

NCRI Primary Care Clinical Studies Development Group

Introduction

This has been an important year for the Primary Care Clinical Studies Development Group (PCCSDG) and it has continued to advance programmes of work on a broad front. Overall the structure of the Group and the Subgroups has remained constant; the subgroups are based around stages in the cancer journey and this seems to work well for a cross-cutting group such as primary care. As indicated in last year's report national initiatives such as the National Awareness of Early Diagnosis Initiative and the Cancer Survivorship Plan are important to our activity and members of the group are actively involved in these initiatives. The Group has needed to adapt to a changing funding environment; for example, the new strategic plan from Cancer Research UK did not include areas of activity such as survivorship, follow up and psychosocial care of cancer patients, all fields in which our group is active. The Group, in common with colleagues from other CSDG's, has engaged in discussions with CRUK and other funders about alternative sources of support for these areas of research. Further we have engaged with colleagues at NAEDI in developing their research plan for the next 4 to 5 years. There are also significant new funds available through the National Institute of Health and Research and members of the Group have had recent success in obtaining programme grant funding.

Membership and structure

Dr Joan Austoker, Dr Kerenza Hood, Dr Stephen Barclay and Dr Amanda Farrin have left the Group and Ms Rosalind McNally has stepped down from the Group as a consumer representative. Dr Karen Kerr has been replaced by Dr Hannah Whiteman as the Cancer Research UK representative.

The Group has been strengthened by the addition of Dr Gill Hubbard, Mr Chris Hurt and Dr Peter Murchie who bring expertise in survivorship research, statistics and clinical trials, and primary care oncology respectively. All were previous members of subgroups, and Dr Murchie was Cancer Research UK Clinical Fellow, the approach of engaging with primary care cancer researchers early in their careers is one the Group will continue to pursue.

As indicated in our previous report, the membership of the PCCSDG continues to be multi-disciplinary. We have found that there is, typically, a limited response to general advertisements for new members for the Group, and we have greater success if we specifically identify and encourage individuals we consider to be of value to apply. As we have previously indicated the primary care and cancer research community in the UK is relatively small and as a consequence we have made the argument for relatively low turnover of the Group. Of course this doesn't mean that individuals should be "members forever" and, particularly with the change in Chairmanship and rearrangements in leadership of the subgroups (alongside our recruitment of new members), we believe the membership structure is reasonably dynamic and responsive to the research and funding environment. We have engaged more closely over the last 12 months with "service colleagues" through initiatives such as NAEDI and the Survivorship Initiative, this has put us in close contact with groups such as the National Cancer Action Team and the Cancer Policy Unit of the DoH. It remains a strong priority for the Group to strengthen these "service links".

Chairmanship of the Group was due for rotation this year, and after a process of advertisement and interviews Professor Clare Wilkinson (a member of the Group since its inception) was appointed as Chair, from 2009-2012. Professor David Weller

becomes a member of the Group as he relinquishes the Chair. Dr Christine Campbell has indicated that she plans to relinquish the Portfolio Coordinator role in the coming months. Her successor will be decided by Professor Clare Wilkinson in discussion with the NCRN Coordinating Centre and CS(D)G Secretariat. David Weller, Christine Campbell and Clare Wilkinson have gone through a number of discussions to ensure a smooth handover and transition process.

Portfolio and accrual

An issue for us remains the appropriate badging of studies in order to strengthen and broaden our portfolio. There are still many studies with an identifiable primary care component which do not appear in our portfolio. This is an issue which will be actively taken up by the new chair. Cross-cutting groups such as ours do often miss out on appropriate acknowledgement of funded studies as there is an understandable natural tendency to badge studies along disease/site-specific lines. patients were recruited to primary care studies in 2008/09.

We are in communication with the NCRN about prevention and screening trials; our group has generated a number of ideas about adapting the NCRN infrastructure to make it more able to readily accommodate these different kinds of trials.

Table 1: Primary Care CSDG portfolio

Acronym	Title	PI(s)	Status
Barrett's Oesophagus	A sibling pair study to identify Barrett's oesophagus susceptibility genes.	Dr Rebecca Fitzgerald	Open
DELAYS2	Diagnosis earlier looking at your symptoms – development and evaluation of a patient-centred tool to measure diagnostic delays	Dr Richard Neal	In set up
Experiences of fertility preservation for cancer survivors	Experiences of fertility preservation for cancer survivors	Dr Scott Wilkes	Closed
Herbal Medicines and Cancer	The use of herbal medicines by people with cancer	Mrs Christine Gratus	In set up
MMP9 and FOBt	Establishing the added benefit of measuring MMP9 and FOBt as part of the colorectal cancer screening programme	Professor Sue Wilson	Closed
MMP9 CR-UK	Evaluation of the suitability and acceptability of serum MMP9 as a screening test for colorectal cancer	Professor Sue Wilson	Closed
MMP9 UHB	A prospective study to assess the value of MMP-9 in improving the appropriateness of urgent referrals for colorectal cancer	Professor Sue Wilson	Closed
MOLEMATE	The MOLEMATE UK trial: The management of suspicious pigmented lesions in primary	Dr Fiona Walter	Open

	care.		
PICT -	Establishing the potential for primary care to tackle social inequalities in established colorectal cancer (components 2 and 3)	Dr Neil Campbell	Closed
Public perceptions of bowel cancer screening	A primary care-based intervention for improving patient participation in bowel cancer screening (pilot study and RCT)	Mr Paul Hewitson	In set up
Self test study	Self test kits for cancer: Prevalence of use, characteristics of users and implications of self-testing for health care services - a feasibility study	Professor Sue Wilson	Closed
Survivors of Adult Cancer	Survivors of adult cancer: Their use of primary care services and unmet needs	Dr Peter Rose	Open
The Chest Study	Reducing time to presentation with symptoms of lung cancer: phase II complex intervention study	Dr Neil Campbell	Closed
TIME	Time to consult with symptoms of lung cancer: Is it related to deprivation or rurality	Dr Neil Campbell	Closed
Understanding the Experience of Colposcopy	Understanding the experience of colposcopy: A step towards service improvement	Ms Dawn Swancutt	Closed

19 cancer patients were recruited to Primary Care studies in 2008/09 and 360 non-cancer patients

Trials in development

We have categorised these under our subgroup headings.

Early Diagnosis Subgroup

- *The "CAPER" studies*- Led by Willie Hamilton are ongoing with validation work recently published. Although an application to HTA to develop new diagnostic algorithms to improve diagnostic performance for colorectal cancer in primary care was not successful funding will likely be sought for a revised application in coming months.
- *Teenage and young adult cancers* - A collaborative group that includes Dr Christine Campbell, Dr Una MacLeod, Professor David Weller, Dr Bob Grant, Dr Richard Neal and members of the TYA CSG (Professor Tim Eden, Dr Jeremy Whelan, Dr Ian Lewis, and Dr Lorna Fern) continue to develop proposals with the aim of improving the diagnosis of cancers in this age group. A licence is being sought for GRPD work. A paper is in preparation, based on an audit of the rates of and reasons for consultations in primary care in teenagers and young adults.
- *NIHR programme application* – An application on Improving Early Diagnosis of Cancer was submitted for this programme of applied research funding stream,

the proposal was short listed and a full bid has been submitted. The funding decision is pending.

- *Policy Research Programme* – Members of the group have been involved in an outline bid to the PRP for a Policy Research Unit in Cancer Screening, Awareness and Early Diagnosis.
- *Pancreas* – A grant submission has been made by Dr Richard Neal, with colleagues: the proposal looks at the early diagnosis of symptomatic pancreatic cancer, again the outcome is awaited.
- *A national audit of cancer diagnosis in primary care*- Under the auspices of NAEDI and in collaboration with the RCGP, Dr Greg Rubin is leading this initiative involving an analysis of general practice research database data, an audit based analysis of cancer diagnoses in UK general practice, and the development of a detailed audit tool.
- *Other* – We continue to work with colleagues regarding myeloma, bladder, and lung cancer proposals.

Prevention Subgroup

Much of the activity of this subgroup has focused on progressing the HPV core-messages project, as well as more limited activity on new applications

- *HPV core-messages project* – This is being funded by CRUK PBSC, it has a strong focus on the development of appropriate education materials. Progress to date is summarised below:
Systematic reviews of the literature and information/education material have been carried out by Cardiff University staff:
 - A systematic review of public and health professionals' knowledge, views and perceptions of HPV in the context of vaccination and testing is underway. Searches have been conducted and references screened for potential relevance. Qualitative papers on views about vaccination have been assessed, and included papers data extracted (n=15). Major themes and sub-themes have been identified and a framework is being developed to code the data. Qualitative studies on HPV testing (n=11) and surveys (vaccination and testing) (n=47) have been identified.
 - A systematic review of reviews to support core message generation has been started. Searches have been conducted and 6,738 references are being screened for relevance. A web-based review of HPV materials will follow.

Qualitative interviews with girls in the vaccination programme & parents, women in the cervical screening programme and relevant health professionals have been carried out by Oxford University staff:

29 girls aged 12-13 years were interviewed after vaccination, along with 10 of their parents; at least 1 more girl and 20 more parents are to be interviewed. In the 17-18 year-old "catch-up" group, 4 vaccinated girls have been interviewed with a further 11 girls and 10 parents waiting. Recruiting is ongoing and the team are currently looking for girls and parents who have declined vaccination (about 20 of each).

Community wide validation surveys will be carried out by University of Birmingham staff:

The questionnaire survey will include two UK wide surveys of representative samples of the public and providers, designed to validate core messages. The survey instruments are in final draft, the selection of core message (constitutes part of the questionnaires) is almost complete. A detailed protocol is in final draft and due to be completed at the end of June. Identification of study research sites will commence early July. Application for appropriate approvals (e.g. NHS R&D) will be made in July.

Three poster abstracts have been submitted for the NCRI conference in October on the systematic review of views on HPV vaccination and testing, the qualitative interviews with girls in the vaccination programme and their parents, and an overview of the study as a whole.

Melanoma - The recent joint submission with colleagues from the NCRI Melanoma CSG to Cancer Research UK to examine the diagnostic pathways, patients' experiences and pathological features of thin versus thick melanomas across the UK was unsuccessful. Based on feedback from that submission and further discussion with colleagues the study focus and design are being modified and it is planned to submit a proposal to NIHR later this year.

Smoking – A NPRI Phase 3 application entitled 'Testing the feasibility of nicotine assisted reduction to stop in pharmacies'. The RedPharm Study, led by Dr Paul Aveyard and including Professor David Weller, was recently funded by the NPRI Prevention Research Advisory Board. We remain keen to develop further activity in this area.

- *NCRI Conference in 2010*- Two sessions have been agreed for the 2010 conference of high relevance to our group – one is smoking cessation (with Professor Clare Wilkinson to chair) the other is patient/population research in HPV.

Follow-up Subgroup

As above, much of the activity of this subgroup over the last 12 months has focused on progressing work on established or recently funded projects:

- *Prostate cancer* – The two year collaborative study funded by Cancer Research UK is close to completion. A review of international guidelines has been published, and a number of other publications have been submitted or are in preparation. A feasibility study of an intervention study informed by the literature reviewing, qualitative interviews with patients and health professionals and examination of current practice is in development.
- *Lung cancer* – The NCRI SuPaC Lung Cancer Initiative funded study to examine the optimal roles of primary care in lung cancer follow up now has researchers in post in Edinburgh and Cardiff universities, project documents have been developed and data collection is due to commence in the next few weeks.
- *Survivorship research within the UK* – Members of the subgroup are involved in the National Cancer Survivorship Initiative, and contributed to discussions at the recent NCRI Rapid Review meeting.

It is likely the name of this subgroup will be changed in coming months as the priorities and proposal development plans are reviewed under the leadership of the new Chair.

Primary Palliative Care Subgroup

This subgroup remains very active both with continued activity on currently funded studies and in the development of a number of new proposals (not all are listed here).

On-going studies

Other studies members are involved in which are not in the portfolio include:

- Pro-active follow-up in primary care from early in the cancer trajectory: the introduction of a framework developed by service users. Murray SA, Barclay S, Kendall M, Linden D, Munday D, Lovick R, McPherson S. Macmillan Cancer Support. £150,000. July 2009 - Dec 2011.
- The prevalence and predictors of intractable breathlessness in advanced COPD in patients following optimisation of treatment in primary care. White P, Shipman C, Higginson I, Moxham J, Murray SA, Pinnock H, Booth S, Seed P. Dunhill Medical Trust £97,935. April 2009-Sept 2010.
- Dignity therapy for older people in care homes: assessing potential effectiveness, feasibility and acceptability. Hall S, Higginson IJ, Chochinov H, Murray S, Harding R, Richardson A. Dunhill Medical Trust £104,224. September 2008–February 2010.
- Definition and evaluation of models of primary and secondary care collaborative working at the end of life. Murray SA, Worth A, Mason B, Boyd K, Kendall M, Higginson I, Shipman C, Barclay S, Munday D, Dale J, Irvine M Bowes. National Institute for Health Research, SDO. £426,000 July 2009 to Oct 2011
- Evaluation of electronic Palliative Care Summary in Scotland. Murray SA, Mason B, Kendall M. £10,000. Scottish Executive.
- Methods for evaluating service delivery models for end of life care: development of best practice guidance. Higginson I, Fayes P, Grande G, Harding R, Hotopf M, Lewis P, McCrone P, Morgan M, Murray SA, Todd C. MRC/NIHR Methodology Research Panel. £399,476. June 2009 – May 2011.
- Understanding place of death for patients with non malignant disease: a systematic literature review. Murtagh F. National Institute for Health Research, SDO June 2009-May 2010.
- End of Life Care strand of NIHR CLAHRC for Cambridge and Peterborough. S Barclay, C Shipman, A Rogers, J Fleming, T Denning, C Brayne, P Jones et al. £820,000 Sept 2009 – Oct 2013

Trials in development

Trials in development include:

- PACE study: Plans and Care Expectations of patients with advanced COPD and lung cancer. Barclay S, Murray S, Munday D, Farquhar M, Rintoul R, Mahadeva R, Shipman C, Rogers A, Crang C, Loftus R. Macmillan Cancer Support £150,000.
- Learning from Life's End; a retrospective study of End of Life Care in Primary Care. Barclay S, Higginson I, Shipman C, White P, McCrone P, Cohn S, Graffy J. NIHR Research for Patient Benefit £250,000.

Meetings

The Group have lead or been involved in a number of key meetings including:

- *Ca-Pri Conference* - The second annual scientific meeting of the International Primary Care and Cancer Group was held on April 24th and 25th 2009 in Copenhagen, Denmark, having received generous support from the National Cancer Institute (USA), the Danish Cancer Society and the National Cancer Institute of Canada. This group was established by the NCRI PCCSDG; its name has now changed to the Ca-Pri Network. This was a very successful event with approximately 80 delegates from North America, Europe and Australia. Professor Mike Richards the UK National Cancer Director gave a plenary presentation. Building on the framework for international collaborative research developed in Edinburgh in 2008, delegates discussed specific projects with clear potential to take forward in the next year, these were largely around early diagnosis and the role of primary care in survivorship and follow up in patients with cancer. The group is led by an executive and planning is already underway for the next meeting in Toronto in May 2010.
- *Second National Primary Palliative Care Conference* - After a very successful inaugural conference at Edinburgh University in 2008, this meeting occurred on 29th April 2009 in Liverpool. CeCO, PCRS and COMPASS were involved, with major input from members of the Primary Palliative Care subgroup. The next conference will be held in Cambridge in 2010.
- *Annual meeting of the International Primary Palliative Care Research Group* - Again led by the Primary Palliative Care subgroup, this international grouping includes generalists from other NCRI-like institutions in Canada and Australia, and is active in encouraging and guiding research. It met on July 8th in St Andrews, before the Society of Academic Primary Care Conference.

The Primary Palliative Care Subgroup was an important factor in advocating for a strong presence for primary care research in the European Palliative Care Research Conference in Vienna in 2009, and organised a plenary entitled "Primary palliative care research come of age"

Collaborations

Our group continues to work with a number of other CSDG's, most of which have already been mentioned:

- Lung Cancer CSG – the formation of an early diagnosis collaborative.
- TYA CSG – a revised proposal is currently under development and a paper in preparation.
- Melanoma CSG – similarly a revised proposal will be submitted shortly.
- Bladder CSG – ongoing meetings with Dr Alison Birtle and Mr John Kelly.
- Haematological CSG – discussions are underway with the Chair of this group to develop a project addressing follow up of patients with acute lymphocytic leukaemia.

NCRI Cross-cutting Groups

An important development for our group has been the organisation of CSDG initially one off cross-cutting working groups. This has been discussed at some length at the Chair's Forums where it was recognised that greater co-ordination of activity in areas such as early diagnosis and survivorship across the CSDG's would result in greater efficiency of effort. It was agreed to convene a small series of meetings to cover issues that significantly cross site-specific boundaries. Professor Greg Rubin (Chair of Early Diagnosis subgroup) and Dr Christine Campbell (Portfolio Co-ordinator) attended a meeting to review the fields of early diagnosis, screening and prevention on Friday 26th June 2009. Discussion of possible future work was in the context of the NAEDI research strategy that is being developed with the NCRI funders.

3-year strategy

With the rotation of Chairmanship this is an opportune time to bring new vision and energy to the Group. Clare Wilkinson has already begun the process of restructuring subgroups and setting new priorities for the Group, the longer term strategy for the Group will reflect these efforts. Nevertheless the broad aim of the group will continue to be to build capacity in primary care and cancer research. Despite some recent disappointments in obtaining funding for applications we remain committed to developing and submitted high quality and internationally relevant funding bids, in collaboration with colleagues from across NCRI CS(D)Gs.

We noted at the last Chair's Forum that there is likely to be resources available for new strategic planning processes for CSDG's, possibly engaging international colleagues. It would be an excellent time for the Primary Care CSDG to take advantage of such an opportunity, our last strategic planning process was extremely helpful and set many exciting new directions for the group – but it was several years ago now and it would be very helpful to review our overall aims and strategies.

Another important issue for us will be one of resource, the role of Portfolio Co-ordinator (which Dr Christine Campbell has held since the inception of the Group) has been critical for a cross-cutting development group such as ours and Professor Clare Wilkinson will be activity seeking extra resource for this role.

As previously indicated we will continue to adapt our activities to reflect the changing funding environment, we will continue to need to examine the research networks and resource available to us, the primary care research networks in all four countries of the UK are developing well and the MRC General Practice Research Framework continues to be an important player. Similarly we have important relationships with the NIHR School of Primary Care in England, and the Primary Care Schools in Scotland and Wales.

Further, we will need to maximise opportunities for engagement with the National Cancer Research Network and to strengthen our links with relevant clinical trials units.

The current application development subgroup structure is likely to continue more or less as it currently exists, although changes in naming and subgroup Chairs are being considered under Professor Wilkinson's leadership.

We will continue to examine our membership closely and seek to ensure that we have all appropriate disciplines covered.

Importantly we wish to strengthen our international activities and will continue to invest significant time and efforts in Ca-Pri which is due to meet again in Toronto in 2010.

We will also contribute to the national initiatives emerging from the Cancer Reform Strategy, many of which involve a considerable focus on primary care.

Finally, we will further strengthen our links with other CSDGs and other cancer research colleagues. Professor Clare Wilkinson will have much more to say about future visions in next year's annual report.

Priorities for next year

- As indicated in the previous report it is important that we deliver on our range of currently funded projects and ensure they are delivered to a high standard and they lead to further funded projects.
- To review our structure and continue to ensure that each of our subgroups is set up to develop major new projects.
- To continue to adapt to the changing cancer research funding environment, and in particular to take advantage of new opportunities arising out of initiatives such as NAEDI and Cancer Survivorship Initiative.
- To ensure that the new Chair, Professor Clare Wilkinson, is fully supported in enacting her new vision and plans for the Group.
- To make sure we deliver on currently funded projects; it is vital that the projects that we now have funded are undertaken to a high standard and that they contribute to our track record.
- To continue our capacity building and obtain funding for 3 possibly 4 new major trials in each of our application sub-development group areas.
- To further strengthen our links with other CSDG's and across the cancer research community.
- To undertake careful succession planning so that the new chair is well in place in early 2009.

Note from out-going Chair:

It has been a tremendous privilege to lead this group for the last 6 years and I am particularly delighted to be leaving Chairmanship of the group in such capable hands! A huge vote of thanks to group members, the NCRI CSGs Secretariat (who provide exemplary support) and to Dr Christine Campbell our portfolio coordinator.

Professor David Weller, Chair