NCRI Psychosocial Oncology Clinical Studies Development Group (POCSDG)

The NCRI Psychosocial Oncology Clinical Studies Development Group was established in 2004 under the chairmanship of Professor Michael Baum. The Group has now met six times in full committee but much additional work has been carried out within the Sub-Groups and electronically.

The remit of the Group is:

- To encourage the development of research protocols in psychosocial oncology, either freestanding or linked to trials of treatment within the NCRN.
- To work closely with all the NCRI Clinical Studies Groups in order to develop site-specific psychosocial oncology protocols.
- To work in collaboration with the other relevant Clinical Studies Development Groups.
- To consider research protocols submitted to CTAAC or PBSC where the main outcome measures are within the field of psychosocial oncology.

The NCRI Psychosocial Oncology Clinical Studies Development Group welcomed the report of the NCRI Strategic Planning Group on Supportive and Palliative Care, which highlighted the need to strengthen the organization and coordination of the workforce involved in psychosocial oncology research. Although these objectives were sound clear and straightforward, in practice they posed a greater challenge than any of those faced by the site-specific clinical study groups. Quality of life (QOL) end points are now often routinely included in therapeutic intervention trials. This progress has both strengths and weaknesses for the NCRI POCSDG and the site specific CSGs. Firstly it is progress indeed that QOL end-points are now acceptable but at the same time these are often bolted on as after thoughts and without the requisite expertise and support. Secondly they have become so ubiquitous as to distract attention from what should be the portfolio of the PSOCSDG and to oversimplify the problems of survivorship, sociological coping and existential issues in the spiritual domain. With this background the Group has over the last year continued to establish working practices, particularly with respect to how it requests proposals and evaluates projects sent in from other CSGs or independent agencies, and support its subgroups.

Membership

During the last year two new members, Prof Ann Barrett and Prof David J de L Horne have been appointed to the committee, ensuring that all relevant areas of expertise were covered. Dr Peter Harvey has indicated that he will step down from the Group during the next membership rotation. He has been a wise counsel on the Group and an excellent chair of the Interventions Subgroup. We wish him well and thank him for his valuable contributions over the last three years. The chairman’s life has been made much easier with the appointment of Judith Mills as portfolio coordinator within the last 12 months. At this point the chairman also wishes to acknowledge the wonderful support of Eileen Loucaides of the NCRN HQ staff, without whom nothing of worth would have been achieved. Prof. Julia Brown has been appointed as the new chair with effect from Autumn 2006.

Subgroups

In addition to the existing three subgroups, which had been set up to address the critical special interest areas of interventions, measurement of subjective outcomes and survivorship a fourth was established in May 2005 to look at the spiritual domain. The four semi-autonomous sub-groups advise the main committee on these areas.

Interventions Subgroup (Chair: Peter Harvey)

This subgroup agreed a definition of an intervention to which they would work, notably, any activity that acts to *'…prevent or reduce psychological distress and at the least, maintain a sense of psychological well being for people with cancer.'*

A number of issues have been identified that need wider discussion over the next three years. These include: the lack of available resources in terms of personnel to carry out psychosocial research outside of a few centres; the lack of a broad evidence base relating to the 'psychosocial trajectory' experienced by people with cancer; the variety of different outcomes that may need to be included for different sub-groups of patients; the lack of knowledge of current use of available resources (tracking interventions); the dearth of multi-centre research studies in this area; access to potential trial participants being one step removed from other clinicians.

Quality of life (QOL) Subgroup (Chair: Julia Brown)

The main remit of this subgroup has been to act as a resource of expertise for the site specific CSDGs wishing to evaluate QOL in clinical trials and to provide advice to researchers who are including a large amount of psychosocial research within their projects.

The early involvement of members of the POCSDG in trials being developed by other Groups has been stressed. The chairman has written to chairs informing them of the Group's sub-groups and the willingness and importance of POCSDG members to work with them. The Group has commented in detail on a number of proposals to date.

Survivorship Subgroup (Chair: Nigel Palmer – Consumer representative)

The Survivorship Sub-Group has met a number of times and has agreed a broader definition of survivorship rather than the five years post-treatment one commonly used in this country. Considerations have included whether support groups contribute positively or negatively and also issues concerning patients' return to work. Work in both these areas is expected to lead to study proposals. Amongst other matters considered are the psychological pressures patients experience at the end of treatment and, also, issues arising for participants at the end of an RCT. Several Sub-Group members have been involved in developing the SUPAC bids.

Mr Palmer was involved in the Bristol SUPAC bid, and also on the management group of the National Cancer Nursing Research project set up to examine the needs of patients as they come to the end of treatment. Both he and Mrs April Matthews, another of our consumer representatives, are involved in developing a research project on the quality of information given by telephone help lines.

Spirituality Subgroup (Chair: Dr. Louise Jones)

This new sub-Group was established in May 2005 with the remit to consider the neglected area of spirituality in life-threatening disease. Despite increasing secularization of society, in the face of life threatening illness the eternal existential problems remain in sharp focus. What happens at the moment of death and how we can prepare for that are unavoidable concerns. Clinical experience informs us that

spiritual issues, however they may be defined, can be highly relevant both to the physical and psychological management of the palliative and terminal phase of illness. So far the subgroup has responded formally to the EORTC 's Spiritual Wellbeing Module and submitted a proposal for a study to CRUK. Other study proposals are in development

Portfolio and accrual
The Group has 8 studies in its portfolio (see table below) and have commented on a number of other studies. 1360 patients have been recruited into psychosocial oncology studies.

Priorities
The Psychosocial Oncology Clinical Studies Development Group is working within the context of an NHS that is starved of funds, constantly in a state of re(dis)organization and in a state of terminal decline of morale amongst clinical staff and in the absence of psychosocial oncology departments. It will now have to be proactive and rather than just measuring "outcomes" actively intervene to improve these outcomes amongst survivors in the sociological, subjective and spiritual domains.
Below the subgroups briefly describe how they hope to achieve these gains over the next three years.

Interventions Subgroup – 3 year plan
The subgroup have identifies a number of strategic, design and methodology issue which need to be addressed in addition to specific projects to complete.

Strategic issues years 1-3

- Support the development of Trials Units with the relevant expertise to deal with psychosocial research questions and methodologies.
- Identify 'nodes' for each network and Trials Units to act a local focus for the development, promotion and co-ordination of psychosocial research.
- Support the development of pilot and small-scale local studies prior to rolling out large-scale national ones.
- Consult a wide variety of different groups in any exercise to assess future research – one priority being both the patient and the professional users of psychosocial services.
- Liaise with some of the site-specific groups, particularly those areas which have a smaller and less developed psychosocial research base and those areas in which there is a enthusiasm and support for joint working, to work with in identifying psychosocial needs.
- Identify what research is currently being funded over the whole of the UK by requesting the information form the current NCRI Partners, Cancer Networks, the authors of the NCRI Report.

Design and methodology issues years 1-2

- Intervention studies in psycho-social research may challenge the more traditional designs that are needed for straightforward treatment comparisons in other areas and more account may need to be taken of more difficult to control variables. This means that a wide variety of methodologies (*e.g.* qualitative and quantitative) as well as designs (*e.g.* simple and 'complex' (as used by the MRC) will be appropriate. Designs should be appropriate to the research question to be answered.

- Research proposals need to be evaluated on the basis of their impact both in terms of degree of impact on individuals and the numbers of individuals impacted upon (*e.g.* an intervention that might have a large impact on a small number of patients or one that has a smaller impact on a much larger number)

Specific Projects years 1 and 2

- Support work to assess the psychosocial needs of in-patients.
- Work with the QoL sub-group in developing reporting standards for QoL outcomes in existing clinical trails.
- Assess the impact of socio-demographic factors on the offering, uptake and implementation of psychosocial interventions.
- Develop study on Interventions for carers.
- Assess the impact of social factors and co-morbidity on the need for and provision of psychosocial interventions.
- Psychosocial interventions for managing long-term treatment effects (*e.g.* fatigue, body image/integrity.
- Assessment of patients' and carers' use of formal and informal psychosocial support during and after treatment.

Quality of Life Subgroup –3 year plan

The Subgroup's plan has two main strands

1. To comment and advise upon NCRN Research protocols which incorporate quality of life assessments.
2. To research into and set standards for the design of, data collection and conduct of research protocols incorporating quality of life assessments.

Year 1

- Develop links with ISOQOL, EORTC QOL Group.
- Develop standards for the design of and data collection, conduct of research protocols, which include quality of life assessment. Working alongside ISOQOL, EORTC, QOL Group.
- Advertise the remit of the subgroup more widely, in particular to clinical trials units.

Years 2 & 3

- Develop further research into design of research protocol including a quality of life assessment.
- Develop guidelines for choice of quality of life instruments.

Ongoing

- Comment and advise on all NCRN research protocols, which incorporate of quality of life assessment.

Spirituality Subgroup- 3 year plan

There are two main strands to the subgroup's plans

1. Research ideas of clinical relevance taking a grass roots approach to patient and carer experiences of spiritual care and expressions of spiritual belief in relation to illness, death and dying and bereavement.

2. Research into underpinning theoretical concepts to gain a greater understanding of the biological mechanisms of belief, and associated ethical and moral philosophical issues.

Clinical Issues

Year 1

- Develop a simple research protocol to evaluate spiritual need in all patients with advanced cancer and how these needs are currently being met in hospice, community and hospital settings.
- Gain an understanding of how chaplaincy services within hospice and hospital settings currently operate and what kind of support they are providing. Understand the extent of spiritual support currently being offered by clinical staff and assess at what point chaplaincy services are required.

Years 2 and 3

- Use the findings from year 1 to inform the development of an intervention to meet multi-cultural, multi-faith, interdenominational spiritual need in patients with advanced disease.

- Observe the effect of met and unmet spiritual need on psychological and physical status (needs for medication) in advanced progressive disease, the terminal phase and the dying process.

- Consider such interventions in the context of the Liverpool Pathway for the Care of the Dying.

Theoretical issues

Year 1 - 3

- Develop links with neuro-imaging at UCL to investigate neurobiological processes in spiritual experience and how these might be affected by sight; sound and psychotropic drugs such as are used in advanced disease.

- Develop ideas around moral philosophical issues of relevance to patient care such as advance care planning, cardio-pulmonary resuscitation and assisted suicide

Overall:

- Encourage and assist in the development of protocols from researchers both within and out with the subgroup that are designed to assess delivery of spiritual care.

Survivorship Subgroup- 3 year plan

The key priority is to achieve an evidence-based understanding of the frequency, content, setting, and experiences of follow-up care received by cancer survivors in order to develop standards for such care with a view towards prevention, early detection, or amelioration of long-term or late effects of cancer and its treatment.

Years 1-2

- Completion studies, currently 5 in number, in which sub-group members are currently engaged and work with new studies as they become available and opportunities arise.
- Develop a clear aim, proactive approach and response to this area of research with a best to develop this as a main direction to follow.
- Take opportunities to promote the survivorship sub-group at appropriate conferences and meetings - e.g. BPOS; IPOS; NCRI Conference; etc.
- Act as a source of information for survivorship research. Make contact/links with the funding bodies with relevant DH organisations (e.g. Cancer Action Team), NIHR, etc. to assist in co-ordinating and not duplicating research ideas and to exchange information. Establish contacts and links with the Cancer Networks, and the universities within their boundaries.
- Establish a liaison/ongoing relationship with the US Office of Cancer Survivorship with a view to exchanging information and ideas and developing opportunities to share research initiatives.
- Ensure membership of the sub-group is appropriate for the tasks in hand.
- Establish a link to the 2 SUPAC Collaboratives - CECO and COMPASS - to offer support that would be to our mutual interests.
- Work more closely with the other sub-groups both within POCSDG and other CSGs.

Years 2-3

- Consider areas of relevance to survivorship for future work. Encourage and support people to submit proposals.
- Consider the use of Communication Skills training that has been developed by Lesley Fallowfield and Amanda Ramirez for other health professionals involved in longer term care of survivors.
- Develop studies looking at various psychosocial aspects of follow up after treatment intended to be curative e.g. identity/body image/body integrity; patients who survive but remain ill; how to be a member of a club you didn't want to join; management of uncertainty; etc.

Psychosocial Oncology Group Portfolio

Acronym	Title	PI(s)	Status
Clinical meaning & utility of the SPI: longitudinal study	Clinical meaning and utility of the Social Problems Inventory (SPI) in oncology practice: longitudinal study	Dr Penny Wright	Closed
	Clinical meaning & utility of the SPI:X-sectional study Clinical meaning and utility of the Social Problems Inventory (SPI) in oncology practice: cross sectional study	Dr Penny Wright	Closed
SCNSUK05	Unidentified or unmet - what are the supportive care needs of people following cancer treatment?	Prof Alison Richardson Maggie Crowe	Open

	Development of an EORTC Quality of life module for cholangiocarcinoma	Dr JK Ramage	Open
FH01 - HTA Mammography Trial	Evaluation of mammographic surveillance services in women under 50 with a family history of breast cancer	Dr James Mackay	Open
OES/STO Merge	A study to combine the EORTC quality of life questionnaire modules, the QLQ-OES18 and QLQ-STO22 to measure quality of life in patients with oesophageal or gastric cancer, or cancer of the oesophago-gastric junction	Miss Jane Blazeby	Open
Quality of Life in secondary liver tumours	Development of an EORTC QoL questionnaire for patients with malignant carcinoid tumours. (b)A study of the clinical and psychometric validation study of a disease-specific questionnaire module(QLQ-LMC21) in assessing the quality of life of patients	Dr JK Ramage Mr Myrddin Rees	Open
SLIPER	Development of an integrated clinical assessment strategy for women receiving pelvic radiotherapy.	Ms Isabel White	Open

Professor Michael Baum, Chair