temple I.K and Westwood G (2006) Do Once and Share: Clinical Genetics. Department of Health Connecting for Health Programme *(www.bshg.org.uk/documents/official_docs/DOAS_final_printed_report[1].pdf)*

Weil J (2000). Psychosocial Genetic Counseling. New York, Oxford University Press.

Appendices to Section 5

Appendix 5.1: Course details: UK MSc Genetic Counselling, Manchester University and Cardiff University.

SECTION 6: The occupation must practise based on evidence of efficacy.

Please provide evidence of research into the efficacy of the applicant occupation's practice. You are encouraged to attach copies of articles published in journals accepted as learned by the health sciences community.

Genetic counselling is a relatively young profession with a growing body of knowledge. Evidence of this is outlined below in reference to peer reviewed journal publications and genetic counselling textbooks. In addition, genetic counsellors regularly present original research at national and international meetings.

The majority of clients seen for genetic counselling are the 'worried well', i.e. they are currently healthy but at risk from inheriting, developing or passing on a condition to their children. One of the main objectives of genetic counselling is information giving *(Clarke et al 1996, Wang et al 2004)*, tailor-made to the client's personal situation. Within a patient-centred approach, genetic counselling offers information to help clients make decisions about their situation (see previous sections). As this process is communication based, usually with no pharmacological or other intervention *(McAllister et al 2007a, 2007b, 2008a, 2008b)*, it is well recognised that identifying appropriate outcome measures for genetic counselling is difficult *(Wang et al 2004, Biesecker and Peters, 2001)*. For these reasons it is not surprising that generic measures of health status and quality of life are not often used in evaluations of genetic counselling *(Wang et al 2004)*.

McAllister et al (2007a, 2007b; 2008a, 2008b) provide an overview of research evidence on efficacy of genetic counselling: "There is evidence that genetic counselling is effective in educating clients about inheritance and recurrence risks" *(Wang et al 2004, Evans et al 1994, Somer et al 1988, Wertz et al 1986)*. Some studies using satisfaction after genetic counselling as outcome measure have indicated high levels of satisfaction *(Wang et al 2004, Shiloh et al 1990, Tercyak et al 2001)*. Levels of depression and anxiety have been used in a number of outcome studies (*Wang et al 2004, Bish et al 2002, Julien-Reynier et al 1999)* but in cases where bad news is given, it is often appropriate for people to feel anxious or depressed, at least in the short-term. Outcomes may change significantly over time as individuals and families adapt to their situation (*Chapple et al 1995)*. Decisions about whether to undergo genetic testing, or whether or not to have children, have been investigated as possible outcomes. This approach has been criticised because in most cases these decisions cannot be considered right or wrong *(Clarke et al 1996, Wang et al 2004)*."

Since identification of the BRCA1 and BRCA2 genes that predispose to breast cancer, there has been an increasing demand for cancer genetic counselling. Although genetic counsellor registration includes both cancer and general genetic counselling, the increasing demand for cancer genetic counselling has lead to specialisation of some genetic counsellors and the appointment of senior roles in the profession, such as that of Consultant Genetic Counsellor in Cancer Genetics *(Jacobs 2008)*.

Several studies have explored the psychological impact of genetic counselling and testing for cancer predisposition. This work has lead to changes in clinical practice, for example, whilst early studies demonstrated little impact of genetic counselling on anxiety and cancer risk perception amongst women at high risk of breast cancer (*Watson et al, 1999)*, a more recent study by *Watson et al (2005)* concluded that genetic counselling had a positive impact on the management of breast cancer risk. The timing and communication of genetic information is another area where practice has changed as a result of research. For example, *Ardern-Jones et al (2005)* explored the impact of genetic testing at the time of breast cancer diagnosis and *Bish et al (2002)* looked at the impact of giving preliminary and incomplete genetic test results. Studies are ongoing in this area.

Genetic counsellors have played a key role in developing genetics services in the UK and several pilot studies have suggested that integrating genetics services into primary care will be effective. *Westwood et al (2006)* reported the results of a pilot study offering genetic counselling appointments in a primary care setting, showing that patients were more likely to attend the appointments and were satisfied with the location of the clinic. Further pilot projects funded by the Government White Paper 'Our inheritance your future' *(Department of Health 2003)* have continued to demonstrate high levels of satisfaction and improved access, in particular to minority groups *(Gulzar et al 2007; Jacobs et al 2007; Srinivaser et al, 2007).* Another example of genetic counsellors' involvement in developing genetics services is the 'DiaLGEN project' *(Appendix 6.1)* based in Liverpool which has successfully developed links between genetics and other agencies such as fetal medicine, adult haematology and cardiology units.

Whilst at present there is no clear consensus about appropriate measures of genetic counselling practice that indicate efficacy, research is on going to address this (McAllister et al 2007a; 2008a, 2008b, Payne et al 2006a, 2006b, 2007; 2008) and new opportunities are emerging for this developing profession.

References to above part of section 6:

Ardern-Jones A, Kenen R, Eeles R (2005) Too much, too soon? Patients and health professionals' views concerning the impact of genetic testing at the time of breast cancer diagnosis in women under the age of 40. *Eur J Cancer Care 14* (3), 272-281.

Biesecker BB, Peters K (2001) Process studies in genetic counseling: peering into the black box. *Am J Med Genet 106*, 191-198.

Bish A, Sutton S, Jacobs C, Levene S, Ramirez A, Hodgson S (2002) Changes in psychological distress after cancer genetic counselling: a comparison of affected and unaffected women. *Brit J Cancer 86*, 43-50.

Bish A, Sutton S Jacobs C, Levene S, Ramirez A, Hodgson S (2002) No news is (not necessarily) good news: impact of preliminary results for BRCA1 mutation searches. *Genet Med 4*(5), 353 – 358.

Chapple A, May C, Campion P (1995) Lay understanding of genetic disease: A British study of families attending a genetic counselling service. *J Genet Counsel 4*(4), 281-300.

Clarke A, Parsons E, Williams A (1996) Outcomes and process in genetic counselling. *Clin Genet 50*, 462-469.

Department of Health (2003) Our Inheritance, Our Future. Realising the potential of genetics in the NHS (Cm 5791-II)

Evans DG, Blair V, Greenhalgh R, Hopwood P, Howell A (1994) The impact of genetic counselling on risk perception in women with a family history of breast cancer. *Brit J Cancer 70*, 934-938.

Gulzar Z, Goff S, Njindou A, Hearty H, Rafi I, Savage R, Matta G, Ferras J, Hodgson S. (2007) Nurse-led cancer genetics clinics in primary and secondary care in varied ethnic population areas: interaction with primary care to improve ascertainment of individuals from ethnic minorities. *Familial Cancer 6*(2), 205 – 212.

Jacobs C, Rawson R, Campion C, Caulfield C, Heath J, Burton C and Kavalier F (2007) Providing a community based cancer risk assessment service for a socially and ethnically diverse population. *Familial Cancer 6*(2) 189 – 195.

Jacobs C (2008) Genetic counselling about cancer genetics in the UK and the role of the consultant genetic counsellor. *European Oncology Nursing Society Newsletter*, Summer, 16-17.

Julien-Reynier C, Eisinger F, Chabal F, Aurran Y, Bignon Y, Machalard-Roumagnac M, Maugard C, Nogues C, Vennin P, Sobol H (1999) Cancer genetic consultation and anxiety in healthy consulates. *Psychol Health 14*, 379-390.

McAllister M, Payne K, Nicholls S, MacLeod R, Donnai D, Davies LM (2007a) Improving service evaluation in clinical genetics: identifying effects of genetic diseases on individuals and families. *J Genet Counsel 16*(1), 71-83.

McAllister M, Davies L, Payne K, Nicholls S, Donnai D, MacLeod R (2007b) The emotional effects of genetic diseases: Implications for clinical genetics *Am J Med Genet* Part A 143A: 2651-2661.

McAllister M,_Payne K, Nicholls S, MacLeod R, Donnai D, Davies L (2008a) Patient empowerment in clinical genetics services. *J Health Psychol 13*(7): 887-897

McAllister M,_Payne K, MacLeod R, Nicholls S, Donnai D, Davies L (2008b). What process attributes of clinical genetics services could maximize patient benefits? *Eur J Hum Genet* doi: 10.1038/ejhg.2008.121

Payne K, Nicholls S, McAllister M, Macleod R, Middleton-Price H, Donnai D, Davies L. (2006a) Outcome measurement in clinical genetics services: a systematic review of validated measures. Poster presentation at British Society for Human Genetics, York, September 2006 *J Med Genet: 43*(1): Suppl 1: S62.

Payne K, Nicholls S, McAllister M, Macleod R, Middleton-Price H, Donnai D, Davies L. (2006b) Towards outcome measures for clinical genetics services: a comparison of genetics healthcare professionals and patients' views. Poster presentation at British Society for Human Genetics, York, September 2006 *J Med Genet 43*(1): Suppl 1: S61

Payne K, Nicholls S, McAllister M, Macleod R, Middleton-Price H, Donnai D, Davies L. (2007) Outcome measures for clinical genetics services: a comparison of genetics healthcare professionals and patients' views. *Health Policy 84*: 112-122.

Payne K, Nicholls S, McAllister M, Macleod R, Middleton-Price H, Donnai D, Davies L. (2008) Outcome measurement in clinical genetics services: a systematic review of validated measures. *Valuing Health 11*(3), 497 – 508.

Shiloh S, Avdor O, Goodman RM (1990) Satisfaction with genetic counseling: dimensions and measurement. *Am J Med Genet 37*, 522-529.

Somer M, Mustonen H, Norio R (1988) Evaluation of genetic counselling: recall of information, post-counselling reproduction, and attitude of the counselees. *Clin Genet 34*, 352-365.

Srinivaser J, Rowett E, Dharni N, Bhatt H, Day M, Chu CE 2007 Improving access to cancer genetics services in primary care: socio-economic data from Kirklees. *Familial Cancer 6*(2) 197 – 203.

Tercyak KP, Johnson SB, Roberts SF, Cruz AC (2001) Psychological response to prenatal genetic counseling and amniocentesis. *Patient Educ Couns 43*, 73-84.

Wang C, Gonzalez R, Merajver SD (2004) Assessment of genetic testing and related counseling services: current research and future directions. *Soc Sci Med 58*, 427-1442.

Watson M, Lloyd S, Davidson J, Meyer L, Eeles R, Ebbs S, Murday V (1999) The impact of genetic counselling on risk perception and mental health in women with a family history of breast cancer. *Brit J Cancer 79* (5-6) 868 – 874.

Watson M, Kash KM, Homewood J, Ebbs S, Murday V, Eeles R (2005) Does genetic counselling have any impact on management of breast cancer risk? *Genet Testing 9*(2) 167 – 174.

Wertz DC, Sorenson JR, Heeren TC (1986) Clients' interpretation of risks provided in genetic counseling. *Am J Hum Genet 39*, 253-264.

Westwood G, Pickering RM, Latter S, Lucassen A, Little P, Temple K (2006) Feasibility and acceptability of providing nurse counsellor genetics clinics in primary care *J Adv Nurs 53* (5); 591 – 604.

Please provide evidence demonstrating the scientific and measurable basis for measuring practice outcomes. You are encouraged to provide evidence demonstrating the scientific basis for applicant occupation's body of knowledge and other aspects of its practice as well, if possible.

Genetic counselling is a rapidly evolving specialty. Change drivers include exponential increases in knowledge about the genetic basis of disease, and associated changes in technologies that have increased options for patient decision-making. Many approaches to outcome measurement have been attempted in the last 20 years; however none have proved adequate to take full account of patient benefits. In view of this, quality indicators (e.g. scope of service, accessibility/responsiveness, quality of clinical care, links with genetic laboratory services, quality of data collection/handling) as proxies for outcome measures were advocated until there is more robust evidence (*Clinical Genetics Committee of the Royal College of Physicians of London, 1998*).

Because of the nature of the problems for which patients seek genetic counselling, the profession argues that traditional approaches to outcome measurement in healthcare are neither relevant nor appropriate *(Clarke 1997, MacLeod 2003).*

A recent systematic review of the literature on outcome measures used in genetic counselling identified existing validated outcome measures and the key domains captured by these measures *(Payne et al 2008*). Thirty-seven non-genetics-specific and 30 genetics-specific measures were identified, but little consensus emerged across studies about which measures are most relevant. Forty-six of the 67 measures were used and reported in just one paper. The other 21 were used more than once. None of the measures were preference-based i.e. could establish the weight, or importance, that individuals attach to changes in health state or well being after genetic counselling. Domains identified include anxiety and depression, coping, decision-making, distress, family environment, health status, knowledge, mood, perception of risk, perceived personal control, psychological impact, quality of life, satisfaction and expectations, self-esteem, spiritual well-being and worry. The review concluded that no single validated outcome measure encompasses domains that represent all potential patient benefits from genetic counselling.

The findings from the systematic review were used to develop a Delphi survey, which is a research tool that uses an iterative multistage process to transform opinion into group consensus. In this case, the approach was used to establish where there was consensus amongst patients and genetics healthcare professionals about which outcome measures were thought to be important (*Payne et al 2007)*. The Delphi survey identified the following nine outcome domains as useful: knowledge of the condition, quality of life, risk perception, satisfaction, ability to cope, perceived personal control, meeting of expectations, decision-making, and accuracy of diagnosis.

In parallel with the systematic review and the Delphi survey, the same team conducted qualitative research to explore outcomes that are valued by patients and providers of clinical genetics services. The qualitative research indicated that there are aspects of patient benefit that are not captured by outcome measures used to evaluate clinical genetics services. For example, no existing measures can together capture (1) all of the potential emotional benefits (2) the ability to make informed decisions relating, not only to healthcare, but also to many non-health aspects of life (3) benefits to relatives and future generations. However, qualitative research has identified these as key aspects of good patient outcomes *(McAllister et al 2007a, 2007b, 2008).*

The findings from the Delphi survey were then triangulated with the findings from the qualitative research, and helped to further focus from the nine outcome domains identified in the Delphi survey, to a set of six outcome domains: knowledge of the condition, quality of life, ability to cope, perceived personal control, decision-making, and accuracy of diagnosis (*McAllister et al, submitted)*. These six outcome domains are a useful starting point to develop a core set of outcome measures suitable for evaluating clinical genetics services. Work is ongoing to develop a battery of outcome measures to capture all the patient benefits from genetic counselling.

References to above part of section 6:

Clarke AJ (1997) Outcomes and process in genetic counselling *Clin Genet 50*: 462-469

Clinical Genetics Committee of the Royal College of Physicians of London (1998) *Commissioning Clinical Genetic Services.*

Macleod R (2003) *The genetic counselling process: An interpretative phenomenological analysis of patient-counsellor interactions* PhD thesis, University of Manchester

McAllister M, Payne K, Nicholls S, MacLeod R, Donnai D, Davies LM (2007a) Improving service evaluation in clinical genetics: identifying effects of genetic diseases on individuals and families. *J Genet Counsel 16*(1), 71-83.

McAllister M, Davies L, Payne K, Nicholls S, Donnai D, MacLeod R (2007b) The emotional effects of genetic diseases: Implications for clinical genetics *Am J Med Genet* Part A 143A: 2651-2661.

McAllister M, Payne K, Nicholls S, MacLeod R, Donnai D, Davies L (2008). Patient empowerment in clinical genetics services. *J Health Psychol 13*(7):887-897

McAllister M, Payne K, MacLeod R, Davies L. Towards outcome measures for clinical genetics services. *Submitted*

Payne K, Nicholls S, McAllister M, Macleod R, Middleton-Price H, Donnai D, Davies L. (2007) Outcome measures for clinical genetics services: a comparison of genetics healthcare professionals and patients' views. *Health Policy 84: 112-122*

Payne K, Nicholls S, McAllister M, MacLeod R, Donnai D, Davies LM (2008). Outcome measurement in clinical genetics services: a systematic review of validated measures. *Value in Health 11*(3):497-508

Please attach any additional evidence that demonstrates that the applicant occupation subscribes to the ethos of evidence-based practice. You are encouraged to provide examples of how treatment strategies have changed in the light of evidence.

There are many examples demonstrating that genetic counselling subscribes to the ethos of evidence-based practice and that genetic counsellors are influential in changing practice.

Within the field of cancer genetics, assessment of a family history of breast cancer, identifying risk, communicating risk information, identifying when genetic testing is appropriate and counselling about risk management are all based on a systematic review of the evidence undertaken by the National Institute for Clinical Excellence (NICE) (*McIntosh et al 2004, updated 2006).* Risk assessment tools *(Appendix 6.2)* produced by genetic counsellors for managing patients with familial breast cancer in primary and secondary care are based on these national guidelines (2006) and demonstrate a commitment to evidence based practice. Similarly the algorithm for managing colorectal cancer risk (*Appendix 6.3),* identifying risk management, indicating when and what type of tumour block testing is appropriate and explaining the rationale for the pathway, has been designed by genetic counsellors and is based on current evidence (*Dunlop 2002a, 2002b, JCMG 2006a, Sieber et al 2003, Wijnen et al 1997).*

Several protocols have been developed in collaboration with other members of the multidisciplinary team, demonstrating that genetic counsellors play a key role in changing practice in the light of evidence. An example of such a protocol (*Appendix 6.4)* demonstrates the evidence-based management of women undergoing risk-reducing salpingo-oophorectomy. This clinical protocol is used by the multidisciplinary clinic for women who carry a genetic predisposition to breast and ovarian cancer in the South East of England.

An example of a change to practice in the field of general genetics is demonstrated in the genetic counselling of men and women with a Fragile X pre-mutation. Fragile X syndrome is the second most common cause of learning disability. Boys affected by the mutation inherit the condition from their mothers. The underlying genetic cause of the condition is complex with the gene expanding to a full mutation in affected boys. However, men and women can also carry an intermediate size gene known as a pre-mutation. Until relatively recently, families coming to genetic clinics were informed that these gene sizes had no health implications for carriers but there were risks of the gene expanding in future generations and women would be at risk of having an affected boy. It has now been proven that women who carry a pre-mutation have an increased risk of premature ovarian failure *(Murray et al 1998, Allingham et al 1999)* and men with the pre-mutation are at risk of developing a late onset ataxia condition (*Berry-Kravis et al 2003, Hagerman et al 2001, Jacquemont et al 2007)*. This evidence has impacted on our clinical practice and patients attending genetic counselling clinics requesting genetic tests are now fully counselled around the impact of a pre-mutation test result. In addition, families known to genetic services in the past are in the process of being contacted with this new information *(Appendix 6.5).*

Finally, genetic counsellors are represented on the national and international bodies that change and guide clinical practice in genetics. These bodies include the British Society of Human Genetics (BSHG), UK Cancer Genetics Group (CGG), European Society for Human Reproduction and

Embryology (ESHRE), Genetics Interest Group (GIG), European Society of Human Genetics (ESHG), the Human Genetics Commission (HGC) and the Genetics and Insurance Committee (GAIC). Important policy documents that have been produced by these bodies include the genetic testing of children (*CGS 1994*), Consent and Confidentiality in Genetic Practice *(JCMG 2006b)* and the framework for practice on professional roles in the multidisciplinary team in genetics (*CGS/AGNC 2006)*.

The essential role of genetic counsellors in changing clinical practice and the commitment of the profession to the ethos of evidence-based practice is perhaps most clearly demonstrated by the recent election of a genetic counsellor (Dr Chris Patch) to the role of Chair Elect for the BSHG, the overarching body for the clinical and scientific aspects of genetics in the UK.

References to above part of Section 6:

Allingham-Hawkins D J, Babul-Hirji R, Chitayat D, Holden J J A, Yang K T, Lee C, Hudson R, Gorwill H, Nolin S L, Glicksman A, Jenkins E C, Brown W T and 27 others (1999) Fragile X premutation is a significant risk factor for premature ovarian failure: the international collaborative POF in fragile X study--preliminary data. *Am J Med Genet 83*: 322-325

Berry-Kravis E, Lewin F, Wuu J, Leehey M, Hagerman R, Hagerman P, Goetz C G (2003) Tremor and ataxia in fragile X premutation carriers: blinded videotape study. *Ann Neurol 53*: 616-623

Clinical Genetic Society (1994) The Genetic Testing of Children; Report of a Working Party of the Clinical Genetics Society. *www.bshg.org.uk/documents/official_docs/testchil.htm*

Clinical Genetics Society and the Association of Genetic Nurses and Counsellors (2006) Professional Roles in the Multidisciplinary Team in Genetics: A Framework for Practice*.* *(www.clingensoc.org/Docs/WP_AGNC_CGS.pdf)*

Dunlop MG (2002a) Guidance on large bowel surveillance for people with two first degree relatives with colorectal cancer or one first degree relative diagnosed with colorectal cancer under 45 years. *Gut 51*(Suppl V):v17–v20

Dunlop MG (2002b) Guidance on gastrointestinal surveillance for hereditary non-polyposis colorectal cancer, familial adenomatous polyposis, juvenile polyposis, and Peutz-Jeghers syndrome. *Gut 51*(Suppl V):v21–v27

Hagerman R J, Leehey M, Heinrichs W, Tassone F, Wilson R, Hills J, Grigsby J, Gage B, Hagerman P J (2001) Intention tremor, parkinsonism, and generalized brain atrophy in male carriers of fragile X. *Neurology 57*: 127-130

Jacquemont S, Hagerman R J, Hagerman P J Leehey M A (2007) Fragile-X syndrome and fragile X-associated tremor/ataxia syndrome: two faces of FMR1. *Lancet 6*: 45-55

Joint Committee on Medical Genetics (2006a) The Human Tissue Act 2004: an assessment of the Act and its implications for the specialties of clinical and laboratory genetics. Report of a Working Party. *(www.bshg.org.uk/documents/official_docs/HTA_questions_geneticists_and_clinical_scientists_JCMG_wor[1]..pdf)*

Joint Committee on Medical Genetics (2006b). Consent and confidentiality in genetic practice: guidance on genetic testing and sharing information. *(www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21[1].8.06.pdf)*

McIntosh A, Shaw C, Evans G, Turnbull N, Bahar N, Barclay M, Easton D, Emery J, Gray J, Halpin J, Hopwood P, McKay J, Sheppard C, Sibbering M, Watson W, Wailoo A, Hutchinson A (2004; updated 2006) Clinical guidelines and evidence review for the classification and care of women at risk of familial breast cancer. London: National Collaborating Centre for Primary Care/ University of Sheffield. NICE guideline CG014. *(www.nice.org.uk/nicemedia/pdf/CG41fullguidance.pdf)*

Murray A, Webb J, Grimley S, Conway G, Jacobs P (1998) Studies of FRAXA and FRAXE in women with premature ovarian failure. *J Med Genet 35*: 637-640

Sieber OM, Lipton L, Crabtree M, Heinimann K, Fidalgo P, Phillips RK, Bisgaard ML, Orntoft TF, Aaltonen LA, Hodgson SV, Thomas HJ, Tomlinson IP (2003) Multiple colorectal adenomas, classic Adenomatous Polyposis and germline mutations in MYH. *New Engl J Med 348*, p791-799

Wijnen J, Khan PM, Vasen H, van der Klift H, Mulder A, van Leeuwen-Cornelisse I, Bakker B, Losekoot M, Møller P, Fodde R (1997) Hereditary Non Polyposis Colorectal Cancer families not complying with the Amsterdam criteria show extremely low frequency of mismatch repair gene mutations *Am J Hum Genet 61*: 329 – 333

Appendices to Section 6

Appendix 6.1: The 'DiaLGEN' Service Development Project. Summary of final report, December 2007; Regional Genetics Service, Liverpool Women's Hospital NHS Foundation Trust

Appendix 6.2: Guy's Breast Cancer Risk Assessment Flow Charts, February 2007; South Thames Regional Genetics Service

Appendix 6.3: Guy's Pathway for Managing Colorectal Cancer Genetics Referrals, March 2007; South Thames Regional Genetics Service

Appendix 6.4: Protocol for Risk Reducing Bilateral Salpingo-Oophorectomy, July 2007; Multidisciplinary Clinic for BRCA1/2 Families, Guy's and St Thomas' NHS Foundation Trust

Appendix 6.5 Fragile X update letter, October 2008; Regional Genetics Service, Manchester

SECTION 7: The occupation must have at least one established professional body which accounts for a significant proportion of that occupational group.

Please see attached documents relating to the Association of Genetic Nurses and Counsellors (AGNC):

Constitution or rules

- AGNC Constitution (Accepted 11.09.95, amended 11.09.00 &17.09.04) *(Appendix G.2)*

Copies of minutes of meetings

- Minutes of AGNC Committee meetings: 08.11.07, 06.02.08, 19.06.08, 15.09.08, 06.11.08 and 30.03.09 *(Appendices 7.1, 7.2, 7.3, 7.4, 7.5, 7.6)*
- Minutes of AGNC Joint meetings: 14.02.06, 07.02.07, 05.02.08 and 30.03.09 *(Appendices 7.7, 7.8, 7.9, 7.10)*
- Minutes of AGNC Reciprocity Working Group meeting 13.06.06 *(Appendix 7.11)*
- Minutes of AGNC Annual General Meeting 19.09.06, 18.09.07 and 15.05.08 *(Appendices 7.12, 7.13, 7.14)*

The Standing Orders of the governing body and its constituent committees.

- Genetic Counsellor Statutory Regulation Steering Group, Terms of Reference *(Appendix 7.15)*
- AGNC Knowledge and Skills Framework (KSF) Working Party: Terms of Reference *(Appendix 7.16)*
- Letter to members of the AGNC Supervision Working Party with suggested Terms of Reference: 09.08.04 *(Appendix 7.17)*

The election rules and results

- Letter from AGNC Career Structure and Salaries Working Group about forthcoming vote, February 2004 *(Appendix 7.18)*
- Request for Nominations to AGNC Committee 2006 *(Appendix 7.19)*
- Nominations for AGNC Committee Elections 2007 *(Appendix 7.20)*
- Voting Form for AGNC Committee Elections 2007 *(Appendix 7.21)*
- Request for Nominations to AGNC Committee 2008 *(Appendix 7.22)*

Please see additional supportive documents:

- AGNC Report to BSHG Council Meeting 18.01.07 (*Appendix 7.23)*
- Summary of AGNC Awards *(Appendix 7.24)*

Please provide evidence demonstrating the number of practitioners of the applicant occupation.

A survey of Regional Genetic Services undertaken in August 2008 identified 253 individuals practising under the title Genetic Counsellor. Of these, 91% are members of the AGNC. Of those who are not members of the AGNC, 5% are members of the NMC, 2% have no membership of a professional body and the remaining 2% are members of other professional bodies including the Canadian Association of Genetic Counsellors, the National Society of Genetic Counselors (US), the Association of Clinical Cytogeneticists and UKCP.

If there is more than one established professional body or representative organisation for the applicant occupation, please attach evidence that all bodies are involved in and support this application. You are encouraged to provide evidence of a steering group or similar structure, and to provide evidence of its work.

Medical genetic services in the UK (England, Scotland, Wales and Northern Ireland) are organised through 22 regional Clinical Genetics Centres. Each centre was contacted in August 2008 and asked to provide information about the number of individuals known to be practicing as genetic counsellors in their region, including genetic counsellors within the NHS and private practice and those affiliated with the regional centre and those not affiliated with the regional centre. The survey requested information about the professional background of the genetic counsellors at the point at which the individual entered the Genetic Counsellor profession. The survey also collected information about the professional body/ies to which these individuals belonged (see above).

The professional qualifications of genetic counsellors currently employed across the UK at the point of entry into genetic counsellor practice are:

- nursing qualification - 60%,
- UK MSc in Genetic Counselling - 33%,
- US, Canadian or Australian MSc in Genetic Counselling - 3%,
- genetic/biological science academic background - 2%
- midwifery, social work or psychology qualification - 2%

Data on the retirement plans of practicing genetic counsellors show that around 11% of the current workforce is due to retire within the next 5 years. Of this “near-retirement” group, 93% are from a Nursing background. Likewise, the entry level qualifications of recruited trainee genetic counsellors (see section 9) show that 63% of entrants to the genetic counsellor profession have either the UK MSc in Genetic Counselling or academic qualifications, compared to 37% who have a prior professional qualification such as nursing.

This demonstrates that the demographic of the genetic counsellor professional group is changing. The multidisciplinary entry qualifications *(see section 10)* are resulting in a profession with a broader range of professional skills and specialities than was seen two decades ago. Within this mix of backgrounds, some practitioners have access to statutory professional regulation while others do not, which highlights the need to consolidate the genetic counselling profession into a discrete and regulated group.

An attempt was made to contact genetic counsellors in private practice. The AGNC has developed a network of regional representatives, which includes a representative for genetic counsellors in the private sector. However, this representative was no longer contactable and therefore it has proved to be difficult to access genetic counsellors who only work privately to ascertain how many there are, who they are and their areas of practice.

In order to reach any genetic counsellors that do not access information through the AGNC and who are not known to regional genetic centres, a letter inviting contact and opinion from individuals across the UK practicing under the title Genetic Counsellor was sent in March 2007 to a number of publications: Journal of Family Healthcare, RCN Forum, Nurse Researcher, Nursing Times, Nursing Standard, Nursing Management, Health Service Journal and to academic centres in an attempt to reach genetic counsellors working in specialist clinical areas, educational roles and in research. No objections to applying for statutory regulation were received by the GCSRSG.

Are there any professional bodies or other representative organisations for the applicant occupation that have not been informed of this application?

No. The British Society for Human Genetics (BSHG), of which the AGNC is a constituent group, has been informed and is supportive of this application (evidenced in *Appendix 14.3P*).

If there are practitioners who have not followed the defined routes of entry to the profession, please discuss potential grandparenting requirements and implication.

Grandparenting Arrangements

The voluntary registration process began on 1/3/2002. Since then genetic counsellors without the minimum entry level criteria for registration or routes of entry in Section 9 who had been in post for at least two years prior to March 2002 (full-time or equivalent part-time) have been eligible to register via a ‘Grandparent Clause’. The deadline for the closure of this clause (submission of portfolio before September 2008) was widely publicised by the Genetic Counsellor Registration Board.

Those eligible for grandparenting were invited to submit a portfolio of evidence for assessment according to the academic level for Masters Degree in the same way as newer applicants' submissions.

The grandparenting clause has now closed. In summary, all genetic counsellors in practice since March 2000 have had the opportunity to register through a grandparent clause, whatever their background or academic qualifications and have had a time period of eight years and six months to submit their portfolio for registration.

The GCSRSG would therefore recommend that the HPC do not introduce a further grandparenting clause for genetic counsellors if our application is accepted.

SECTION 8: The occupation must operate a voluntary register(s).

Please complete this section for each voluntary register that covers the applicant occupation. How many practitioners of the applicant occupation are on the voluntary register?

111 (as at October 2008)

Are these figures independently audited, and if so, by whom?

Figures are audited within the GCRB but are not independently audited.

Please give the date of opening of the register.

September 2002

Finally, please provide evidence indicating how many practitioners of the applicant occupation are not on any of the voluntary registers for which you have provided details above.

A survey of Regional Genetic Services undertaken in August 2008 (see Section 7) identified 253 individuals practicing under the title 'Genetic Counsellor' (including trainees).

As there are now 111 genetic counsellors on the voluntary register, we would estimate that **44%** of the genetic counselling profession are registered currently.

The process of acquiring voluntary registration has been limited in the past by the number of suitable and trained assessors available. Therefore, within every cohort of genetic counsellors that submitted their intention to register between 2002-2006, a percentage of applicants were turned away due to a shortage of assessors. Hence, although there are approximately 142 genetic counsellors within the profession yet to register, this is at least in part due to logistical reasons. As more people are becoming registered, the shortage of assessors is resolving and hence this should not be an issue in future years.

Tables 8.1 and 8.2 below provide further details of the professional and/or academic backgrounds of the registrants. During the first two years of the voluntary register, the majority of Registered Genetic Counsellors were also Registered Nurses. This changed to a situation in which a higher proportion of genetic counsellors registering had no other professional registration. With the expected future changes in the demography of the genetic counsellor professional group (see Section 7), this pattern is expected to continue. *Table 8.3* demonstrates the gradual increase in the proportion of genetic counsellors on the voluntary register without current access to statutory regulation.

Table 8.1 Genetic counsellors entering the UK voluntary register since its inception: data by professional/academic background.

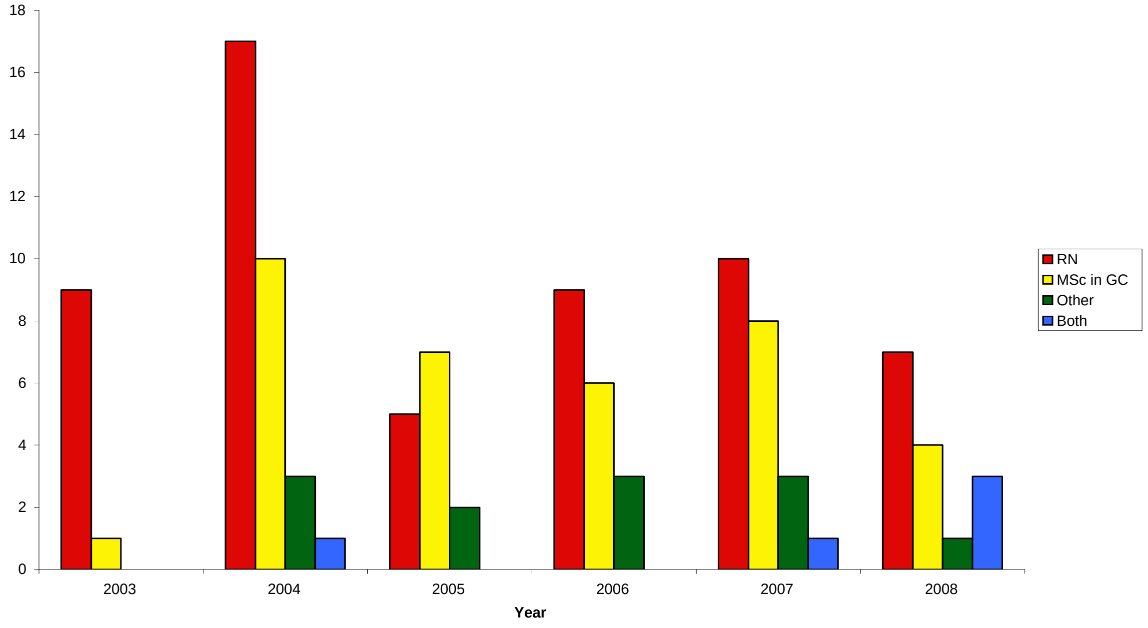
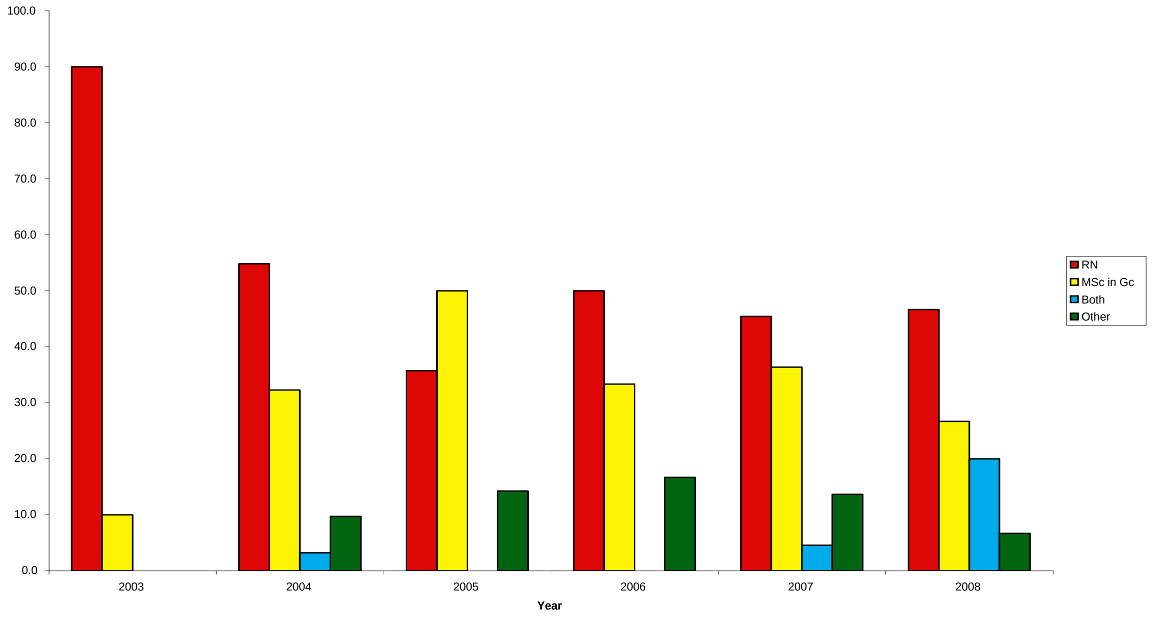


Table 8.2 Genetic counsellors entering the UK voluntary register since its inception: annual proportions by professional/academic background.

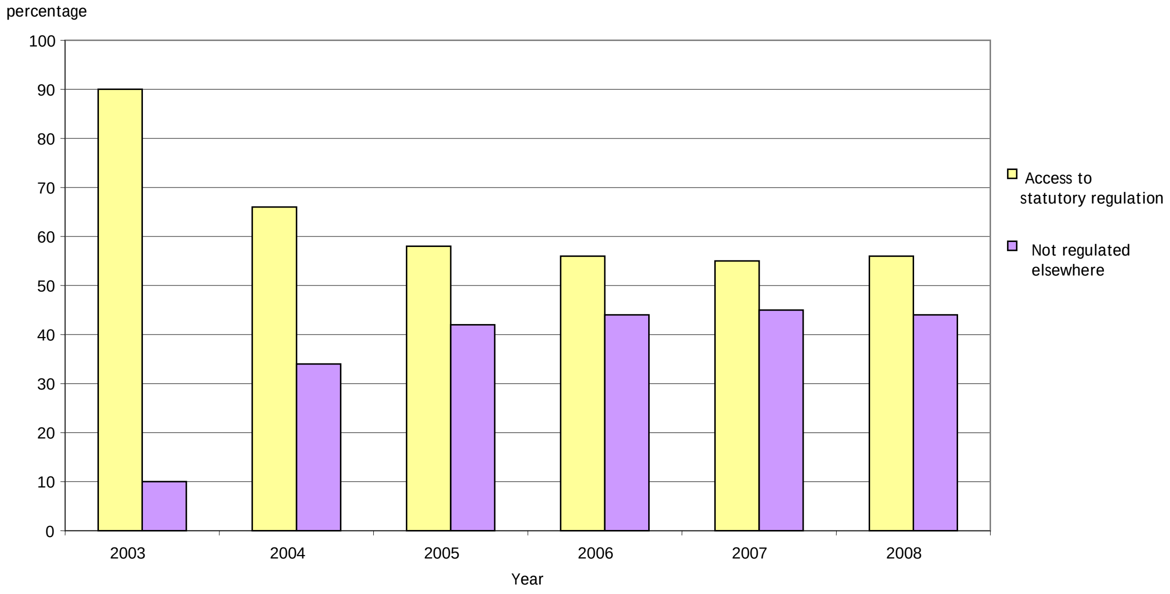


Notes on legend of above tables:

RN=Registered Nurse
Both=both RN and MSc in GC,

MSc in GC=Masters Degree in Genetic Counselling
Other=other professional/academic background, registered under grandparent clause.

Table 8.3 Genetic counsellors on the UK voluntary register since its inception: comparison of proportions of those with access to statutory regulation to those with no current access to statutory regulation (cumulated totals)



SECTION 9: The occupation must have defined routes of entry to profession.

The Genetic Counsellor Registration Board (GCRB) awards the GCRB Certificate of Registration. The details of entry qualifications, training and awarding the GCRB certificate are outlined in Sections 9 and 10. This route to registration is similar to the Clinical Scientists and Biomedical Scientists.

Please provide evidence as to how entry to the applicant occupation is controlled, by providing:

Details of the routes of entry

Without statutory regulation, entry into the profession is not currently controlled. However, employers do recognise the minimum entry level criteria for genetic counsellors as evidenced by job advertisements (*see Appendices 9.15, 9.16 and 9.17 and www.agnc.org.uk).*

All new entrants into the profession are required to undergo a training period of at least two years prior to becoming eligible to apply for registration.

Pre-requisites for potential trainee genetic counsellors

Trainee genetic counsellors working towards Registration as a Genetic Counsellor need to fulfil **AT LEAST ONE** of the following sets of "entry-level" criteria (A or B) on obtaining a training post:

(Set A)

- Attainment of a GCRB accredited Master of Science (MSc) degree in genetic counselling including substantial clinical and experiential component and basic training in counselling skills of at least 90 guided learning hours

(Set B)

- Attainment of a first or Master's degree

  plus

- Attainment of a professional qualification as a registered nurse or midwife, and maintenance of current professional registration

  plus

- Previous experience as a senior registered practitioner, having developed and demonstrated proficiency as an autonomous professional in a health or social care setting

  plus

- Completion of a genetics course of no less than 20 hours duration, which has academic accreditation[1]

  plus

- Completion of training in counselling skills of at least 90 guided learning hours[2].

NB.

[1] Accredited as a module or course, the focus of which is genetic science, at an institution of higher or further education

[2] Guided learning hours (GLHs) are defined as "all times when a member of staff is present to give specific guidance towards the learning aim being studied on a programme. This includes lectures, tutorials and supervised study in, for example, open learning centres and learning workshops. It also includes time spent by staff assessing a learner's achievements… " (Ref: Learning and Skills Council, Funding Guidance for Further

Education in 2004/05).

The Counselling and Psychotherapy Central Awarding Body (CPCAB) has a minimum requirement of 90 GLHs in courses resulting in the award of a Level 3 Certificate in Advanced Counselling Skills (CSK-L3). As this qualification is intended for those wishing to use counselling skills as an important element of their work as a helping professional, those entering genetic counselling training are expected to have counselling training equivalent to CSK-L3.

Evidence that demonstrates that only individuals choosing one of the entry routes are recognised as being practitioners of the profession. You are encouraged to provide supporting statements to this effect from educational institutions and employers.

The training period

- The period of training shall be no less than 2 years if the trainee is working full-time or the equivalent if the trainee is working part-time. The training must take place in a Centre meeting the criteria set by the GCRB as a suitable training environment (see Section 10). The period prior to seeking Registration as a Genetic Counsellor cannot commence until the applicant has obtained a training post (or equivalent) with access to a named training scheme mentor.

Assessment of the trainee prior to Registration as a Genetic Counsellor

- Assessment for admission to the Genetic Counsellor Register is based upon the applicant providing a portfolio of evidence demonstrating that they are able to achieve the core competencies to the required standard for the full spectrum of genetic counselling (adult, paediatric, prenatal and cancer genetics).

- An individual may submit an intention to register application to the GCRB after a minimum of two years full-time (or equivalent part-time) clinical practice in an approved training environment

- The GCRB allocates a Primary and Secondary Assessor to each applicant for Registration. Assessors are senior Registered Genetic Counsellors who have undertaken GCRB assessor training in the previous 2 years and have been practicing for at least 5 years. Both Assessors carry out independent and detailed reviews of submitted evidence, which are submitted to a Board Advisor. Assessors then collaborate to identify issues to be discussed at assessment interview with the applicant. The Primary Assessor conducts the assessment interview with the applicant and makes appropriate recommendations about registration.

- An evaluation of the process exists for all mentors, assessors and applicants. The GCRB regularly reviews the feedback sought and responds appropriately.

- Applicants who are referred (i.e. because the submitted portfolio is not satisfactory) have one further opportunity to re-submit.

For further detail and supportive evidence, please see the following appendices:

Appendix	**Title of document**	**Detail/supportive evidence**
9.1	*Criteria for Accredited MSc Degree in genetic counselling 2003*	*Admission criteria, programme design and content, fieldwork placements, learning outcomes, assessment, evaluation, accreditation process (GCRB approved).*
9.2	*Registration Plan for Genetic Counsellors 2008*	*Details of existing scheme of voluntary professional self-regulation.*

9.3	*Genetic Counsellor Registration. Applicant Guidelines 2009*	*Guidelines describing process of registration. Recommended to be read thoroughly before developing a portfolio.*
9.4	*Genetic Counsellor Registration: Application form 2009*	*Application form for existing scheme of voluntary professional self-regulation.*
9.5	*Genetic Counsellor Registration Assessor & Mentor Guidelines. 2009*	*Voluntary professional self-regulation scheme: document to provide mentors and assessors with the required guidance to help them prepare an applicant for registration or to assess the document in accordance with GCRB requirements.*
9.6	*Genetic Counsellor Registration Assessment Document 2009*	*For completion by primary assessors, secondary assessors and Board advisors.*
9.7	*GCRB Genetic Counsellor Registration. Mentoring Framework 2009*	*Information about the mentoring process for Registration mentors.*
9.8	*Genetic Counsellor Registration Board Terms of Reference 2009*	*Terms of Reference of GCRB.*
9.9	*GCRB Report on UK Registration of Overseas Genetic Counsellors 26.02.08*	*Written by the UK Registration of Overseas Genetic Counsellors Working Group, on behalf of the Genetic Counsellor Registration Board UK and Eire and the Association of Genetic Nurses and Counsellors UK and Eire Committee.*
9.10	*GCRB UK Registration of Overseas Genetic Counsellors Application form 2009*	*For use by overseas applicants applying for UK Registration.*
9.11	*GCRB Registration/Re-Registration Appeals Process, 2009*	*Information about submitting an appeal to GCRB in event of application for registration or re-registration being declined by GCRB*
9.12	*Information Pack for Approved Training Centres. October 2008*	*Detailed information about the Department of Health funded national genetic counsellor training scheme in Approved Training Centres (to form basis of future locally funded training posts in Approved Centres)*
9.13	*Career Structure for Genetic Counsellors.* *Version 2: September 2008*	*National career structure developed by AGNC Career Structure and Salaries Working Group. Original version (July 2005) accepted by AGNC membership and formed basis of subsequent Agenda for Change national genetic counsellor job profiles (see appendix 9.14), post banding and career structure. Now routinely used by employing Trusts in the UK.*
9.14	*National Profiles for Genetic Counsellors. Agenda For Change Job Evaluation Handbook. Second Edition, July 2005*	*See comment above*
9.15, 9.16, 9.17	*Advertisements for Genetic Counsellor posts in NHS Trusts (Trainee Grade Band 6, Genetic Counsellor Band 7 and Principal Genetic Counsellor Band 8)*	*Examples of recent job advertisements by NHS Trusts, demonstrating acceptance of career structure and person specifications.*

Information about the applicant occupation's QAA Subject Benchmark or equivalent. If none yet exists, please provide evidence demonstrating an intention to work towards this benchmark.

Both MSc Courses, in common with other University Courses in the UK, are required to have a Programme Specification. Both courses are approved by the AGNC and accredited by the GCRB. The remit of the GCRB also includes setting and monitoring standards for entry into the profession.

Because of the “dual entry” path into the genetic counselling profession, the GCRB and the AGNC Committee recognises the key importance of having QAA standards of teaching and learning within practice settings, as well as within higher education institutions. To this end, a separate Working Party is currently being established to take this matter forward, to ensure that there is a QAA Subject Benchmark or equivalent for genetic counselling.

SECTION 10: The occupation must have independently assessed entry qualifications.

Please provide details of qualifications recognised as being a necessity for entry to the applicant occupation, including details of the provider bodies and system of monitoring.

(1) ON ENTRY TO TRAINING AS A GENETIC COUNSELLOR

As stated in Section 9, trainee genetic counsellors working towards Registration as a Genetic Counsellor need to fulfil at least one of two sets of "entry-level" criteria (A or B) on obtaining a training post:

Set A:

- Attainment of a GCRB accredited Master of Science (MSc) degree in genetic counselling.

In the UK, there are currently two such MSc degree courses. The awarding authorities are the University of Manchester and Cardiff University. Each course is accredited academically by the University in which it is taught.

University of Manchester
The MSc programme is subject to internal monitoring procedures including annual programme review and external Teaching Quality Assessment as part of the Faculty of Medicine and Human Sciences of the University of Manchester.

Cardiff University
The MSc programme is subject to feedback from students each year and also assessment by the External Examiner. The course is also assessed through the Teaching Quality Assessment (TQA) scheme and the rolling programme of course validation through Cardiff University.

Set B:

- Attainment of a first or Master's degree

  plus

- Attainment of a professional qualification as a registered nurse or midwife, and maintenance of current professional registration

  plus

- Previous experience as a senior registered practitioner, having developed and demonstrated proficiency as an autonomous professional in a health or social care care setting

  plus

- Completion of a genetics course of no less than 20 hours duration which has academic accreditation

  plus

- Completion of training in counselling skills of at least 90 guided learning hours.

Professional Registrations, along with the relevant academic qualifications, are verified by employing Health Authorities and by the GRCB upon submission of Intention to Register.

(2) TRAINING AS A REGISTERED GENETIC COUNSELLOR IN AN APPROVED TRAINING CENTRE

(a) Approved Training Centres

Genetic counsellor trainees have to obtain a training post under the supervision of a Centre meeting the criteria set by the Training Post Panel and the GCRB as a suitable training environment, including:

- *A multidisciplinary approach to patient care*
- *A supervised clinical caseload*
- *Clinical case meetings*
- *A named registered genetic counsellor to act as a training supervisor/mentor.*
- *Established links with departments related to clinical genetics, including laboratories and other related clinical specialities (e.g. fetal medicine, cancer services and paediatrics)*
- *Clinical and counselling supervision*
- *Opportunities for participation in clinical audit and research*
- *Access to educational opportunities through departmental seminars, study days and journal clubs with clinical application*
- *Learning resources, including appropriate IT facilities and library resources*
- *A minimum of 3 genetic counsellors who are either registered or eligible for registration. In a department with 4 or more genetic counsellors, the proportion of genetic counsellors who are either registered or eligible for registration in each training centre should be a minimum of 75% of the total number of genetic counsellors in post.*

(b) Registration Portfolio

Assessment for admission to the Genetic Counsellor Register is based upon the applicant providing a portfolio of evidence demonstrating that they are able to achieve the core competencies to the required standard for the full spectrum of genetic counselling (adult, paediatric, prenatal and cancer genetics).

The portfolio of evidence submitted to the GCRB must contain the following:

- *Mentor's report*
- *Report from manager/senior colleague*
- *Evidence of ability to fulfil each genetic counsellor competency as defined by the GCRB*
- *3 case studies (one focusing mainly on an ethical issue, one on a scientific issue and one on a counselling issue)*
- *2 video or audio-taped counselling sessions, with notes by applicant and supervisor*
- *Log book recording 50 cases demonstrating breadth of experience*
- *Evidence of further education and learning outcomes, comprising a minimum number of training units.*
- *Essay, report or published article of up to 5000 words demonstrating ability to synthesise literature and access information for evidence-based practice*

An individual may submit an 'intention to register' application to the GCRB after a minimum of two years full-time (or equivalent part-time) clinical practice under the supervision of a Regional Genetic Centre providing a suitable learning environment. This experience must have been undertaken within 5 years of the date of application for registration.

The GCRB allocates a Primary and Secondary Assessor to each applicant for Registration. Assessors are Registered Genetic Counsellors who have undertaken approved assessor training and have been in clinical practice for a minimum of 5 years. Both Assessors carry out independent and detailed reviews of submitted evidence, which are submitted to a Board Advisor. Assessors then collaborate to identify issues to be discussed at assessment interview with the applicant. The Primary Assessor conducts the assessment interview with the applicant. The GCRB reviews all assessment reports and awards successful applicants the GCRB Certificate of Registration.

(c) The Genetic Counsellor Registration Board (GCRB)

The GCRB's remit *(Appendix 9.8)* includes setting and monitoring standards for entry into the profession, registration as a genetic counsellor, maintenance of registration and disciplinary proceedings. GCRB members are elected by UK Registered Genetic Counsellors and include Registered Genetic Counsellors, a lay representative, an academic and a medical geneticist. It takes advice from other relevant individuals or organisations when appropriate.

(3) REGISTERED GENETIC COUNSELLORS

Renewal of Registration with the GCRB is every 5 years. Renewal of registration requires the demonstration of continuing professional development and maintenance of standards of practice. A genetic counsellor whose registration has lapsed must re-register by submitting a new portfolio of evidence.

Appendices and References pertaining to Section 10

APPROVED TRAINING CENTRES

Genetic Counsellor Training Posts Scheme: Information Pack for Approved Training Centres: October 2008 *(see Appendix 9.12)*

GENETIC COUNSELLOR REGISTRATION BOARD (GCRB)

Terms of Reference 2008 *(Appendix 9.8)*

GENETIC COUNSELLOR REGISTRATION

See *Appendices: 9.2, 9.3, 9.4, 9.5, 9.6, 9.7 and 9.10*

RENEWAL OF REGISTRATION

See Appendices 13.1, 13.2, 13.3, 13.4 and 13.5

SUPERVISION

See Appendix 13.6

Other pertinent references on Supervision:

Middleton A, Cowley L, Clarke A (2007). Editorial on Supervision. *J Genet Counsel* 16 (2) 123-125

Middleton A, Wiles V, Kershaw A, Everest S, Downing S, Burton H, Robathan S, Landy A (2007). Reflections on the Experience of Counseling Supervision by a Team of Genetic Counselors from the UK. *J Genet Counsel* 16 (2) 143-155

SECTION 11: The occupation must have standards in relation to conduct, performance and ethics.

Please attach evidence describing the applicant occupation's written standards of conduct, performance and ethics.

Summary of statements

No.	Title	Summary
1	**Responsibilities & scope of practice**	Genetic counsellors have a responsibility to maintain professional standards and high standards of personal conduct, always acting within the current AGNC Code of Ethics and scope of genetic counsellors' practice.
2	**Duty of care**	Genetic counsellors should always act in the best interests of patients, respecting the patient as an individual, avoiding causing harm, and promoting and protecting the interests and dignity of the individual, irrespective of gender, age, race, ability, sexuality, economic status, lifestyle, culture and religious or political beliefs.
3	**Respecting confidentiality**	Genetic counsellors must respect the confidentiality of clients
4	**Obtaining informed consent**	Genetic counsellors must obtain informed consent prior to genetic counselling or genetic testing in accordance with professional guidance.
5	**Collaborative practice**	Genetic counsellors should work collaboratively with other health care professionals in the interests of patients, teaching and research.
6	**Maintaining professional knowledge & competence & minimising risks to patients**	Genetic counsellors' practice must be evidence-based, recognising professional boundaries and referring onto other health professionals if appropriate. Knowledge and skills must be maintained through continuous professional development, genetic counselling supervision and registration.
7	**Personal & professional integrity & honesty**	Genetic counsellors must ensure that they act within legal and ethical boundaries and carry out duties in a professional and ethical way, behaving with integrity and honesty.
8	**Professional indemnity**	In the interests of registrants and patients it is recommended that Registered Genetic Counsellors have professional indemnity insurance.

Statement 1: Responsibilities and scope of practice

Genetic counsellors have a responsibility to maintain high standards of professional and personal conduct, always acting within the current AGNC Code of Ethics *(Appendix 11.1)* and scope of genetic counsellors' practice.

1.1 'Genetic Counsellors'

In order to protect patients and professionals it is anticipated that the title 'Registered Genetic Counsellor' will be protected in law and genetic counselling will be recognised as a profession. The Health Act 1999 seeks to secure and regulate professionals and the services they provide.

The title 'Registered Genetic Counsellor' can only be used after an individual has undergone the process of genetic counsellor registration (see sections 8, 9 and 10). It is mandatory for genetic counsellors to renew their registration every 5 years whilst they continue to practice.

1.2 Genetic counsellors' code of ethics and scope of practice

The AGNC Code of Ethics clarifies and guides the conduct of genetic counsellors. It acknowledges that ethical practice is essential in four main areas of responsibility: self-awareness and development, relationships with clients, relationships with colleagues and responsibilities within the wider society. All genetic counsellors must be aware of the ethical implications of their professional role, and adhere to the principles and guidelines in this code.

(AGNC Code of Ethics, 2003)

1.3 Scope of practice

See section 4

1.4 Delegation of duties

Genetic counsellors who delegate duties to others, such as genetic counsellor students and trainees who are not Registered Genetic Counsellors must be satisfied that the person is competent to undertake that duty and provide an appropriate level of supervision. Genetic counsellors delegating duties to genetic counsellor students and trainees will retain responsibility for the care provided for the client at all times.

Statement 2: Duty of care

Genetic counsellors should always act in the best interests of patients, respecting the patient as an individual, avoiding causing harm, and promoting and protecting the interests and dignity of the individual, irrespective of gender, age, race, ability, sexuality, economic status, lifestyle, culture and religious or political beliefs.

2.1 Relationships with clients

Genetic counsellors should:

2.1.1 Enable clients to make informed independent decisions, free from coercion

2.1.2 Respect the client's personal beliefs and their right to make their own decisions.

2.1.3 Respect clients, irrespective of their ethnic origin, sexual orientation, religious beliefs, gender and age.

2.1.4 Avoid any abuse of their professional relationship with clients.

2.1.5 Protect all confidential information concerning clients obtained in the course of professional practice: disclosures of such information should only be made with the client's consent, unless disclosure can be justified because of a significant risk to others. Where this occurs, disclosure should only occur after discussion with suitably qualified colleagues.

2.1.6 Report to an appropriate person or authority any circumstance, action or individual that may jeopardise client care, or their health and safety.

2.1.7 Seek all relevant information required for any given client situation

2.1.8 Refer clients to other competent professionals if they have needs outside the remit or professional expertise of the genetic counsellor.

(AGNC Code of Ethics, 2003)

Statement 3: Respecting confidentiality

Genetic counsellors must respect the confidentiality of patients and families.

3.1 Respecting confidentiality

Genetic counsellors should be familiar with and act within the guidance set out in '*Consent and Confidentiality in Genetics Practice: Guidance on genetic testing and sharing genetic information' (JCMG 2006)*

Statement 4: Obtaining informed consent

Genetic counsellors must obtain and record informed consent in accordance with professional guidance and current legislation.

4.1 Obtaining informed consent

Genetic counsellors should be familiar with and act within the guidance set out in '*Consent and Confidentiality in Genetics Practice: Guidance on genetic testing and sharing genetic information' (JCMG 2006).*

Statement 5: Collaboration with colleagues

Genetic counsellors should work collaboratively with other health care professionals in the interests of patients, teaching and research.

5.1 Relationships with colleagues

Genetic counsellors should:

5.1.1 Collaborate and co-operate with other colleagues in order to provide the highest quality of service to the patient.

5.1.2 Foster relationships with other members of the clinical genetics team, to ensure that patients benefit from a multidisciplinary approach to care.

5.1.3 Assist colleagues to develop their knowledge of clinical genetics and genetic counselling

5.1.4 Report to an appropriate person or authority any circumstance or action which may jeopardise the health and safety of a colleague.

(AGNC Code of Ethics, 2003)

Statement 6: Maintaining professional knowledge and competence and minimising risks to patients

Genetic counsellors' practice must be evidence-based, recognising professional boundaries and referring on to other health professionals if appropriate. Knowledge and skills must be maintained through continuous professional development, genetic counselling supervision and registration (*see section 13)* and comply with statutory health and safety policies.

Statement 7: Personal and professional integrity and honesty

Genetic counsellors must ensure that they act within legal and ethical boundaries and carry out duties in a professional and ethical way, behaving with integrity and honesty.

7.1 Self-awareness and development

Genetic counsellors should:

7.1.1 Be aware of their own physical and emotional health and take appropriate action to prevent an adverse impact on their professional performance.

7.1.2 Report to an appropriate person or authority any conscientious objection that may be relevant to their professional practice.

7.1.3 Maintain and improve their own professional education and competence.

(AGNC Code of Ethics, 2003)

7.2 Responsibilities within the wider society

Genetic counsellors should:

7.2.1 Provide reliable and expert information to the general public.

7.2.2 Adhere to the laws and regulations of society. However, when such laws are in conflict with the principles of practice, genetic counsellors should work toward change that will benefit the public interest.

7.2.3 Seek to influence policy makers on human genetic issues, both as an individual and/or through membership of professional bodies.

(AGNC Code of Ethics, 2003)

Statement 8: Professional indemnity

It is recommended that Registered Genetic Counsellors have professional indemnity insurance. This is in the interests of registrants and patients in the event of claims and professional negligence.

8.1 Independent practice

Whilst some employers have vicarious liability for the negligent acts and/or omissions of their employees, such cover does not normally extend to activities undertaken outside the registrant's employment. Independent practice would not be covered by vicarious liability. It is the individual registrant's responsibility to establish their insurance status and take appropriate action.

(*NMC 2008)*

References to Section 11

Joint Committee on Medical Genetics (2006). Consent and confidentiality in genetic practice: guidance on genetic testing and sharing information.
(www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21[1].8.06.pdf)

Nursing and Midwifery Council (2008). Standards of conduct, performance and ethics for nurses and midwives.
www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=3954

Additional document used in the preparation of the Genetic Counsellors Code of Conduct, Performance and Ethics

Health Professionals Council (2008) Standards of Conduct, Performance and Ethics.
www.hpc-uk.org/assets/documents/10002367FINALcopyofSCPEJuly2008.pdf

Appendices to Section 11

11.1 *Association of Genetic Nurses and Counsellors (2003).* AGNC Code of Ethics. (www.agnc.org.uk/About%20us/codeofethics.htm)

SECTION 12: The occupation must have disciplinary procedures to enforce these standards.

Please attach evidence demonstrating the system used for disciplining practitioners. Please also attach descriptions of the procedures used to administer the system, along with at least three anonymised case reports. The information will be handled confidentially and will not be shared outside the HPC.

The Genetic Counsellor Registration Board Disciplinary Procedure is attached *(Appendix 12a).* A legal opinion for this document has been sought and given by Mr. Graham Miles of Morgan Cole *(Appendix 12b).*

The GCRB are awaiting the outcome of the HPC application before seeking the funds required to make this procedure fit for purpose. The GCRB currently receives fees sufficient for the registration process alone and if the profession is not successful in statutory regulation, alternative ways of managing a voluntary register including implementing this disciplinary procedure will need to be considered.

The GCRB has not yet received any complaints regarding a registered genetic counsellor and as the disciplinary procedure is still under development, we have no cases to present. *Appendix 12c* demonstrates three examples of complaints received by hospital trusts and how these were dealt with at Trust level.

Appendices and References to Section 12

Appendix 12a: Genetic Counsellor Registration Board for the UK and Eire: Disciplinary and Appeals Procedure, October 2007 *(Pending Implementation)*

Appendix 12b: GCRB Disciplinary and Appeals Procedure, Legal Opinion, July 2008

Appendix 12c: **CONFIDENTIAL** Anonymised Professional Conduct Case Reports December 2006

SECTION 13: The occupation must require commitment to Continuous Professional Development (CPD).

Please provide evidence demonstrating that the profession is committed to the principles of CPD. You are encouraged to provide details of any planned or existing CPD schemes.

Genetic counsellors have to renew their registration with the GCRB every 5 years. This requires the demonstration of continuing professional development and upholding of standards of practice. Full details are provided in *Appendices 13.1,13.2,13.3, 13.4 and 13.5*.

A number of national and international conferences are held which provide UK genetic counsellors with opportunities for CPD and are regularly used for this purpose. These include:

National

- British Society for Human Genetics (BSHG): Annual 3 day Conference
- Association of Genetic Nurses and Counsellors (AGNC): Annual 1-2 day Spring Meeting
- Clinical Genetics Society (CGS): Annual 1-2 day Spring Meeting
- Cancer Genetics Group (CGG): Biannual meeting
- Genethics Club: Biannual meeting

International

- European Society of Human Genetics (ESHG): Annual 3 day conference
- European Meeting on Psychosocial Aspects of Genetics (EMPAG): Biennial 2-3 day meeting held concurrently with ESHG Conference
- International Society of Nurses in Genetics (ISONG): Annual 3 day conference
- National Society of Genetic Counselors (NSGC) of USA: Annual 4 day conference

'Within house'
Multidisciplinary journal clubs, seminar series and study days are a regular feature of NHS clinical genetics services.

Many genetic counsellors have also attended courses to advance their counselling skills. It is now accepted practice for UK genetic counsellors to have access to both genetic counselling supervision and clinical supervision *(Appendix 13.3).*

Appendices to Section 13

Appendix 13.1: GCRB Renewal of Registration, Applicant Guidelines, 2009

Appendix 13.2: GCRB Renewal of Registration: Application Form, 2009

Appendix 13.3: GCRB Renewal of Registration: CPD Documentation Form, 2009

Appendix 13.4: GCRB Renewal of Registration Reference: Report of Registered GC colleague, 2009

Appendix 13.5: GCRB Renewal of Registration Reference: Report of Manager, 2009

Appendix 13.6: AGNC Supervision Working Group (2007). Report from the UK and Eire Association of Genetic Nurses and Counsellors (AGNC) Supervision Working Group on Genetic Counselling Supervision. *J Genet Counsel* 16 (2) 127-142

SECTION 14: Views of others

Please attach any documents you have received from other organisations or individuals in which a view is expressed about your application.

The attached letters and emails of support have been received from:

Professional Groups

Joint Committee on Medical Genetics (JCMG)	*(Appendix 14.1P)*
Royal College of Physicians (RCP)	*(Appendix 14.2P)*
British Society for Human Genetics (BSHG)	*(Appendix 14.3P)*
European Society of Human Genetics (ESHG)	*(Appendix 14.4P)*
European Meeting on Psychosocial Aspects of Genetics (EMPAG)	*(Appendix 14.5P)*
Royal College of Nursing (RCN)	*(Appendix 14.6P)*

The NMC have not raised any specific concerns regarding our application for statutory regulation although they raise the issue of costly dual registration (see *Appendix 14.7P*). Previous correspondence stated that they would not be in opposition to nurses retaining their NMC registration if they also became HPC registered genetic counsellors.

Service Users:

Genetics Interest Group (GIG)	*(Appendix 14.1S)*
Huntington's Disease Society	*(Appendix 14.2S)*
Breakthrough Breast Cancer	*(Appendix 14.3S)*
Antenatal Results and Choices	*(Appendix 14.4S)*
Contact a Family	*(Appendix 14.5S)*
Fragile X Society	*(Appendix 14.6S)*

The following groups were also approached, but no formal reply was received.
General Medical Council
Royal College of General Practitioners
UNITE
Eurogentest

SECTION 15: Impact on Council's ability to carry out its functions effectively.

Regulation by the Council is, to a large extent, dependent on participation by members of the regulated profession in a number of roles. The inability or limited ability of an applicant occupation to provide this input will never, of itself, be a reason for the Council to recommend that the application should be turned down. However, the Council will discuss this in its report to the Secretary of State accompanying its recommendation for an application. If the applicant occupation wishes, it can provide information or comment on this issue here:

The genetic counsellor profession is a small group with a strong commitment to the development and regulation of its practitioners. The profession can demonstrate this commitment through the sub-committees and networks that have been put in place within the organisation.

The professional body for genetic counsellors is the Association of Genetic Nurses and Counsellors (AGNC) and the majority of practicing genetic counsellors are members (*see section 7*). Through the AGNC, a sturdy UK-wide network of regional representatives has been developed to enhance communication within the occupational group and the membership is proactive in developing policy and strategy for the genetic Counsellor profession. The profession has defined a framework for registration as a genetic counsellor practitioner to uphold standards of practice and has created a Board (GCRB), independent of the AGNC Committee, to set and monitor registration standards and be responsible for practice-related disciplinary issues. To ensure continuing development of the profession, the membership has actively engaged in the creation of working groups to consider and advise on specific issues. These working groups have included:

- **Education Sub-Committee**
  - To identify the need for Genetic Counselling Registration
  - To identify training modalities to support registration applicants, assessors and mentors

- **Career Structure and Salaries Working Group**
  - To develop a national career structure for genetic counsellors

- **UK Registration of Overseas Genetic Counsellors Working Group**
  - To facilitate reciprocity of training and registration of genetic counsellors with other countries

- **Knowledge and Skills Framework Working Group**
  - To develop KSF outlines for the genetic counsellor roles defined in the national career structure

- **Clinical Supervision Working Group**
  - To make evidence-based recommendations to support the needs of genetic counsellors for supervision

Alongside this, the AGNC is a constituent group of the British Society for Human Genetics (BSHG) and is present on the BSHG Committee. The genetic counselling profession is involved in the UK Joint Committee on Medical Genetics and is a stakeholder in the Department of Health Extending Professional Regulation work. The genetic counsellor profession therefore has an active role in the development of strategy and policy relating to genetics in medicine and is confident of the competency of its members in supporting the decision-making and operational processes of the Health Professions Council.

The genetic counsellor profession recognises the importance of statutory regulation as a means of maintaining quality and high standards of practice in the rapidly expanding field of clinical genetics to enhance client safety and protect the professional title. The profession is willing to support the Council's operations as required.

Standards of Proficiency For Genetic Counsellors
March 2009

Expectations of a health professional

1a Professional autonomy and accountability

Registrant genetic counsellors must:

1a.1 be able to practise within the legal and ethical boundaries of their profession

- understand the need to act in the best interests of service users at all times
- understand what is required of them by the Health Professions Council
- understand the need to respect, and so far as possible uphold, the rights, dignity, values and autonomy of every service user including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing
- be aware of current UK legislation applicable to the work of their profession

1a.2 be able to practise in a non-discriminatory manner

1a.3 understand the importance of and be able to maintain confidentiality

1a.4 understand the importance of and be able to obtain informed consent

1a.5 be able to exercise a professional duty of care

1a.6 be able to practise as an autonomous professional, exercising their own professional judgement

- be able to assess a situation, determine the nature and severity of the problem and call upon the required knowledge and experience to deal with the problem
- be able to initiate resolution of problems and be able to exercise personal initiative
- know the limits of their practice and when to seek advice or refer to another professional
- recognise that they are personally responsible for and must be able to

justify their decisions

1a.7 recognise the need for effective self-management of workload and resources and be able to practise accordingly

1a.8 understand the obligation to maintain fitness to practise

- understand the need to practise safely and effectively within their scope of practice
- understand the need to maintain high standards of personal conduct
- understand the importance of maintaining their own health
- understand both the need to keep skills and knowledge up to date and the importance of career-long learning

1b Professional relationships

Registrant genetic counsellors must:

1b.1 be able to work, where appropriate, in partnership with other professionals, support staff, service users and their relatives and carers

- understand the need to build and sustain professional relationships as both an independent practitioner and collaboratively as a member of a team
- understand the need to engage service users and carers in planning and evaluating diagnostics, treatments and interventions to meet their needs and goals
- be able to make appropriate referrals
- *understand the structure and function of health, education and social care services in the UK and current developments, and be able to respond appropriately*
- *be able to establish effective working relationships to function within a multidisciplinary team and as part of the wider health and social care network.*
- *recognise and maintain professional boundaries*
- *recognise own limitations in knowledge and capabilities, discuss with colleagues or refer clients when necessary*

1b.2 be able to contribute effectively to work undertaken as part of a multi-disciplinary team

1b.3 be able to demonstrate effective and appropriate skills in communicating information, advice, instruction and professional opinion to colleagues, service users, their relatives and carers

- be able to communicate in English to the standard equivalent to level 7.0 of the International English Language Testing System, with no element below 6.5

- understand how communication skills affect the assessment of service users and how the means of communication should be modified to address and take account of factors such as age, physical ability and learning ability

- be able to select, move between and use appropriate forms of verbal and non-verbal communication with service users and others

- be aware of the characteristics and consequences of non-verbal communication and how this can be affected by culture, age, ethnicity, gender, religious beliefs and socio-economic status

- understand the need to provide service users (or people acting on their behalf) with the information necessary to enable them to make informed decisions

- understand the need to use an appropriate interpreter to assist service users whose first language is not English, wherever possible

- recognise that relationships with service users should be based on mutual respect and trust, and be able to maintain high standards of care even in situations of personal incompatibility

1b.4 understand the need for effective communication throughout the care of the service user

- recognise the need to use interpersonal skills to encourage the active participation of service users

The skills required for the application of practice

2a Identification and assessment of health and social care needs

Registrant genetic counsellors must:

2a.1 be able to gather appropriate information

- *be able to establish a relationship in order to elicit client's concerns and expectations*

2a.2 be able to select and use appropriate assessment techniques

- be able to undertake and record a thorough, sensitive and detailed assessment, using appropriate techniques and equipment

- *be able to elicit, identify, synthesise and interpret relevant medical and genetic information, whilst acknowledging family and psychological history*

- *be able to make appropriate and accurate genetic risk assessment*

2a.3 be able to undertake or arrange investigations as appropriate

2a.4 be able to analyse and critically evaluate the information collected

2b Formulation and delivery of plans and strategies for meeting health and social care needs

Registrant genetic counsellors must:

2b.1 be able to use research, reasoning and problem-solving skills to determine appropriate actions

- recognise the value of research to the critical evaluation of practice

- be able to engage in evidence-based practice, evaluate practice systematically and participate in audit procedures

- be aware of a range of research methodologies

- be able to demonstrate a logical and systematic approach to problem solving

- be able to evaluate research and other evidence to inform their own practice

.

2b.2 be able to draw on appropriate knowledge and skills in order to make professional judgements

- be able to change their practice as needed to take account of new developments

- be able to demonstrate a level of skill in the use of information technology appropriate to their practice

2b.3 be able to formulate specific and appropriate management plans including the setting of timescales

- understand the requirement to adapt practice to meet the needs of different groups distinguished by, for example, physical, psychological, environmental, cultural or socio-economic factors

- *be able to acknowledge the implications of individual and family experiences, beliefs, values and culture for the genetic counselling process*

- *be able to demonstrate ability to organize and prioritise a case load*

2b.4 be able to conduct appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skilfully

- understand the need to maintain the safety of both service users and those involved in their care

2b.5 be able to maintain records appropriately

- be able to keep accurate, legible records and recognise the need to handle these records and all other information in accordance with applicable legislation, protocols and guidelines

- understand the need to use only accepted terminology in making records

2c Critical evaluation of the impact of, or response to, the registrant's actions

Registrant genetic counsellors must:

2c.1 be able to monitor and review the ongoing effectiveness of planned activity and modify it accordingly

- be able to gather information, including qualitative and quantitative data, that helps to evaluate the responses of service users to their care

- be able to evaluate intervention plans using recognised outcome measures and revise the plans as necessary in conjunction with the service user

- recognise the need to monitor and evaluate the quality of practice and the value of contributing to the generation of data for quality assurance and improvement programmes

- be able to make reasoned decisions to initiate, continue, modify or cease treatment or the use of techniques or procedures, and record the decisions and reasoning appropriately

2c.2 be able to audit, reflect on and review practice

- understand the principles of quality control and quality assurance
- be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures
- be able to maintain an effective audit trail and work towards continual improvement
- participate in quality assurance programmes, where appropriate
- understand the value of reflection on practice and the need to record the outcome of such reflection
- recognise the value of case conferences and other methods of review
- *be able to demonstrate reflective skills within the counselling context and in personal awareness, for the safety of clients and families, by participation in genetic counselling supervision, as defined by the AGNC Supervision Working Group (AGNC Supervision Working Group 2007).*
- *contribute to the development and organisation of genetic services*

Knowledge, understanding and skills

3a Knowledge, understanding and skills

Registrant genetic counsellors must:

3a.1 know and understand the key concepts of the bodies of knowledge which are relevant to their profession-specific practice

- understand the structure and function of the human body, relevant to their practice, together with knowledge of health, disease, disorder and dysfunction

- be aware of the principles and applications of scientific enquiry, including the evaluation of treatment efficacy and the research process

- recognise the role of other professions in health and social care

- understand the theoretical basis of, and the variety of approaches to, assessment and intervention

- *understand key scientific concepts in genetics and patterns of genetic inheritance*

- *be able to make appropriate and accurate genetic risk assessment from an individual's family history and medical information*

- *be able to convey clinical and genetic information to clients appropriate to their individual needs*

- *be able to explain options available to clients, including the risks, benefits and limitations of any course of action*

- *be able to identify and respond to emerging needs of the client or family*

- *be able to identify and support clients' access to local, regional and national resources and services*

- *be able to make a psychosocial assessment of client's needs and resources and provide support, ensuring referral to other agencies*

- *be able to use a range of counselling skills to facilitate client's adjustment and decision-making*

- *develop the necessary skills to critically analyse research findings and inform practice development*

3a.2 know how professional principles are expressed and translated into action through a number of different approaches to practice, and how to select or modify approaches to meet the needs of an individual, groups or communities

3a.3 understand the need to establish and maintain a safe practice environment

- be aware of applicable health and safety legislation, and any relevant safety policies and procedures in force at the workplace, such as incident reporting, and be able to act in accordance with these

- be able to work safely, including being able to select appropriate hazard control and risk management, reduction or elimination techniques in a safe manner in accordance with health and safety legislation

- be able to select appropriate personal protective equipment and use it correctly

- be able to establish safe environments for practice, which minimise risks to service users, those treating them, and others, including the use of hazard control and particularly infection control

Reference:

AGNC Supervision Working Group (2007). Report from the UK and Eire Association of Genetic Nurses and Counsellors (AGNC) Supervision Working Group on Genetic Counselling Supervision. Journal of Genetic Counseling 16 (2) 127-142

Document prepared by Georgina Hall and Chris Barnes
Genetic Counsellor Statutory Regulation Steering Group (GCSRSG)
March 2009

Statutory Regulation for Genetic Counsellors

Georgina Hall, MSc RGC
Principal Genetic Counsellor

On behalf of:

Genetic Counsellor Statutory Regulation Steering Group (GCSRSG)
Association of Genetic Nurses and Counsellors (AGNC)

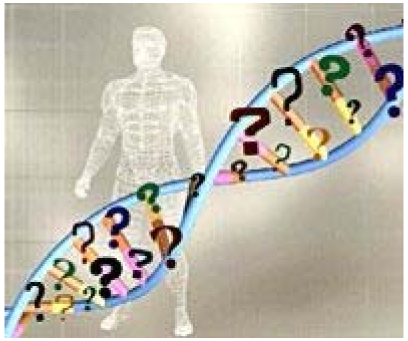
Overview

- Who are genetic counsellors?
- Public protection
- HPC application
- Future

Who are
Genetic Counsellors?

Genetic Medicine

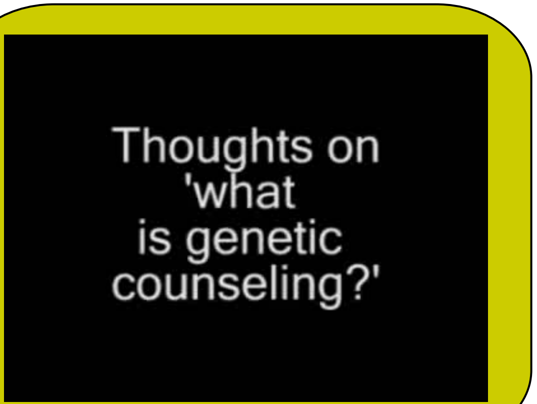
- Genetics play a role in every area of health care



- Human Genome project

Who are genetic counsellors?

- Role in health care:
  - Work in multidisciplinary regional genetic centres
  - Translate complex genetic information
  - Assess and interpret risks
  - Provide information and plan clinical management
  - Support decision making
  - Use counselling interventions
  - See families as well as individuals, from all age groups
  - Act as a resource and educate other health care providers



Thoughts on 'what is genetic counseling?'

Patient

“Genetic counsellor”

“A genetic counsellor provides information on the inheritance of illnesses and their recurrence risks; addresses the concerns of patients, their families, and their health care providers; and supports patients and their families dealing with these illnesses”

World Health Organisation

1950 Post war eugenics
Non-directive genetic counselling

1980 Genetic Nurses, Health visitors & Social workers

1992 MSc Genetic Counselling

1998 AGNC Association of Genetic Nurses and Counsellors

2009

Commitment to skills mix

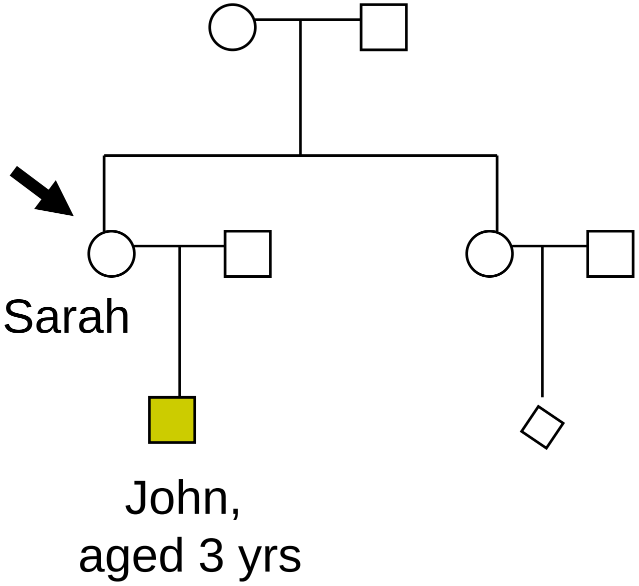
Distinct Profession

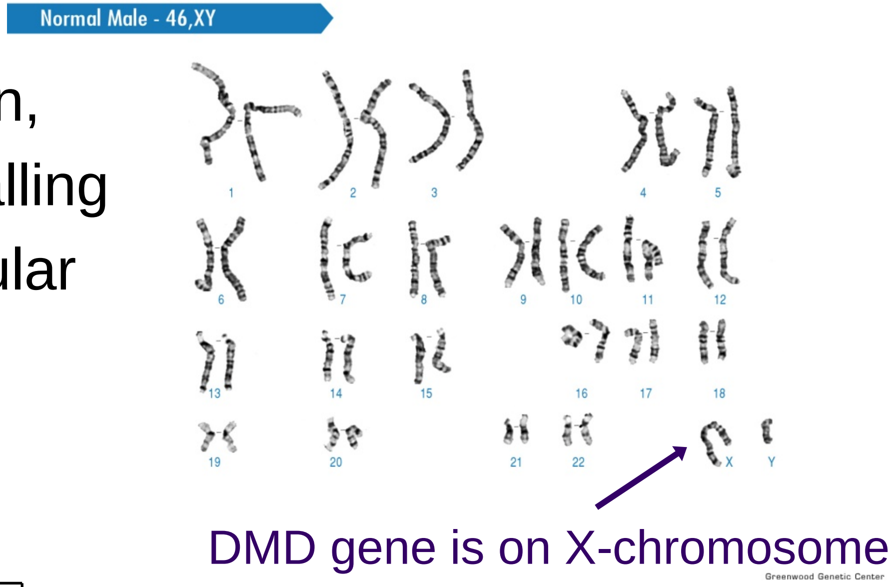
- Distinct from:

  - Doctors
  - Clinical scientists
  - Nurses
  - Therapeutic counsellors

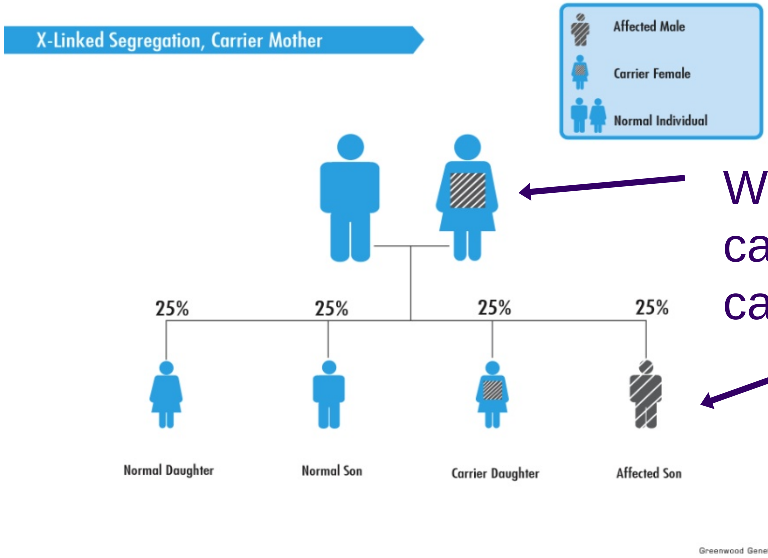
Case example

- Sarah’s son, John, unable to run and falling
- Duchenne Muscular Dystrophy (DMD)





DMD gene is on X-chromosome



Women may be carriers, sons can be affected

Public Protection

Public protection

- Increasing numbers unregulated genetic counsellors
- Protected title
- Genetics in wider healthcare

- Risks to public
  - Cancer screening and surgery
  - Predictive testing
  - Interpreting antenatal results
  - Choices in pregnancy
- Private genetic services

Why Statutory Regulation?

- Stakeholders in Extending Professional Regulation Steering Group

- Unsuitable for alternative forms of regulation:
  - Licensing
  - Employer-led
  - Voluntary registration

- Public protection given the nature and risks of our work.

Our HPC application

HPC Application

- Voluntary Register (Genetic Counsellor Registration Board – GCRB)
  - Since 2002

- Defined routes of entry
  - Nursing or MSc genetic counselling
  - 2 years training followed by competency portfolio
  - GCRB certificate of registration

- Independently assessed entry qualifications
  - University accreditation
  - Exploring QAA benchmarking for GCRB Certificate of Registration

HPC Application

- Disciplinary procedure
  - Indicative Sanctions Guide

- Commitment to CPD
  - Monitored and regulated by GCRB
  - 5 yearly
  - Demonstrate range of learning activity as well as references (conduct and competence) and participation in supervision

Future

Future of Genetic Counselling

- Expansion of genetics into wider healthcare
- Education of other health professionals
- Increasing autonomy
- Rapid advances in genetic testing
  - Diagnostic
  - Susceptibility
  - Pharmacogenetics, gene therapy, treatment trials

Summary

- Public protection
- Emerging profession
- Protected title “Genetic Counsellor”
- Organised and processes in place to join the HPC

Questions