



Clinical Standards for a Genetics Unit

The Clinical Governance Sub-Committee

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This document was prepared by John Dean, Amanda Collins, Wayne Lam and members of the Clinical Governance Sub Committee. The Sub-Committee is grateful to the AGNC for their helpful comments on an earlier draft.

Introduction

The aim of clinical governance is to provide a framework through which NHS organisations are accountable for continually improving the quality of their services, and to safeguard high standards of care by creating an environment in which excellence in clinical care will flourish.

There should therefore be processes and systems in place to monitor quality of care, with mechanisms to flag up any deficiencies in the system. While some aspects of quality are, by their nature, difficult to quantify, others can be assessed, and the influence of workload measured and taken into account. The issues underlying quality of care in clinical genetics have been discussed in various reports published by the Royal College of Physicians¹⁻³, and auditable standards have been described in a document prepared for the Department of Health in England⁴.

We believe that each Genetics Unit should have quality monitoring processes in place and believe that most units already do. The purpose of this document is to provide a quality standard template for the clinical genetics community.

Standards

The underlying principle of any clinical standard should be centred on patient care. There are many aspects of patient care whose quality can most easily be considered separately. In this document, we have therefore considered quality of patient care under the following subheadings:

1 Patient /Service interface

- 1.1 Multidisciplinary Teamwork
- 1.2 Accessibility
- 1.3 Confidentiality
- 1.4 The Genetic Clinic Appointment
- 1.5 Pre-clinic consultation and work-up

2 Basic Skills

- 2.1 Knowledge Based Practice
- 2.2 Counselling skills

3 Communication of outcome

- 3.1 Correspondence and Follow-up

4 Data management

- 4.1 Documentation

5 Monitoring and feedback of the system

- 5.1 Audit

It is not the intention of this document to prescribe how frequently each standard should be monitored, nor how many standards should be monitored simultaneously. In each instance where a standard cannot met, the obstacles to achieving the target should be documented.

1.1 Multidisciplinary Teamwork

Statement			
Members of the clinical genetics unit (Clinical Geneticists, Genetic Counsellors and Administrative staff) are part of a multidisciplinary team, working with other members of the clinical genetics team, with genetics laboratory scientists and with other health care professionals to ensure that the health care delivered to patients is comprehensive and co-ordinated.			
Standard	Process	Audit Target	Achieved
Identify all members of the clinical team required for the delivery of care.	Clinical staffing levels should be in accordance with national professional guidance.	Consultants 4 WTE/million Counsellors 8 WTE/million	Y/N % Y/N %
Members of the team should be aware of one another's skills and roles and share common goals.	All should share in the assessment of needs and the planning, implementation and evaluation of care for the individuals and families in their care.	Regular meetings exist between heads of medical, counselling and administrative staff.	Y/N
Members of the team actively seek collaborative working relationships.	The genetic management of all routine referrals is evaluated and planned at regular meetings between Clinical Geneticists and Genetic Counsellors.	Regular meetings exist between medical and counselling staff to monitor management of referrals.	Y/N
Effective communication systems enable frequent opportunities for discussion.			
The working environment supports formal and informal communication and collaborative working.	Regular meetings between clinicians and laboratory staff occur to discuss patient care.	At least monthly laboratory clinical meetings occur.	Y/N

	Clear lines of clinical responsibility should be established with a consultant clinical geneticist or principal/consultant genetic counsellor designated as responsible for each patient or family care episode.	The consultant clinical geneticist and/or principal/consultant genetic counsellor and other genetics clinical staff responsible during each care episode are clearly documented in the notes.	Y/N
Clear supervision arrangements exist when patients are seen independently by trainee medical staff or genetic counsellors below principal grade.	Meetings take place between the supervisor and supervisee to discuss clinical management and counselling issues for these patients.	The outcome of the discussions are documented in the notes.	Y/N
Good communications exist with other health care professionals and other genetics teams to facilitate optimal care for genetics patients (some have multisystem disorders, some are relatively uncommon).	Regular contacts between genetics clinical staff and other health care professionals concerned with genetic patients occur.	Regular meetings of multidisciplinary teams or networks occur involving genetics clinical staff and other relevant health care professionals.	Y/N
	Regular meetings between genetics clinical staff from different genetics units occur to discuss patient care	Regular meetings exist with staff from other clinical genetics units.	Y/N

1.2 Accessibility

Statement				
The clinical genetics service is equally accessible to all patients and health care professionals in the districts we serve.				
Standard	Process	Audit Target	Achieved	
<p>Information about the service, including points of contact, is well publicised.</p> <p>The team will maintain a high profile in each district.</p> <p>Comprehensive clerical services and facilities are available to enable clinicians to meet the needs of their clients.</p> <p>The clinical service is provided at times and places appropriate to potential users</p>	Clear information on agreed referral protocols and pathways should be widely available and regularly reviewed	On-line information about the service is available to potential users	Y/N	
		Referral protocols and pathways are widely available in various media.	Y/N	
		The team will promote knowledge of the service through teaching health professionals. A record will be kept of the educational activities of all clinicians.	A record of teaching will be kept	Y/N
		Referral patterns should be regularly audited with discrepancies highlighted and investigated.	Referrals / PCT/ million population should be similar (mean +/- 20%)	Y/N
		Adequate secretarial and information management staff are available.	Administrative Staff: 1.0 WTE per consultant, 0.5 WTE per counsellor.	Y/N %
			Database manager: 1.0 WTE per genetic unit	Y/N %
		The number of appointments available LOCALLY should reflect the referral rate and local population.	Appointments available/100 referrals should be similar (mean +/- 20%)	Y/N

1.3 Confidentiality

Statement			
Patient confidentiality will be maintained at all times by all staff within the clinical genetics service.			
Standard	Process	Audit Target	Achieved
<p>Patient confidentiality is a priority for all members of the service.</p> <p>The safe disposal of confidential documentation will be ensured.</p> <p>No member of staff shall give confidential information to an unauthorised person, either in person or by email, telephone or fax.</p> <p>The data protection act will be upheld.</p> <p>Provision is made for the safekeeping of all records.</p>	<p>Clinical Geneticists will adhere to the GMC guidelines.</p> <p>Genetic Counsellors will adhere to the competencies set out by the AGNC Registration Board as part of Professional Registration including the AGNC Code of Ethical Conduct, as well as other codes of conduct relating to individual professional backgrounds.</p> <p>Secretaries will adhere to their contract of employment.</p>	<p>Confidentiality is an identified component of the induction programmes for all staff.</p> <p>The appropriate team/dept head deals with lapses of confidentiality, and disciplinary action may be taken. Incidents and action taken are documented.</p>	<p>Y/N</p> <p>Y/N</p>
	Shredders and labelled waste bags are available such that all confidential waste can be disposed of appropriately	100%	Y/N
	Notes are in locked rooms/cabinets when staff are not present, or are in staffed areas.	100%	Y/N
	Computer files are password protected	100%	Y/N
	Access to notes, filing cabinets, computers and privileged information shall be limited to identified medical, counselling and secretarial staff.	Unfamiliar staff are always challenged	Y/N

1.4 The Genetic Clinic Appointment

Statement			
The genetic clinic appointment aims to provide individuals and families with appropriate and relevant information. It will address individuals and families personal information needs and will encourage active participation during the consultation.			
Standard	Process	Audit Target	Achieved
<p>Patients attending their first appointment should be given information about what to expect at a genetic clinic appointment prior to attending.</p> <p>There will be identification of special requirements such as translators and convenient appointment times.</p> <p>If clinically appropriate, the multidisciplinary clinical team may recommend that pre-clinic consultation take place. This may occur by correspondence, by telephone, by home visit, or at a family history clinic.</p>	Written information will be provided for patients and families informing them of what to expect at their genetic clinic appointment, and how to cancel or change an appointment date or time.	90% compliance	Y/N
	This information and confirmation of the referral will be sent within 2 weeks of referral.	90% compliance	Y/N
	The decision to arrange pre-clinic consultation will be documented.	90% compliance	Y/N
	Whenever possible routine appointment dates and times will be sent to individuals and families not less than 4 weeks in advance of the clinic date where appropriate.	90% compliance	Y/N
	Genetics clinical staff should have adequate time and resources to ensure that proper preparation is made before seeing the patients.	Time should be allocated for clinic preparation in the weekly timetable. All genetics clinical staff should have access to the Internet, online databases and current journals	Y/N

<p>>90% of all new referrals will have first contact with genetics clinical staff within 13 weeks of receipt of the referral, either through a clinic appointment or pre-clinic consultation. <i>Exceptions: If the individual or family make other arrangements (e.g. such as an appointment for an infrequently held outreach clinic); if it is considered inappropriate by the geneticist or genetic counsellor.</i></p> <p>Where pre-clinic work-up takes place, > 90% of new referrals will be offered a clinic appointment within 13 weeks of completion of pre-clinic work-up. <i>Exception: If the multidisciplinary team decides that no clinic appointment is necessary following the pre-clinic work-up – see 1.5.</i></p> <p>The service is able to respond rapidly to urgent referrals</p>	<p>A private room will normally be provided for all consultations.</p>	<p>100% compliance</p>	<p>Y/N</p>
	<p>Individuals and families should be seen within 20 minutes of their appointment times.</p>	<p>90% compliance</p>	<p>Y/N</p>
	<p>Patients should be <i>offered</i> an appointment within 13 weeks of referral, unless pre-clinic work-up is planned.</p>	<p>90% compliance</p>	<p>Y/N</p>
	<p>Patients should be <i>offered</i> an appointment within 13 weeks of completion of pre-clinic workup where appropriate (see 1.5).</p>	<p>90% compliance</p>	<p>Y/N</p>
	<p>The number of observers should be kept to a minimum and agreed with the family.</p>	<p>Evidence of the agreed number, and how many observers were actually present at the consultation in the file.</p>	<p>Y/N</p>
	<p>Urgent referrals (often prenatal diagnosis or neonate) are seen by a team member within 5 working days</p>	<p>90% compliance</p>	<p>Y/N</p>

1.5 Pre-clinic consultation and work-up

Statement			
To facilitate the communication of appropriate and relevant information to individuals and families, assessment of family history and of individual and family information needs before the clinic appointment is often useful.			
Standard	Process	Audit Target	Achieved
If clinically appropriate, the multidisciplinary clinical team may recommend that pre-clinic consultation take place.	When pre-clinic consultations are arranged, these will be offered within 13 weeks of referral.	90% compliance	Y/N
	A pre-clinic consultation may occur by correspondence, by telephone, by home visit, or at a family history clinic.	The nature and location of the pre-clinic consultation will be documented.	Y/N
Where the genetic risk is identified as low by the multidisciplinary clinical team though the pre-clinic work-up, a clinic consultation may not be necessary. Where individual and family information and counselling needs are met as part of the pre-clinic consultation, a clinic consultation may be deemed unnecessary by the multidisciplinary clinical team.	The genetic risk assessment and/or individual and family information needs will be documented in the record.	100% compliance	Y/N
	Where no appointment is planned, a letter documenting this decision, the genetic risk assessment and any management advice will be written to the patient, the referring agency and the GP within 2 weeks of completion of pre-clinic workup.	90% compliance	Y/N
	Correspondence with the referring agency and patients following pre-clinic consultation should comply with the correspondence and follow-up standard described below.		

2.1 Knowledge Based Practice

Statement			
Clinical Genetics is underpinned by knowledge that is, wherever possible, evidence-based and in keeping with considered best practice.			
Standard	Process	Audit Target	Achieved
Educational facilities and opportunities are made available to clinical geneticists and genetic counsellors.	Individuals are responsible for their own continuing education. They will organise and undertake their own private study. Study leave is available for both medical and non-medical counselling staff. Individuals are required to keep a record of all courses and meetings attended.	A departmental record of educational activity is kept.	Y/N
Departmental policies, procedures and guidelines are easily available and regularly reviewed/updated based on clinical evidence.	Each department is responsible for provision of easy access to online resources and a range of up-to-date textbooks and journals relevant to medical and non-medical clinical staff.	Textbooks, journals, library facilities, computers are readily available to all staff.	Y/N
	Departments will have regular clinical meetings where upcoming cases or continuing care of patients can be discussed.	A record of regular clinical meetings is kept.	Y/N

Where available, National Guidelines will be used to inform patient care.	National guidelines will be readily accessible to medical and non-medical clinical staff.	Medical and non-medical genetics staff have access to online or paper copies of national guidelines.	Y/N
	Use of national guidelines or care pathways will be documented in the file where appropriate. Exceptions will be documented.	90%	Y/N
The importance of research in clinical practice shall be recognised.	Time for research will be recognised in Consultant job plans. Other staff will be supported in research with time and financial support as appropriate.	A collection of all departmental publications will be kept.	Y/N

2.2 Counselling Skills

Statement			
All clinical staff should be skilled in genetic counselling, which is a communication process that deals with human problems associated with the occurrence, risk of occurrence and consequences of occurrence of a genetic disorder in a family.			
Standard	Process	Audit Target	Achieved
All clinical staff should have prior supervised experience in genetic counselling before seeing patients on their own.	All new staff should be assessed and a training programme made available for the development of this skill.	Staff induction programmes include assessment and supervised experience in genetic counselling.	Y/N
	All clinical staff should have access to national training courses in genetic counselling.	A national counselling course is offered to all staff during their employment if not already attended	Y/N
Regular non-confrontational review of this skill in all members seeing patients. (e.g. Video review of session, audio taping, someone sitting during clinical session, clinical supervision, or peer supervision).	A clinical appraiser should be identified and readily available to staff.	A clinical appraiser is available.	Y/N

3.1 Correspondence and Follow-up

Statement			
All referring and actively involved agencies will be kept well informed of the outcome of their referral. All genetic patients and families will be offered follow up as necessary and appropriate and will be kept well informed.			
Standard	Process	Audit Target	Achieved
All individuals or families will be followed-up or discharged appropriately.	The decision regarding follow-up and who is responsible for arranging it should be clearly documented	90%	Y/N
All agencies involved should be noted during the consultation	Involved agencies are recorded in the notes	90%	Y/N
All referring agencies and the GP should be sent a written reply to the referral (<i>exception: patient makes a reasonable request for information to be withheld</i>).	The letter should include information of when and where the consultation took place, which <i>relevant</i> medical, nursing or counselling staff were present, which consultant clinical geneticist or principal/consultant genetic counsellor is responsible for the family, and who may be contacted in the genetic department should there be any queries, questions or concerns. All exceptions should documented.	Reply to Referrer 100%	Y/N
		Letter to GP 100%	Y/N

	Letters to referrers should include appropriate information on the implications and management (where appropriate) of the genetic condition (where identified).	100%	Y/N
Individuals and families seen should be sent information summarising the consultation discussions.	The information should include details of who may be contacted in the genetic department and how, should there be any queries, questions or concerns. Exceptions: <i>a) A joint clinic referral arranged by another department. B) If it is a follow-up appointment and there is no further information. C) If it is considered contraindicated. Exceptions will be clearly documented.</i>	90%	Y/N
	Letters should be sent within 14 days of the consultation	90%	Y/N
Every effort should be made to ensure individuals and/or families are able to read and understand their written correspondence.			

4.1 Documentation

Statement			
All records are accurate relevant and complete.			
Standard	Process	Audit Target	Achieved
Comprehensive record systems are provided. Accurate records are kept on all individuals and families.	Pedigrees reflect the standard on the CGS website, Clinical Governance Section.	90%	Y/N
Staff are aware of legal and professional standards with regard to documentation (e.g GMC standards).	All hand written entries are dated and signed.	100%	Y/N
Staff are proficient in the use and completion of records. Documentation is clear, accurate and up-to-date.	All paperwork is secured in the files according to the departmental system	100%	Y/N

5.1 Audit

Statement			
All Patient activities should be recorded, transparent and easily accessible.			
Standard	Process	Audit Target	Achieved
Data of all patient contact should be entered into a database.	Database exists	100%	Y/N
Outcome data should be generated for all consultations.	Outcome entered on database for all consultations	100%	Y/N
Where possible all individuals and families should have a recognised disease code.	Standardised Internal or Internationally accepted disease codes will be used	These are easily utilised on the database	Y/N
Regular Audits will be performed.			
Audits should be undertaken as an intra-departmental and extra-departmental exercise.	All staff will participate in audit, both internal and external	A record of departmental audits will be kept	Y/N
A system of critical incident reporting is in place.	Local NHS forms/processes will be used	Local NHS forms have been used appropriately and copies kept.	Y/N
The experience of users of the Genetics Service should be monitored and inform changes and developments.	Patient and non-genetics staff satisfaction audits are regularly undertaken.	Evidence of these and resultant action.	Y/N

GLOSSARY

This is a list of definitions of some of the terms used in this document.

Clinical geneticist	medically qualified person involved in the care of genetic patients and families
Genetic counsellor	non-medically qualified person involved in the care of genetic patients and families. Includes all those who would naturally belong to the AGNC, for example, genetic nurses, genetic health visitors, genetic associates, genetic social workers.
Genetic patient	patient referred to genetic services for healthcare
Genetic family	family referred to genetic services for healthcare
Genetics clinical staff	clinical geneticists and genetic counsellors
Clinical genetics support staff	all members of the clinical genetics team not covered by “genetics clinical staff”
Clinical genetics team	all healthcare staff involved in the genetic care of genetic patients and families including clinical genetics staff and support staff.
Patient or family care episode	contact or series of contacts between a patient or family and the clinical genetics centre, following a referral.
National guidelines	guidelines for patient or family care that have been drawn up in accordance with widely accepted standards such as SIGN (Scottish Intercollegiate Guidelines Network) or NICE (National Institute for Clinical Excellence) or which are accepted as best practice by a medical Royal College or a National Specialist Society.
Pre-clinic consultation/work-up	a process which takes place prior to the main genetic counselling appointment, through which family history information is obtained, checked for accuracy with medical records, public records, cancer registries and other sources, and in which the information and counselling needs of the genetic patient or family are assessed.
New Referral	where a healthcare professional requests the assessment of an individual or family by the clinical genetics service. Includes: new patients, patients not seen in the last 12 months, and current patients that require further counselling because of a new issue. Excludes: patients seen for the same issue within the previous 12 months, follow ups instigated by the genetics service, and self referrals. Each referral counts as one event, regardless of the number of individuals in the referral.

REFERENCES

- 1 Commissioning Clinical Genetics Services. SJ Davies, P Farndon, PS Harper. London. Royal College of Physicians 1998.
- 2 Clinical Genetics Services, Activity, outcome, effectiveness, quality. A Fryer, IAF Lister Cheese. London, Royal College of Physicians. 1998
- 3 Consultant physicians working with patients (3rd Edition). London. Royal College of Physicians, 2005
- 4 Quality markers for medical genetics services. London. Department of Health, 2002

AUDIT CHECKLIST

CLINICAL GENETICS CENTRE _____

AUDIT DATE _____

1.1 Multidisciplinary team				
	Standard	Performance	Standard Achieved?	Comments
1	Clinical genetics consultants 4 WTE/million	Actual staff WTE/million		
2	Genetic counsellors 8 WTE/million	Actual staff WTE/million		
3	Regular management meetings involving medical, counselling and support staff	Frequency of meetings		(attach example minutes)
4	Regular clinical referral team meetings (weekly)	Frequency of meetings		
5	Regular clinical-laboratory team meetings to discuss patient care	Frequency of meetings		
6	Documented lines of clinical responsibility	% care episodes with documentation		State date and method of assessment (e.g. casenote audit, electronic system)
7	Clear supervision arrangements for trainees	% care episodes with documentation		State date and method of assessment (e.g. casenote audit, electronic system)
8	Regular multidisciplinary team/network meetings			(attach list of regular team or network meetings)
9	Regular meetings with other genetics units	Dates of meetings		(attach dates of meetings in past audit period)

1.2 Accessibility		Performance	Standard Achieved?	Comments
1	Online information about service available	Web address		
2	Referral protocols available	Location (e.g web, hand book, etc)		
3	Department post-graduate teaching commitments			(attach list)
4	Referral patterns: population segments with referral rates > 20% different from mean	State segments		
5	Secretarial/administrative staffing of 1.0WTE per consultant and 0.5WTE per counsellor	WTE per consultant/counsellor		
6	Database manager 1.0 WTE per unit	WTE		
7	Local appointment availability more than 20% different from mean	Clinic affected:		

1.3 Confidentiality		Performance	Standard Achieved?	Comments
1	Confidentiality is part of staff induction		Yes/No	
2	Team leader deals with lapses, lapses are documented	Documentation of lapses in last audit period	Yes/No	Include comment on how lapse dealt with.
3	Shredders and confidential waste bags available		Yes/No	
4	Security of records	In locked cabinets or staffed areas	Yes/No	
5	Password protection of all computer files	100%	Yes/No	
6	Access to records by identified staff only		Yes/No	Document breaches

1.4 The Genetic Clinic Appointment		Performance	Standard Achieved?	Comments
1	Written information about clinic appointment for patients exists	% of referrals who receive leaflet		
2	Written information sent within 2 weeks of referral	% of referrals where this happens		
3	Decision to arrange pre-clinic workup documented	% of referrals where this is documented		
4	Routine appointments arranged at least 4 weeks before date	% referrals where this happens		
5	Clinical preparation time is part of job plans and weekly timetable		Yes/No	
6	Private room available for consultations	%		
7	Individuals/families seen within 20 minutes of appointment time	%		
8	Face-to-face consultation with a clinical staff member within 13 weeks of referral or completion of pre-clinic work-up	%		
9	Number of observers agreed with patient or family	Recorded in a random sample of casenotes?	Yes/No	
10	Urgent referrals seen within 5 working days	%		Document exceptions and reasons for exceptions

1.5 Pre-clinic consultation and work-up		Performance	Standard Achieved?	Comments
1	Pre-clinic consultations arranged within 13 weeks of referral	%		Document reasons for exceptions
2	Nature and location of pre-clinic consultation documented	% correspondence, % telephone, % home visit, % clinic visit		
3	Documentation of risk assessment and family information needs	%		Document reasons for exceptions
4	Outcome documented to referring agency and others if no appointment planned	%		

2.1 Knowledge based practice		Performance	Standard Achieved?	Comments
1	Departmental record of educational activity	Record exists	Yes/No	
2	Textbooks, journals, library, online resources available		Yes/No	
3	Clinical case management meetings occur	Record exists	Yes/No	
4	National guidelines are accessible		Yes/No	
5	Use of guidelines documented	%		
6	Research activities take place	Department Publication collection exists	Yes/No	

2.2 Counselling skills		Performance	Standard Achieved?	Comments
1	Clinical staff induction includes record of counselling skills		Yes/No	
2	National counselling course offered to all staff who have not previously attended such a course		Yes/No	
3	Clinical appraiser available for all staff		Yes/No	

3.1 Correspondence and follow-up		Performance	Standard Achieved?	Comments
1	Follow-up plan is documented	%		
2	Agencies involved in patient/family's healthcare is recorded in notes	%		
3	Consultation outcome letter is sent to referring agency	%		
4	Consultation outcome letter is sent to primary care physician	%		
5	Letters (4,5) include information about implications and management of genetic condition, where known	%		
6	Letter to the patient or family should include genetic personnel contact information	%		
7	Consultation outcome letters are sent within 14 days of the consultation	%		
8	Efforts are made to ensure patient letters are comprehensible to a lay person	Evidence of how this is done		

4.1 Documentation		Performance	Standard Achieved?	Comments
1	Pedigrees are drawn to CGS standards	%		
2	All hand written entries in case records are dated and signed	%		
3	All paperwork is secured in a filing system according to Department's systems.	%		

5.1 Audit		Performance	Standard Achieved?	Comments
1	Patient contact database exists	% contacts recorded		
2	Consultation outcome is entered on database	% outcomes recorded		
3	Standard international diagnosis codes are used in the database (e.g. OMIM)		Yes/No	
4	Record of department audits exists		Yes/No	
5	Local NHS audit processes are used where appropriate		Yes/No	
6	Patient and referral agency staff satisfaction surveys are undertaken		Yes/No	Attach outcome