

NCRI Palliative Care Clinical Studies Development Group

The remit of the Group is in line with the existing Clinical Studies Groups and the primary aim is to develop a portfolio of national collaborative studies, which are clinically relevant and likely to have an impact on day-to-day practice. The full committee is concerned with developing a strategy for the Group and identifying priorities for palliative care research. The development of protocols has been devolved to Sub-Groups where the detailed discussion and review of study proposals takes place. During this year the group has been subject to a formal progress review, to rotation of group members and to rotation of chairman position. 5 members have left the Group and 6 members joined the Group. The Chair was re-appointed in May 2006.

Subgroups

There are two of the 'original' Sub-Groups still working, Pain, and Health Services Research. The Pain group has met on several occasions during the past year, in addition to the twice-yearly meetings of the main Group. Two new Sub-Groups, Cachexia and Palliative Care in a Primary Care Setting had been set up in April and December 2005 respectively, followed by a Breathlessness Group early in 2006.

Progress Review

The progress review in January 2006 was in the main satisfactory, but flagged up some important thoughts for the future. These include the failure of the Health Services Research Subgroup to develop any studies to be taken forward, and the need to broaden the palliative care portfolio. "It is particularly important that studies in the important area of health service research are rapidly developed. Additionally the Group could consider developing ethics studies and work with other CSDGs to develop joint studies on for example complementary therapies or spirituality."

As a result of the review the title of the Clinical Studies Development Group has been changed, dropping the word development. This pleasing change is really an acknowledgement of the achievements of the Chairs of the Pain and Prognosis Subgroups in developing their ideas and taking them through successfully to the funding stage.

More problematic is the question of how the Group should handle the sharp criticism of Health Services Research. "The Panel expressed grave concern over the Health Services Research Subgroup. It is an important area of work but the subgroup had not met for over a year, have not developed a study and lack clarity over their priorities. Those studies being developed are at an embryonic stage....". At the main meeting of the PCCSDG in March 2006 the decision was taken to dissolve the HSR Subgroup pro tem, and to ask the chair of the disbanded subgroup to write a new strategy document and if accepted then a new committee would be formed to take forward that work.

Portfolio and accrual

There are currently 6 open trials in the portfolio and 3 in set up. A summary of the trials is given below. In addition, a number of studies are in development including a study of hydroxymethyl butyrate and eicosapentaenoic acid in cancer cachexia, and a randomised double-blinded controlled parallel trial of s-ketamine, racemic ketamine and placebo in conjunction with best pain management in neuropathic pain in cancer patients.

67 patients were accrued to palliative care studies in 2005-06.

Strategy

The strategy for the Group may be summarised as:

- Developing a large study which makes full use of NCRN resources and which clearly demonstrates the added benefit of being part of NCRI

- The publication of results from a national study in a high quality journal
- Fully integrating palliative care research into mainstream oncology research (palliative care outcomes built into therapeutic studies)
- Agreeing and using common outcome measures in studies
- A better understanding of how sponsored services can have a high positive output on the patient and family unit
- Health Service Research

In addition there is a need to clarify the relationship between the Group and the two SUPAC Collaboratives, to ease communication and prevent unnecessary competition between the CSG and the Collaboratives.

Palliative Care Group Portfolio

Acronym	Title	PI(s)	Status
Antifungal Drug Resistance Study	An investigation into the relationship between antifungal drug use, salivary gland dysfunction and antifungal drug resistance in patients with advanced cancer - Phase 1 (Observational Study)	Dr Andrew Davies	Closed
Antifungal Drug Resistance Study 2	An Investigation into the relationship between antifungal drug use, salivary gland dysfunction and antifungal drug resistance in patients with advanced cancer - Phase 2 (Interventional Study).	Dr Andrew Davies	Open
ASPECTS	(A Study of Patients Experiences of TreatmentS) Understanding patients and clinicians experiences and views of palliative chemotherapy.	Professor Rona Campbell	Open
EPA nutritional supplement to treat Cancer Cachexia	A pragmatic parallel-randomised single blind controlled trial to investigate the efficacy of an oral nutritional supplementation Prosure™ containing the omega-3 fatty acid, eicosapentaenoic acid or EPA to stabilise weight loss and promote weight gain in patients with specific incurable solid tumour cancer and a history of on going weight loss (cachexia)	Dr Chris Baughan,	Closed
MIST-B	Oral morphine in the symptomatic treatment of breathlessness in cancer patients: a pilot study to determine the optimum dosage regime	Dr Polly Edmonds	in Set-up
	Pain and pain management in older people. Pain and pain management strategies in older people with cancer.	Dr Mike Bennett Professor Jose Closs	Open
TENS-CBP	TENS: Transcutaneous electrical nerve stimulation in the management of cancer bone pain	Dr Mike Bennett	In Set-up
STAMP (previously as The two-step study)	An open, randomised, parallel group study in patients with cancer pain, to compare a two-step analgesic ladder (non-opioid to oxycodone) with conventional management using a three-step approach.	Professor Geoff Hanks	Open

	Double blind randomised controlled trial of pregabalin vs placebo in conjunction with palliative radiotherapy for malignant bone pain	Dr Marie Fallon	In Set-up
PIPS	Prognosis in Palliative Care Study	Dr Paddy Stone	Open
EPAT	Edinburgh Pain Assessment Tool	Dr Marie Fallon	Open

Professor Henry McQuay, Chair

Appendix 1: Key strengths and issues from the Interim Progress Review, January 2006

Strengths:

- Getting off to a flying start and tremendous progress in the first three years
- Good chairmanship, with the chair having a good sense of the strengths of his members and successfully bringing the members together
- Committed enthusiastic members
- Successfully developing studies of their own and having them funded
- A number of excellent ideas for future studies
- A well understood subgroup structure which is working very effectively in most areas
- Establishing links with other CSDGs and CSGs

The Group needs to consider:

- Poor attendance of some members and addressing this with some urgency
- The most appropriate balance of specialists required for future priorities
- Co-opting senior members of the two SUPAC Collaboratives onto the Group to ease communication and prevent unnecessary competition between the CSDG and Collaboratives
- Developing and nurturing a strong and effective relationship with the two collaboratives
- The lack of progress from the Health Services research Subgroup, whether or not the subgroup should remain, and if so, its leadership, membership and future strategy
- Broadening the Group's portfolio by rapidly developing health service research, considering ethics studies and developing joint studies with e.g. the Complementary Therapy CSDG or the Spirituality Subgroup of the Psychosocial Oncology CSDG, Lung, Colorectal, Head and Neck CSGs
- Working more closely with one or more CTUs
- Working closely with networks who have identified a particular interest in palliative and supportive care