Clinical Outcomes Group

Membership

John Pasi	Chair
Chris James / Georgie Robinson	Haemophilia Society
Nicola Howe	Pan Thames Haemophilia Consortium
Sue Mather	North West Specialised Commissioning Team
Emma Franklin	Haemophilia Nurses
Rob Hollingsworth / Ben Palmer	National Haemophilia Database
Gerry Dolan	
Charles Hay	
Andrew Will	
Savita Rangarajan	
David Allen / Richard Oakley	Patient representatives
David Stephenson / Paul McLaughlin	Physiotherapists

Remit

To agree and develop a core set of clinical outcome measures that can be applied universally across UK haemophilia / IBD practice and used in a prospective manner.

To define such outcome measures to enable simple and reliable employment

Background and activity since September 2010

The Clinical Outcomes Group has met five times in 2010-11.

The Clinical Outcomes Group was formed as task group of the Data Management Working Party in order to facilitate the development of the agreed set of clinical outcomes. This is followed on as part from the national drive to deliver clinical outcome data across all aspects of health care and the expectation that all services will deliver outcome data.

In essence haemophilia has historically been an area were outcomes have not been systematically collected. Numerous potential outcome measures exist – joint scores, quality of life assessments, gait, radiological assessments etc. However, current definitions of such outcome measures are poorly defined and highly variable dependent on the measure used and are not truly comparable. Hence many measures that have been used are not sufficiently robust or appropriate to meet the needs of commissioners and treaters alike, to compare centre with centre, provider with provider, if each centre chooses its own measures, which is the case at present.

This is especially acute in financial straightened times such as those which are likely to be the case in the next few years where there will be increasing pressure to reduce concentrate costs. Future funding by health authorities/budget holders is likely to become more dependent on agreed health economic clinical outcomes that provide evidence of benefits of a therapeutic approach.

Consensus is, therefore, needed to enable collection of clinical outcomes that are directly evaluable for health economic planning, including standardisation of their terminology and agreement of the tools to be used. This requires agreement by all clinicians, payers and patient groups to draw up an agreed practical set of outcomes that can be reliably measured and are robust.

This group was set up to attempt to draw up a national set of agreed outcomes for this purpose to allow treaters to collect data that can be used to deliver on the national need for outcome data and also in planning discussions. It was not about one treatment versus another but rather prospective evaluation of outcomes measured on an individual basis and developing an evolving picture of haemophilia care.

With the way health financing is going it is essential that the data is collected and can be used to support haemophilia care and advances.

The group considered the following:

Treatment recording and collection of bleed level data nationally

It was agreed that there should be a minimum standard data set for recording treatment used. After discussion based on the widespread use of Haemtrack it was agreed that the standard data set would be that used in Haemtrack and that paper returns and similar records should collect the same data and use the same fields as Haemtrack. The group agreed that electronic returns would be ideal, but that a national standard paper treatment sheet should be made available.

Data would then be collected into Haemtrack to populate the NHD.

To facilitate recording in a standardised manner a definition set for bleeds and prophylaxis has been developed and agreed.

Days lost from work and school

This is often regarded as a good measure of outcome. However, it is restricted in application and necessarily implies that a person with haemophilia is either in school or in employment. To capture the essence of this measure, it has been added to the treatment record but is now recorded as 'Did the bleed interfere with a planned activity?' in order to capture disruption occurring at weekends and for those either retired, out of work or not at school.

Joint scores

Joint scores have been a widely employed outcome measure in haemophilia. Many joint scores have been used in the past and there is considerable variability between scoring system in terms of sensitive to degree and extent of joint impairment and damage. It is important to note however that *no* joint scores are validated in adults.

For children the haemophilia joint health score (HJHS) was chosen as the preferred measure as it is validated and widely used.

In view of the fact that there is no validated scores in adults the HJHS has been develop to extend into adults use by adding additional measures. This has been discussed with the Canadian developers of the HJHS who had similarly hoped to undertake such a project. The HJHS and extended HJHS can now provide a continuum so that a comparable data can be provided collected and followed through.

It was also felt that there should be some contextualising of the haemophilia joint health scores as the joint scores were a static representation. It was agreed that the simplest measure to employ would be the haemophilia activity lists (HAL) and the paediatric haemophilia activity list (PedHAL) although will be this is not as discriminatory.

Patient contract and data returns

A number of centres use patient partnership agreements. It was felt that this was good practice and encouraged and improved that data that could be collected. The Haemophilia Society and Commissioners on the group led on the production of a patient partnership agreement. This would be a model national document for centres to use.

Summary

The purpose of this group was to develop a single set of measures that could be widely applied and lead to standardised data for outcome measure to allow data to be returned at a national level and centre level as will be required by Commissioning bodies. The outcome set proposed is simple and feasible in most CCCs and if used nationally could provide important data on natural history and progression of haemophilia today. The purpose is not to develop competitive benchmarking but to ensure we are all measuring outcomes using the same metrics.

Prof KJ Pasi
Chairman, Clinical Outcomes Group
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