TOWARDS CLINICAL GOVERNANCE IN CLINICAL GENETIC PRACTICE

Report of a Working Group of the British Society of Human Genetics

January 2000

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DEFINITION

Clinical Governance

"A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."

CONTEXT

The overall aim of a Clinical Genetics Service should be to assist those affected by, or at risk of, genetic disorders live and reproduce as normally as possible. Specialist Genetic Services can be distinguished from other medical services by the fact that they deal with families, often over several generations, and that they can provide genetic expertise for any age group affected by, or at risk of, disorders in any body system.

The integration of clinical genetics, laboratory testing and genetic counselling is essential for a comprehensive service to patients to be delivered. This, together with the benefits obtained from strong academic links necessitated by the rapid pace of scientific advance has supported the development of Regional Genetic Centres.

Over many years strong links have built up within the component parts of clinical genetics centres, facilitating integrated delivery of care, and between Regional Centres, resulting in National Networks to improve quality of care.

Following the publication of the framework document" A first class service: quality in the new NHS" in July 1998, the British Society for Human Genetics (BSHG) initiated a working party on clinical governance in clinical genetic practice to report to the BSHG so that the issue of clinical governance could be addressed collectively with all Regional Centres having ownership of agreed standards. To be valid, development of standards must involve non-medical genetic counsellors and representatives of users of the service as well as clinical geneticists and this has been acknowledged in the composition of the working party that has produced this report.

As a first step it was suggested that the elements of clinical governance relevant to clinical genetics be identified and that a survey of present activity be carried out. This would later be combined with Quality Assurance and benchmarking schemes already underway in genetic laboratory based disciplines with a view to developing an integrated approach to clinical governance in genetic services in the UK.

1. THE COMPONENTS OF CLINICAL GOVERNANCE

1.1 Clinical Audit

This has been defined as an initiative which is clinically led and which seeks to improve the quality and outcome of patient and family management. In clinical audit clinicians examine their practices and results against agreed standards and modify their practice where indicated. These modifications and the results are then the subject of further audit. In Clinical Genetic practice the process can be successfully audited but it is recognised that there are major difficulties in establishing valid outcome measures in this discipline. Through audit against nationally agreed guidelines it should be possible for a centre to identify elements of their service which are relatively poorly developed. Improvement of these services would help to ensure equity of access across the UK.

1.2 Clinical Guidelines

The purpose of clinical guidelines is to improve the effectiveness and efficiency of clinical care through the identification of good clinical practice and desired clinical outcomes. Well designed clinical guidelines will be necessary features of clinical governance and provide a means by which Regional Centres can monitor the quality of their services. For example, the Scottish Intercollegiate Guidelines Network (SIGN) recommends that evidence for guideline development should be identified by systematic literature review. It is not surprising that such a limited evidence base exists in Clinical Genetics due to its emphasis on rare diseases and responsibility to at risk and presymptomatic individuals. However, guidelines in Clinical Genetics might concentrate more on specific situations, for example predictive testing for late onset disorders; management of prenatal testing of high risk patients; and management and investigation of a child with dysmorphic features.

1.3 Continuing Professional Development and Appraisal

Central to maintaining and improving standards is the concept of continuing professional development. Most clinical staff have always kept themselves up-to-date but now they are expected to demonstrate their state of knowledge and have accepted the concept of keeping records of their continuing professional development activities. Annual appraisal must include an annual review of the job plan to ensure that individuals are working appropriately and to agreed standards.

1.4 Education and Training

The Regional Genetic Centres act as educators, both for the professions within Clinical Genetics and for other health care workers. Given current resources and limited manpower, and as the role of genetic factors in common diseases becomes recognised, Clinical Genetic Centres cannot accept the responsibility for making all health care workers more genetically literate.

i) Regional Genetic Centres already accept responsibility for education and training of clinical geneticists, non-medical genetic counsellors and genetic scientists.

ii) There is increasing demand with the rapid development of the specialty for involvement of Clinical Genetic professionals in the continuing education of other clinical disciplines. These activities should be included in job plans and commissioned accordingly.

1.5 Clinical Risk Management

A system should be in place for the early identification of adverse events and centres should ensure that they develop methods to identify common patterns and develop systems of accountability to prevent future incidents.

1.6 User Involvement

Clinical Genetics Centres have a tradition of working closely with the Genetic Interest Group in order to be responsive to their patients' expectations. Since the development of appropriate outcome

measures for genetic services, especially for rare disorders, is likely to be very difficult, patient led criteria for determining effective clinical outcomes is important for validating practice. Centres should ensure that user groups are involved in the development of service frameworks. Complaints procedures must be accessible to patients and their families and lessons from the analysis of each complaint should be learned and the recurrence of similar problems avoided in the future.

1.7 Accreditation of Centres for Service and Training

The laboratory components of Regional Genetic Centres already have mechanisms for accreditation of services, and both clinical and laboratory sections have training accreditation procedures. Clear quality standards for clinical services should be developed, preferably at national level and with user involvement.

2. INITIATIVES IN ASPECTS OF CLINICAL GOVERNANCE IN REGIONAL CENTRES

Already, a substantial amount of work has been undertaken in the UK on the development of materials to inform practice in Clinical Genetics. All Regional Genetic Centres in the UK were asked to submit such materials to record what currently is available, with the intention that these should form the nucleus of future guidelines and service frameworks. A brief synopsis of the material received in given below.

2.1 Audit Topics and Outcomes

There were numerous notifications of audits including several on appropriateness of referrals and compliance with locally agreed standards for investigation of various groups of patients. The West of Britain Group carried out a series of joint audit projects covering topics such as counselling for sex chromosome anomalies and nurse only referrals.

2.2 Care Pathways

The Consortium of Scottish Genetics Centres has developed care pathways based on multidisciplinary committee-derived criteria for the management of several Mendelian disorders. The Genetics Centre in Exeter has developed and distributed recommendations with the aim of assisting the specialist and non-specialist in the management of individuals and families with a possible hereditary cancer risk.

2.3 Situation-specific Guidelines

Several centres had developed guidelines for predictive testing for adult onset disorders. Other centres had guidelines for prenatal diagnosis, investigations of children with developmental delay etc.

2.4 Patient Information Sheets

Many centres provided information sheets for patients on different disorders and to give patients information on presymptomatic testing, prenatal diagnosis and about genetic register services.

2.5 Information on Procedures / Protocols for Staff

Several centres had information for new staff giving information about the department and its activities and links with other services. There were also protocols for medical and nursing staff for investigation and management of the more common disorders. Several centres had checklists for certain situations which could be incorporated in patients' notes.

2.6 Others

A number of centres have developed consent forms for DNA storage and consent forms for clinical photographs. One centre had explicit statements of policy regarding genetic screening of children, confidentiality and record keeping. Another centre had an explicit list of standards and policies and a breakdown of activity and costs for different types of medical genetic consultations.

3. THE WAY FORWARD

The British Society for Human Genetics with advice from the Joint Genetics Committee is establishing a mechanism for the development of a framework for clinical governance.

3.1 Setting standards

may include:

- production and dissemination of clinical guidelines
- standards for continuing professional development of professions in clinical genetics
- defining competencies for knowledge of genetics for health service professionals

3.2 Delivering standards

may include:

- establishment of continuing professional development activities
- establishment of educational initiatives for appropriate health professionals
- promoting integrated national or regional audit activities

3.3 Monitoring standards

may include:

- joint activities with appropriate colleges in monitoring continuing profession development
- joint development of processes for revalidation
- participation in mechanisms to assist members who have difficulty maintaining standards