NCRI
National
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Research
Institute

# NCRI Supportive & Palliative Care Clinical Studies Group

## Annual Report 2015-16

Partners in cancer research

# NCRI Supportive & Palliative Care CSG
# Annual Report 2015-16

## 1. Executive Summary (including top 3 achievements in the year)

2015-16 was a momentous year for the Supportive & Palliative Care CSG. In the previous year we had initiated a strategic review and had agreed the name change from the former Palliative & Supportive Care CSG to the new title.

The major challenges for the Group in this year were that, first, our research agenda was perceived to have become detached from the main advances in oncology – especially the early and late toxicities caused by 'old' and emerging new treatment modalities. Second, we also had not undertaken as many large scale multicentre trials of supportive care as other CSGs are doing in their specific disease areas. Thirdly, we had a low profile of recognition in both the oncology and supportive/palliative care professional circles, partly because the Group had never held a national meeting.

During this year we therefore continued the strategic review process and responded to these challenges by undertaking the following actions and achievements:

1. We held the CSG's first annual clinical trials meeting. This took the form of an open conference held in Sheffield on 3 June 2015 and attracted over 120 delegates. It included invited speakers, reports from Subgroups, workshops in collaboration with other CSGs and also on making the Group's work more patient-focused and a dragon's den for new study proposals.
2. We undertook a radical review of the CSG's previous achievements and directions. This led to a new strategic agenda which is focusing less on individual symptoms (e.g. pain, fatigue) or types of intervention (e.g. rehabilitation), and more on the different issues faced by patients and challenges for oncology at different stages of the disease.
3. We disbanded the former subgroups and initiated new subgroups. In accordance with the new strategy, which is based more on needs of patients at different stages, we set up these new subgroups
    - Early stage disease and acute treatment toxicities
    - Advanced stage disease and end of life
    - Survivors and late consequences
4. We have maintained active engagement with other CSGs. The Chair and other members have attended the regular or strategic meetings of several other CGSs with the purpose of informing them of our new structure and strategy and to engender joint research ideas.

## 2. Structure of the Group

The Group has been restructured from its former four subgroups, which were largely based on symptoms (e.g. pain) or systems (e.g. vascular), to three new subgroups focusing on stages of cancer and their associated supportive care needs, including treatment side-effects. Two of the new subgroups (Advanced Disease/End of Life and Survivors/Late Consequences) are chaired by former Subgroup Chairs to maintain continuity of the research activities, while the Early Stage/Acute Toxicities Subgroup has a new Chair.

## 3. CSG & Subgroup strategies

### Main CSG

In 2014-15, the Group started a process of internal review of its activities and also listening to others within the NCRI and outside researchers about how it is perceived in the worlds of oncology and supportive/palliative care. These were important aspects of the national clinical trials meeting that was held on 3 June 2015, and in particular we engaged with the TYA and Haematology CSGs and also representatives from national cancer charities including the Brain Trust, Maggie's Centres and Trekstock. Discussions were also held with the newly formed NIHR Cancer and Nutrition initiative.

This national meeting catalysed the Group's strategic review, from which the new subgroup structure has emerged, with the former subgroups being disbanded. The new subgroups have been given specific tasks:

1. To each host a strategic workshop during 2015-16, bringing together researchers from within the NCRI, other research groups and charities.
2. To ensure that each subgroup has at least one major grant application accepted in 2015-16.
3. To move towards multicentre trials with, wherever possible, a translational component.
4. To engage with relevant industrial partners, e.g. pharmaceutical industry, medical devices manufacturers, medical communications technology companies.

We are already well on the way to achieving these ends, with two national grants already in the second round of funding review. The strategic workshops will commence in the autumn and will deliver their reports to the main CSG in the spring of 2017.

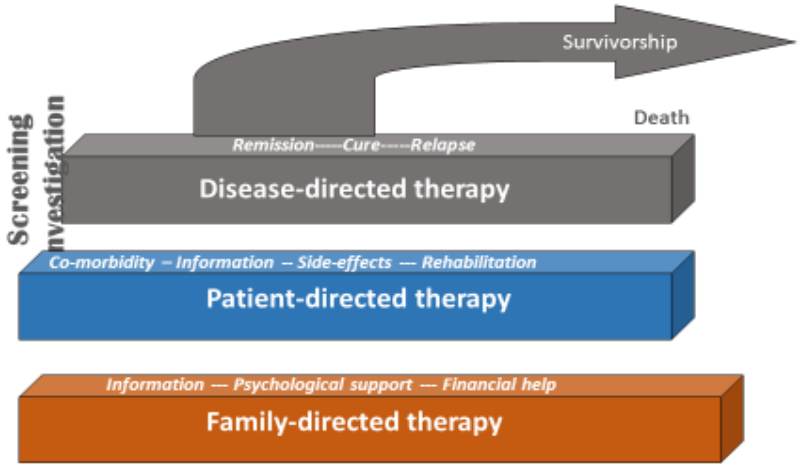
### Former subgroups

The former subgroups that had been active for many years were: Pain & Neuropathy (Chair, Professor Marie Fallon); Fatigue/Cachexia and Rehabilitation (Chair, Dr Matthew Maddocks); Vascular and Thrombosis (Chair, Dr Vaughan Keeley). In 2013-14, a new subgroup was initiated to broaden the scope of the CSG – Gastrointestinal (Chair, Professor Sam Ahmedzai). This new subgroup 'inherited' a number of existing portfolio studies that had a gastrointestinal focus and had started to develop a new research programme based on anti-cancer treatment toxicities such as chemotherapy induced nausea and vomiting and oropharyngeal mucositis. However, Professor Ahmedzai observed that this subgroup's emerging research agenda contained key elements that cut across the other existing subgroups, e.g. pain from mucositis; nutritional problems and weight loss associated with mucositis; different routes of vascular or subcutaneous access for fluids and feeding. It was this realisation that the existing subgroup

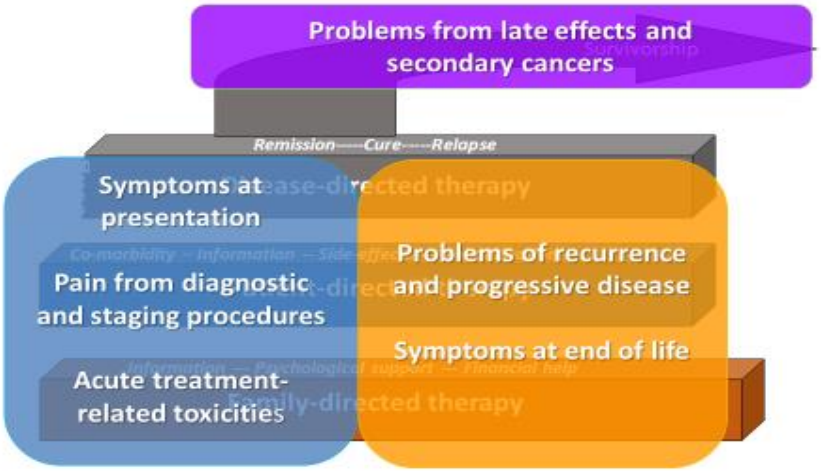
structure led to potential fragmentation of the whole Group's work that led Professor Ahmedzai to ask the CSG to consider a new strategy and corresponding subgroup structure.

The proposed new strategy is based more on the stages of cancer – expressed simply as early, advanced and survivors – than individual symptoms or issues. In the new structure, aspects such as pain, nutrition, vascular access etc can all be considered as foci for research at each stage, so that all members can contribute more efficiently. The new structure is represented diagrammatically as follows:

## Holistic view of disease-modifying (top level) and supportive streams (lower two levels) of cancer therapy




## Research agenda mapped onto supportive and palliative care research needs



### New subgroups and their strategies:

### Early Stage Disease/Acute Treatment Toxicities Subgroup (Chair, Professor Annie Young)

This subgroup will take on a new stream of work in the Group, focusing on the experience of patients in the early phase of disease and treatments. It will address symptoms and complications of the cancer, and also toxicities from the therapies used. In the first year, the main areas to be focused on are:

1. Acute treatment toxicities
    - Surgical
    - Chemo / biologicals – including mucositis, neurological, cutaneous, MSK
    - RT – brain, mucositis
2. Prehabilitation and rehabilitation
    - Exercise, nutrition

### Advanced Disease/End of Life Subgroup (Chair, Dr Matthew Maddox)

This subgroup has evolved from the previously successful Fatigue and rehabilitation Subgroup, and is led by the same Chair. It is broadening its remit to other symptoms in advancing disease and towards the end of life. Priorities for the first year are:

1. Symptoms of advancing disease

This theme incudes thrombosis, cord compression, anaemia, and symptoms which impact adversely on quality of life, including pain, lymphedema, fatigue and breathlessness.

2. Issues towards the end of life

This theme focuses on complex symptoms and issues towards and at the end of life, including the management of dying.

3. Rehabilitation

In advanced disease, rehabilitation aims to improve quality of life by increasing the time people can remain reasonably active and independent.

### Survivors & Late Consequences Subgroup (Chair, Dr Vaughan Keeley)

The subgroup has evolved from the former Vascular and Thrombosis Subgroup, with its special expertise and track record in lymphoedema, but is adapting these to the broader agenda of longterm survivorship and late consequences of disease and treatments. In the first year, there are three key areas for exploration and study development:

1. 'Early' survivors
    - Lymphoedema
2. 'Longterm survivors'
    - Pelvic cancers
3. Rehabilitation
    - Exercise

## 4. Task groups/Working parties

The Group has not formed any new Task Groups or Working Parties in 2015-16. However, the three strategic workshops which will be run by the new Subgroups during Q2 and Q4 of 2016 will lead to specific Task Groups to take their agendas forward during 2016-17. These Tasks Groups will typically last for up to two-three years, with the express aim of initiating new study ideas and

research proposals. They will consist of members from the Supportive & Palliative Care CSG and from other CSGs, invited charities and other research groups.

## 5. Patient recruitment summary for last 5 years

In the Supportive & Palliative Care CSG portfolio, 19 trials closed to recruitment and 8 new trials opened. There has been a significant increase in the number of patients recruited across the board, but especially in interventional studies. So far a weakness of the Group's portfolio is that many of its studies are restricted to one or just a few centres. The new strategy of the CSG is to develop larger and multicentre studies, both observational and interventional.

There have been new industrially sponsored studies and this is a trend that the Group intends to continue.

One of the continuing problems with monitoring the portfolio is that it is not uncommon for studies with a predominantly supportive and palliative care focus to be labelled under a different CSG. This is of course appropriate if the study originated in another CSG but can be co-labelled with the Supportive & Palliative Care CSG. However sometimes the mislabelling is not helpful and a project was completed by the two trainee members during 2015-16 to try and identify all these 'outliers'.

**Table 1 Summary of patient recruitment by RCT/Non-RCT**

| Year | All subjects | | Cancer patients only | | % of cancer patients relative to incidence | |
|---|---|---|---|---|---|---|
| | Non-RCT | RCT | Non-RCT | RCT | Non-RCT | RCT |
| 2011/2012 | 488 | 637 | 130 | 622 | - | - |

**Table 2 Summary of patient recruitment by Interventional/Non-interventional**

| Year | All participants | | Cancer patients only | | % of cancer patients relative to incidence | |
|---|---|---|---|---|---|---|
| | Non-interventional | Interventional | Non-interventional | Interventional | Non-interventional | Interventional |
| 2012/2013 | 570 | 399 | 303 | 399 | - | - |
| 2013/2014 | 1473 | 393 | 524 | 324 | - | - |
| 2014/2015 | 1336 | 498 | 1290 | 473 | - | - |
| 2015/2016 | 869 | 2261 | 706 | 2244 | - | - |

## 6. Links to other CSGs, international groups and network subspecialty leads

During 2015-16, the Chair and other members of the Group 'adopted' other CSGs and have attended their meetings to share ideas and help develop new joint proposals. This is particularly helpful if the Group's members are invited to another CSG's strategy day.

Other NCRI groups which are 'covered' in this way include – Colorectal, CTRad, Gynaecology, Lymphoma, Lung, Prostate, Sarcoma and TYA. The Group is actively involved in the Supportive care, transfusion and late effects Working Party. One of the Group's members is an active

member of the Psychosocial Oncology & Survivorship CSG and our consumer is also represented on the Breast CSG.

In addition, the Chair has attended the first national meeting of the NIHR Cancer and Nutrition initiative and has been recruited to one of its workstreams, thus ensuring that the Supportive & Palliative Care CSG will be part of this new programme of work.

The Group held one national meeting in 2015-16 for LCRN Subspecialty Leads (SSLs) and their associated RDMs. This will be a continuing national event.

Members of the Group have contributed to other national and international meetings and activities: European Society for Blood and Marrow Transplantation (EBMT); European Association for Palliative Care (EAPC); Multinational Association for Supportive Care in Cancer (MASCC); Royal College of Physicians (RCP London); Royal Society of Medicine (RSM); International Society of Geriatric Oncology (SIOG).

## 7. Funding applications in last year

### Table 3 Funding submissions in the reporting year

| **Other committees** | | | |
|---|---|---|---|
| **Study** | **Committee & application type** | **CI** | **Outcome** |
| An evidence synthesis of holistic breathlessness services. | NIHR HS&DR | Dr Matthew Maddocks | Pending |
| HYDRANT: HYDration in advanced disease: Routine practice And New Technologies- Qualitative study (HYDRANT-Q) | Marie Curie | Professor Annie Young | Pending |
| PiPS-2 | HTA | Dr Patrick Stone | Pending |
| Developing a short-term integrated rehabilitation service for people with newly diagnosed thoracic cancer | NIHR Clinical Doctoral Research Fellowship | J Bayly | Funded |
| Improving palliative rehabilitation in palliative care using goal attainment scaling | Dunhill Medical Trust | Dr Matthew Maddocks | Funded |
| Developing a short-term integrated rehabilitation service for people with newly diagnosed thoracic cancer | NIHR TCC | J Bayly | Funded |
| An evidence synthesis of holistic services for refractory breathlessness in advanced malignant and non-malignant disease | NIHR HS&DR | Dr Matthew Maddocks | Pending |
| Understanding the social determinants of outcomes important to older people at the end of life: reducing social inequality in palliative care | Dunhill Medical Trust | Murtagh FEM | Pending |
| The MENAC Trial: A randomised, open-label trial of a Multimodal Intervention (Exercise, Nutrition and Anti-inflammatory Medication) plus standard care versus standard care alone to prevent / attenuate Cachexia in advanced cancer patients undergoing chemotherapy | Marie Curie/CR UK | Professor Ken Fearon | Funded |

## 8. Collaborative partnership studies with industry

The Group does not have a strong history of large scale collaboration with industry, although clinical trials of new medications for cancer-related pain and for the management of opioid-induced constipation have been more prominent in recent years. In 2015-16, we have run commercial trials which have been supported by AstraZeneca, Grunenthal and Mundipharma. One of our trials, Sarcabon, has arisen from the AstraZeneca-MRC new drugs collaboration.

Discussions have been held this year with several different companies with a view to initiating new studies. These include drugs (e.g. for cancer-related cachexia, chemotherapy-induced nausea and vomiting) and also medical devices. In the latter category, we are having discussions with a company to test a new subcutaneous injection and infusion needle which could have wide application in palliative care settings.

Another avenue of commercial linkage is with information technology and internet-based communication tools. For example, we are working with a company that has provided an internet portal for online holistic needs assessment of prostate cancer patients at different stages of disease, using CHAT-P, a new adaptive questionnaire technology developed by University of Sheffield and being implemented in ICARE-P, a HTA-funded feasibility trial run under joint badging of the Prostate and Supportive & Palliative Care CSGs.

## 9. Impact of CSG activities

The previously named Palliative & Supportive Care CSG has been productive in initiating studies in keeping with its former subgroups, namely Pain & Neuropathy, Fatigue/Cachexia and Rehabilitation, Vascular and Thrombosis, and Gastrointestinal. Although the Group has not developed a programme of phased large scale multicentre trials comparable to some other CSGs' national studies, it has nevertheless been important in moving the evidence base of supportive and palliative oncology forwards. Areas in which the Group's previous studies and their PIs have started to influence clinical practice include – more rational use of opioids and other drugs in cancer pain management, including a focus on patient education about medication; better assessment of cachexia and fatigue; multidisciplinary approach to rehabilitation; rational use of anticoagulants at different stages of cancer; more interventional treatments for lymphoedema; improving assessment of risk factors for chemotherapy induced nausea and vomiting; and use of targeted treatments for opioid-induced constipation.

The Group's members are involved in activities such as the James Lind Alliance's Priority Setting Partnership (JLA PSP) with Mare Curie Cancer Care, on setting the research agenda for end of life care. Based on the priorities generated from the 2015 JLA PSP, two grant applications were made in 2015-16 for Marie Curie funding: one of these has progressed to the second stage of review.

The Group's Chair led the committee that produced the NICE guideline for Last Days of Life in Adults (NG31, 2015). That guideline issued four research recommendations, and the Group will actively work these up in the coming year in the anticipation that NIHR or Marie Curie may fund them. Group members also sit on NICE technology appraisals for new medications for cancer symptom control and supportive care, which also gives advance notice of potential research opportunities.

Other examples of horizon scanning arise from the roles that Group members have on advisory and consultancy boards with pharmaceutical companies; some of these contacts are leading to industry-funded research proposals for 2016-17.

The Group is regularly asked to comment and review grant applications from other NCRI groups, MRC, Marie Curie and other research funders.

## 10. Consumer involvement

The CSG's consumer members attend the biannual meetings of the main Group and are actively involved in the Subgroups sharing the work between them. The consumers have commented on draft protocols throughout the year and continue to help inform trial design. They are members of a number of Trial Management Groups.

One of the consumers, Lesley Turner, is a co-applicant on a number of supportive care studies that are funded and in set up such as the MABCan trial which is investigating the perceptions of mindfulness-based intervention and is developing an adapted mindfulness intervention for cancer patients. She is also a co-applicant on another trial producing online decision aids for patients regarding genetic testing.

Lesley is a member of the Breast CSG Symptom Management Subgroup and provides a link between the Breast and Palliative & Supportive Care CSGs. The Group is currently working on hot flushes and sexual issues following cancer treatment and has been successful in obtaining funding for the MENOS4 trial.

She is also a member of the NIHR Cancer and Nutrition Infrastructure Collaboration, working with the World Cancer Research Fund and NOCRI to provide a coordinated framework for future research into the areas of cancer and nutrition. She is the lead for one of the work streams and has presented at a number of meetings and events throughout the year.

Lesley has recently attended a qualitative research and research methods training programme at the University of Warwick organised by her scientific mentor, and she will be used to interview participants in trials in the future.

Lesley also works closely with charities such as Breast Cancer Now and has been appointed to the Grant Committee of the Pfizer Catalyst Programme which is a new initiative allowing academic researcher's access to research drugs from pharmaceutical companies.

Our second consumer representative, Jean Gallagher, was only recently appointed. Jean has been an active member of other NCRI CSGs in the past and is looking forward to engaging in our programme of work in the coming year.

## 11. Open meetings/annual trials days/strategy days

The first Supportive Care in Cancer Clinical Trials day for the UK was held under the joint auspices of the CSG and the North Trent Consumer Research Panel at the University of Sheffield on 3 June 2015. It attracted over 120 delegates from NCRI CSGs, NIHR, LCRNs and charities and was supported by industry. It was widely held as ground-breaking in covering a wide range of supportive and palliative care issues, and focusing on collaboration between the NCRI CSGs and

other organisations present. All the plenary talks and the 'Dragon's Den' were video-recorded and are available on YouTube:
http://www.youtube.com/playlist?list=PLgfR7wqY4Ky6NNjqGoxn7YTL7PJFLJAjo

There were calls for another national clinical trials conference in 2016, but according to this Group's strategic review process, the single national meeting will be replaced by three separate strategic workshops. The Group will consider repeating the large national clinical trials meeting in 2017.

## 12. Priorities and challenges for the forthcoming year

Priorities:

1. The new Subgroups to each hold strategic workshops to generate new research ideas and proposals.
   These will continue the line of work started in the June 2015 national supportive care clinical trials meeting but will be more focused with a small number of invited participants from within the CSG, other NCRI groups, other research groups in the UK (oncology, supportive and palliative care research active units) and specific charities with interests in the different subgroup agendas.
2. At least one major grant application to be generated from each subgroup in 2016-17.
   Marie Curie places an annual call for palliative care research and the CSG will generate at least one application from each Subgroup for that funding stream. Other funding streams to be used include NIHR – RfPB and HTA – and disease-specific charities.
3. Increase engagement with other CSGs, charities, industry and hospice sector.
   At the CSG and Subgroup level, there will be more active engagement through meetings, teleconferences and presentations at conferences to engage with other research organisations. The Group has already been invited to present at the 2016 Help the Hospices conference on the topic of increasing hospices' participation in clinical research.

Challenges:

1. Lack of opportunities for industrial collaboration -
   Compared to oncology, there are relatively few new drugs in supportive and palliative care pipeline. This is because there are fewer new drugs in the pipeline and also companies have found it more expensive and problematic to conduct registration studies in UK. Our approach will be initially to offer to run smaller scale feasibility studies and non-interventional studies, moving onto larger multicentre clinical trials once we have gained the confidence of both industry and the palliative care research communities.
2. Difficulty maintaining oversight of CSG-labelled studies within larger NIHR portfolio -
   Some Supportive & Palliative Care CSG studies are initially badged under other CSGs (which may be appropriate) or within other NIHR divisions, e.g. primary care (which is usually inappropriate). Our trainee members undertook an exercise in 2015-16, reviewing all the NCRI studies that are currently labelled under the Supportive & Palliative Care CSG and allocating them to one or more of the new strategic Subgroups.
3. Problem of designing large multicentre clinical studies, especially interventional trials, because of lack of 'research-ready' palliative care services and especially hospices -
   This is perhaps one of the biggest challenges facing the Group, and is probably the reason that it does not have a track record for large national trials, even in the common

symptoms such as pain, nausea and vomiting, or breathlessness. The Group has a good record of well-designed and conducted studies in single or a small number of centres and we need to translate this beyond regional to national level. A particular aspect of this challenge, which is unique to the Supportive & Palliative Care CSG, is that hospice and end of life care driven research, in general, increasingly includes non-cancer patients. It is long recognised that the Group can include non-cancer patients, but they must clearly not dominate the portfolio.

## 13. Appendices

Appendix 1 - Membership of main CSG and subgroups

Appendix 2 – CSG and Subgroup strategies

- A – Main CSG Strategy
- B – Early Stage Disease/Acute Treatment Toxicities Subgroup Strategy
- C – Advanced Disease/End of Life Subgroup Strategy
- D – Survivors & Late Consequences Subgroup Strategy

Appendix 3 - Portfolio Maps

Appendix 4 - Publications in previous year

Appendix 5 - Major international presentations in previous year

**Emeritus Professor Sam H Ahmedzai (Supportive & Palliative Care CSG Chair)**

## Appendix 1

### Membership of the Supportive & Palliative Care CSG

| Name | Specialism | Location |
|---|---|---|
| Dr Gillian Prue | Chronic Illnesses | Belfast |
| Mrs Jean Gallagher | Consumer | Yorkshire |
| Mrs Lesley Turner | Consumer | Southampton |
| Dr Teresa Young | Health Service Researcher | Middlesex |
| Dr Vicky Coyle | Medical Oncologist | Belfast |
| Dr Caroline Forde* | Medical Oncologist | Belfast |
| Dr Anthony Maraveyas | Medical Oncologist | Hull |
| Dr Dawn Storey | Medical Oncologist | Glasgow |
| Dr Xingwu Zhu* | Medical Oncologist | Middlesex |
| Professor Jane Hopkinson | Nurse | Cardiff |
| Professor Annie Young | Nurse | Warwick |
| Professor Sam Ahmedzai (Chair) | Palliative Medicine | Sheffield |
| Professor Marie Fallon | Palliative Medicine | Edinburgh |
| Dr Christina Faull | Palliative Medicine | Leicester |
| Dr Vaughan Keeley | Palliative Medicine | Derby |
| Dr Matthew Maddocks | Physiotherapist | London |
| Dr Sabine Best | Head of Research, Marie Curie | Leeds |
| Professor Gareth Griffiths | Statistician | Southampton |

*denotes trainee member

## Membership of the Subgroups

These Supportive & Palliative Care CSG Subgroups were in existence at the beginning of 2015/2016, but after the new strategic review, they have been disbanded and new subgroups (listed below) have been initiated.

| Rehabilitation Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Dr Gillian Prue | Chronic Illnesses | Belfast |
| Mrs Sharon Paradine | Consumer | Suffolk |
| Mrs Lesley Turner | Consumer | Southampton |
| Dr Teresa Young | Health Service Researcher | Middlesex |
| Dr Andrew Wilcock** | Medical Oncologist | Nottingham |
| Professor Jane Hopkinson | Nurse | Cardiff |
| Professor Alison Richardson | Nurse | Southampton |
| Professor Annie Young | Nurse | Warwick |
| Dr Anthony Byrne | Palliative Medicine | Penarth |
| Professor Miriam Johnson | Palliative Medicine | York |
| Dr Matthew Maddocks (Chair) | Physiotherapist | London |
| Professor Ken Fearon | Surgeon | Edinburgh |

| Gastrointestinal Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Professor Annie Young | Nurse | Warwick |
| Dr Sam Ahmedzai (Chair) | Palliative Medicine | Sheffield |
| Dr Richard Berman | Palliative Medicine | Manchester |
| Dr Anthony Byrne | Palliative Medicine | Penarth |

| Pain & Neuropathy Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Professor George Lewith | Acupuncturist | Southampton |
| Dr Barry Laird | Clinician Scientist | Edinburgh |
| Dr Jacqui Stringer | Complementary Therapies | Manchester |
| Mrs Sharon Paradine | Consumer | Suffolk |
| Mrs Lesley Turner | Consumer | Southampton |
| Dr Dawn Storey | Medical Oncologist | Glasgow |
| Professor Sam Ahmedzai | Palliative Medicine | Sheffield |
| Professor Mike Bennett | Palliative Medicine | Leeds |
| Professor Marie Fallon (Chair) | Palliative Medicine | Edinburgh |

| Vascular Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Ms Teresa Young | Health Service Researcher | Middlesex |
| Dr Anthony Marayevas | Medical Oncologist | Hull |
| Professor Annie Young, | Nurse | Warwick |
| Dr Vaughan Keeley (Chair) | Palliative Medicine | Derby |
| Dr Simon Noble | Palliative Medicine | Newport |

*denotes trainee member

**denotes non-core member

## New Subgroups

With the initiation of the new subgroups, their membership is 'under construction' and will be completed during 2016-17. The below lists a starting point for an exciting expansion of the Group's work into the new strategic thematic areas.

| Early Stage Disease/Acute Treatment Toxicities Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Dr Gillian Prue | Chronic Illnesses | Belfast |
| Mrs Jean Gallagher | Consumer | Yorkshire |
| Dr Teresa Young | Health Service Researcher | Middlesex |
| Dr Vicky Coyle | Medical Oncologist | Belfast |
| Dr Caroline Forde* | Medical Oncologist | Belfast |
| Dr Anthony Maraveyas | Medical Oncologist | Hull |
| Dr Dawn Storey | Medical Oncologist | Glasgow |
| Dr Xingwu Zhu* | Medical Oncologist | Middlesex |
| Professor Annie Young (Chair) | Nurse | Warwick |
| Dr Sam Ahmedzai | Palliative Medicine | Sheffield |

| Advanced Disease/End of Life Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Mrs Jean Gallagher | Consumer | Yorkshire |
| Dr Vicky Coyle | Medical Oncologist | Belfast |
| Dr Xingwu Zhu* | Medical Oncologist | Middlesex |
| Professor Jane Hopkinson | Nurse | Cardiff |
| Dr Sam Ahmedzai | Palliative Medicine | Sheffield |
| Dr Christina Faull | Palliative Medicine | Leicester |
| Dr Matthew Maddocks (Chair) | Physiotherapist | London |

| Survivors & Late Consequences Subgroup | | |
|---|---|---|
| **Name** | **Specialism** | **Location** |
| Dr Gillian Prue | Chronic Illnesses | Belfast |
| Mrs Jean Gallagher | Consumer | Yorkshire |
| Dr Teresa Young | Health Service Researcher | Middlesex |
| Dr Caroline Forde* | Medical Oncologist | Belfast |
| Dr Dawn Storey | Medical Oncologist | Glasgow |
| Dr Sam Ahmedzai | Palliative Medicine | Sheffield |
| Dr Vaughan Keeley (Chair) | Palliative Medicine | Derby |

*denotes trainee member

# Appendix 2

## CSG & Subgroup Strategies

### A – Main CSG Strategy

In 2014-15, the Group started a process of internal review of its activities and also listening to others within the NCRI and outside researchers about how it is perceived in the worlds of oncology and supportive/palliative care. These were important aspects of the national clinical trials meeting that was held on 3 June 2015, and in particular we engaged with the TYA and Haematology Oncology CSGs and also representatives from national cancer charities including the Brain Trust, Maggie's Centres and Trekstock. Discussions were also held with the newly formed NIHR Cancer and Nutrition initiative.

This national meeting catalysed the Group's strategic review, from which the new Subgroup structure has emerged and the former Subgroups disbanded. The new Subgroups have been given specific tasks:

1. To each host a strategic workshop during 2015-16, bringing together researchers from within the NCRI and also from other research groups, as well as charities.
2. To ensure that each Subgroup has at least one major grant application accepted in 2015-16.
3. To move towards multicentre trials with, wherever possible, a translational component.
4. To engage with relevant industrial partners, e.g. pharmaceutical industry, medical devices manufacturers, medical communications technology companies.

We are already well on the way to achieving these, with two national grants already in the second round of funding review. The strategic workshops will commence in the autumn and will deliver their reports to the main CSG in the spring of 2017.

### B – Early Stage Disease/Acute Treatment Toxicities Subgroup Strategy

Seven years ago, some members of our Subgroup contributed to a needs assessment for cancer patients who had been potentially cured[1] and found that around one third of people had a moderate or great 'unmet' need in living their lives, due to their cancer. Since then, our research on supportive care for people with early stage disease and treatment toxicities has markedly progressed alongside the patient voice.

This Subgroup focuses on:

1. Acute treatment toxicities
    - Surgical
    - Chemotherapy/biologicals – including mucositis, neurological, cutaneous, musculoskeletal symptoms, venous thromboembolism and neutropenic sepsis
    - Radiotherapy – brain, mucositis
2. Prehabilitation and rehabilitation
    - Exercise, nutrition and psychological care (in collaboration with the Psychosocial Oncology & Survivorship CSG)

These workstreams follow on from the research stemming from the CSG over the last few years and integrates well with the subgroups of MASCC (Multinational Association of Supportive Care in Cancer) the international group that some of our CSG contribute to.

We are in the process of developing our own studies within our CSG, e.g. holistic rehabilitation programmes for patients post adjuvant treatment and in collaboration with other CSGs, e.g. patient experiences of watch and wait in certain haematological malignancies and pre-malignancies. In our thrombosis prevention and treatment studies, we are joining with international groups in striving to identify markers of thrombosis. The translational elements will be included in all our toxicity studies.

Cognisant of the NCRI key targets, our multidisciplinary Subgroup is holding its first meeting in Belfast on Wednesday 14 September 2016 to determine and write our first Subgroup proposal for a study for patients in early stage disease that can recruit large numbers in multiple sites (Armes J, Crowe M, Colbourne L, Morgan H, Murrells T, Oakley C, Palmer N, Ream E, Young A and Richardson A. Patients' supportive care needs beyond the end of cancer treatment: a prospective, longitudinal survey. J Clin Oncol. 2009;27(36):6172-9).

### C – Advanced Disease/End of Life Subgroup Strategy

1. Symptoms of advancing disease:

Locally advancing and metastatic disease frequently lead to complications, e.g. thrombosis, cord compression, anaemia, and symptoms, which impact adversely on quality of life including pain, lymphedema, fatigue and breathlessness. Focussed basic and clinical research under this theme seeks to discover more effective ways to prevent, detect and treat these symptoms in the context of advanced disease.

The CSG has a strong history of research into pain, cachexia and breathlessness (for which there were previously dedicated Subgroups) and links forged through the CSG have continued to produce joined up research efforts, e.g. via the UK Breathlessness Research Interest Group. Open studies on the current portfolio cover symptom screening and detection, for example in mesothelioma or interstitial lung disease, symptom management including new agents and new approaches to management, e.g. the TVT trial which compares a 2-step vs. 3-step approach to the treatment of pain. We expect to continue developing studies for the key symptoms described above but also to expend out scope to examine the complications of long-term symptom management drugs and how these can be reduced/managed, as well as exploring symptoms arising from new cancer treatments, e.g. immunotherapies or novel radiotherapy regimens. For this we recognise the importance of joint working with oncology and members of relevant site specific CSGs.

2. Issues towards the end of life:

This theme focuses on complex symptoms and issues towards and at the end of life, including the management of dying. Core values for palliative care include providing the best possible symptom management, supporting families through holistic care that extends to the family unit, and empowering patients facing the end of their life by ensuring excellent care is delivered where they wish to spend their last days.

Existing portfolio studies are examining hydration at the end of life, management of delirium, complex symptoms in frail older people, and management of chronic refractory symptoms, e.g. fatigue and breathlessness, with pharmacological and non-pharmacological strategies. A new study to discover the optimal markers for prognostication (sample size 1,360), including blood biomarkers, will support nationwide working in the forthcoming year; around 40 sites are in set-up and additional sites are expected. We intend to develop new studies from within the CSG but also support active investigators in the continued development of their programmes, especially

for research at the end of life when investigator numbers are limited. In such cases, we will invite investigators into the Subgroup.

3. Rehabilitation:

A rehabilitation approach within supportive and palliative care helps people reach and maintain their optimal levels of physical, sensory, intellectual and social functioning, with minimum dependence on others. In advanced disease rehabilitation aims to improve quality of life by increasing the time people can remain reasonably active and independent.

Current CSG work relating to this theme includes studies on the use of acceptance commitment therapy to deduce psychological distress and improve health behaviours, on dysphagia management in the context of radiotherapy, on a device to support toileting in women with, and on the use of goal setting within hospice based rehabilitation services. The latter study requires a sample of 350 participants and is open to new sites nationally. Studies in set-up include an RCT of a supportive care intervention (nutrition, exercise, anti-inflammatory medication) to treat cancer cachexia. This international study (sample size 250), which includes blood sampling for a cachexia biobank, will be open across multiple UK sites. We intend to develop new CSG studies where possible building on pilot work already completed by Subgroup members and with a design that facilitates multi-site working. The development of new studies will be aided by extending Subgroup members to rehabilitation leaders. There is also opportunity for joint working with the Psychosocial Oncology & Survivorship CSG, whose expertise compliment those held with the Advanced Disease/End of Life Subgroup.

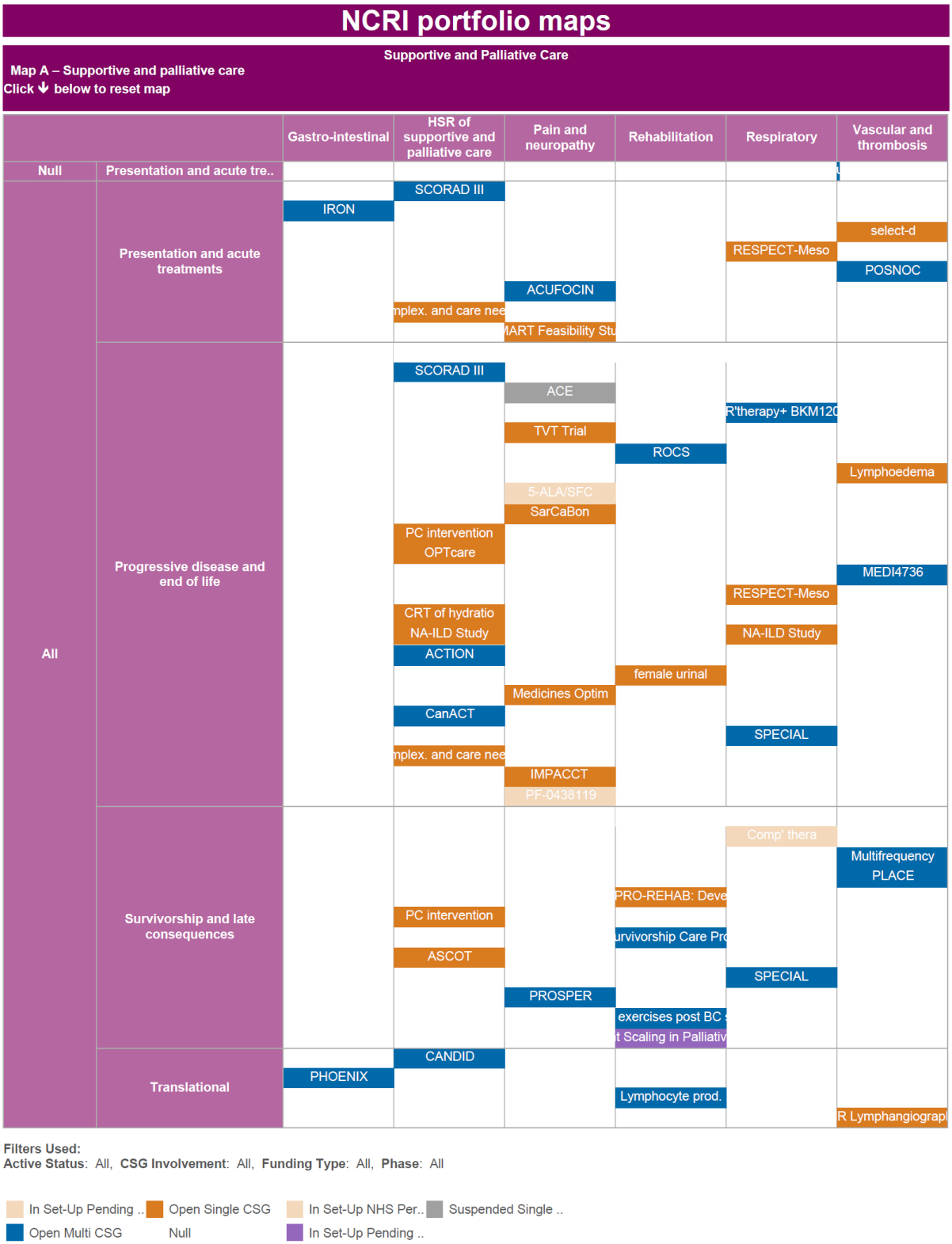
## D – Survivors & Late Consequences Subgroup Strategy

1. 'Early' survivors
    - Lymphoedema related to cancer treatment is a well-recognised long-term complication. It has been studied mainly in breast cancer to date but is also important in other cancers eg head and neck. It continues to be a problem despite changes in treatment introduced to reduce the incidence.
    - The CSG is currently involved in a large study of the early detection and prevention of breast cancer related lymphoedema (NIHR programme grant – BEA and PLACE studies).
    - There is growing evidence that there may be a genetic predisposition to developing lymphoedema after cancer treatment so opportunities exist for genetic studies as well as work on the incidence and aetiology of lymphoedema after other cancer treatments.
    - This could link to other studies of cancer treatment run by other CSGs.
2. 'Long-term' survivors
    - The long-term effects of the treatment of pelvic cancers is being increasingly recognised and there are opportunities to explore these further and look at possible interventions.
    - Links with other CSGs would be essential in taking this forward.
    - This would be a new area of work for the CSG and would require additional expertise.
3. Rehabilitation
    - There is growing evidence that exercise can improve a number of cancer treatment related symptoms including fatigue and may improve survival.

- A working group of relevant experts would need to contribute to study design and again links with other tumour site CSGs would be required.

# Appendix 3

## Portfolio maps



# Appendix 4

## Publications in the reporting year

**EORTC**
Development of a health related quality of life questionnaire module to supplement the EORTC QLQC30 questionnaire for cancer patients with cachexia, Wheelwright S, Hopkinson J, Darlington A-S, Fitzsimmons D, Johnson C. (2015)

**FAWE**
Hopkinson J, Richardson A. (2015) A mixed-methods qualitative research study to develop a complex intervention for weight loss and anorexia in advanced cancer: The Family Approach to Weight and Eating (FAWE). Palliative Medicine. 29, 164-176.

**Food connections: a qualitative exploratory study of weight- and eating-related distress in families affected by advanced cancer**
Hopkinson JB (2016) European Journal of Oncology Nursing. 20: 87-96. http://dx.doi.org/10.1016/j.ejon.2015.06.002

**Neuromuscular electrical stimulation to improve exercise capacity in patients with severe COPD: a randomised double-blind, placebo-controlled trial**
Maddocks M, Nolan CM, Man WD, Polkey MI, Hart N, Gao W, Rafferty GF, Moxham J, Higginson IJ. Lancet Respir Med. 2016;4(1):27–36.

**Patterns of skeletal muscle dysfunction in people with lung cancer**
Maddocks M, Reilly CC, Nunn J, Jolley C, Higginson IJ, Moxham J, Rafferty GF. Journal of Cachexia, Sarcopenia and Muscle Wasting. 2015;6(4):460.

**ALICAT**
Noble SI, Nelson A, Fitzmaurice D, Bekkers M, Baillie J, Sivell S, et al. A feasibility study to inform the design of a randomised controlled trial to identify the most clinically effective and cost-effective length of Anticoagulation with Low-molecular-weight heparin in the treatment of Cancer-Associated Thrombosis Health Technol Assess 2015;19(83)

**BEA/PLACE study**
Bundred N.J, Stockton C, Keeley V, Riches K, Ashcroft L, Evans A et.al. Comparison of multi-frequency bioimpedance with perometry for the early detection and intervention of lymphoedema after axillary node clearance for breast cancer. 2015. Breast Cancer Research and Treatment. 151 (1), 121-129.

**UKCRN 12017**
Maddocks M, Nolan CM, Man WD, Polkey MI, Hart N, Gao W, Rafferty GF, Moxham J, Higginson IJ. Neuromuscular electrical stimulation to improve exercise capacity in patients with severe COPD: a randomised double-blind, placebo-controlled trial. Lancet Respir Med. 2016;4(1):27–36.

**Neuromuscular electrical stimulation to improve exercise capacity in patients with severe COPD: a randomised double-blind, placebo-controlled trial**

Maddocks M, Nolan CM, Man WD, Polkey MI, Hart N, Gao W, Rafferty GF, Moxham J, Higginson IJ. Lancet Respir Med. 2016 Jan;4(1):27-36. doi: 10.1016/S2213-2600(15)00503-2. Epub 2015 Dec 15.

**Respiratory and peripheral muscle function in lung cancer (UKCRN 16030)**
Maddocks M, Reilly CC, Nunn J, Jolley C, Higginson IJ, Moxham J, Rafferty GF. Patterns of skeletal muscle dysfunction in people with lung cancer. Journal of Cachexia, Sarcopenia and Muscle Wasting. 2015;6(4):460.

## Appendix 5

### Major international presentations in the reporting year

**Quality of life in cachexia – assessment and therapy**
Hopkinson, JB (2015) - 8th Cachexia Conference, Paris, France