

## **NCRI Teenage and Young Adult Clinical Studies Development Group**

### **Introduction**

The Teenage and Young Adult Clinical Studies Development Group (TYA CSDG) was established in December 2005 under the Chairmanship of Dr Jeremy Whelan, Consultant Oncologist, University College Hospital, London. Dr Whelan has recently been reappointed as Group Chair for another three years.

The Group was established in order to promote research that is relevant to and takes place for teenagers and young adults with cancer. However, no precise age boundaries are used. The lower end of the range is in the order of 16 depending on the nature of the study and the upper end is commonly placed in the mid-20s but may for some studies extend up to young adults under 40 years of age. Its remit differs from that of the other CSDGs.

The TYA CSDG has a UK wide remit to:

Ensure that teenagers and young adults are considered for and have opportunities to enter disease-specific research protocols generated by NCRI Clinical Studies Groups that relate to specific disease areas.

Where appropriate develop and promote specific protocols for studies in the TYA age group with particular reference to:

- Psychosocial factors in that group.
  - Special biological factors relating to the aetiology and behaviour of cancer in that age group.
  - Research into the optimal provision of health care for patients in that age group and in particular to provide the evidence base for the present and future NICE Improving Outcomes Guidance for teenagers and young adults with cancer.
  - Occasionally to develop and promote new specific therapeutic trials in this age group ensuring adequate statistical power is obtained by appropriate national and international collaboration.

The principal objective was not therefore to establish an extensive trials portfolio. The Group has identified five key areas of research:

- Benchmarking trial availability and access
- Evaluating relevance and activity in other CSG's and CSDG's
- Cancer registration for TYA
- Identifying priorities for health service research
- Survivorship and late effects issues

The progress of each of these projects during the reporting year will be discussed in this report.

The Group underwent its first progress review in January 2009 as a result it has dropped Development from its title. A list of the Group's strengths and the issues which the Group needs to address can be found in Appendix I.

### **Membership and structure**

When the TYA CSDG was first established in 2005, members were sought from a range of backgrounds. In 2008 a further call for members was made both to replace leavers and to increase the size of the Group. It is anticipated that a further invitation for members will go out in 2009, in particular to advance the work of the Group into age-related biological influences of cancer.

The Group has representation from paediatric oncology, adult oncology, haematology, epidemiology, primary care, academic nursing and social science. An additional member is the Chief Executive Officer of the Teenager Cancer Trust (TCT), a charitable organisation supporting the development of services for young people and with a strong advocacy role. The Group benefits from a full time Research & Development Co-ordinator (RDC), Dr Lorna Fern who is funded by the TCT.

Professor Jillian Birch, (Epidemiologist), Dr Robert Carr, (Consultant Haematologist), Dr Angela Edgar, (Paediatric Haematological Oncologist), Dr Liz Forbat, (Senior Research Fellow), Dr Faith Gibson, (Senior Lecturer in Nursing), Ms Sue Morgan, (TCT Consultant nurse) and Dr Dan Stark (Medical Oncologist) have joined the Group since the last annual report.

No members have left the Group in the reporting year but membership renewal is due for the original Group members.

The Group does not include consumer representatives in its membership. This decision was taken after extensive discussion during the early meetings. We have however developed a programme of consumer liaison and involve TYAs in the Group's activities through other means which is described later in the report

The Group does not have subgroups but instead set up three working parties, Health Services Research, Late Effects and Survivorship and Cancer, and Cancer Registration. The first two still exist and the latter one was disbanded in the previous reporting year (2008) having completed its task, however the Group now receives the minutes from the TYA Cancer Registry Steering committee of the North West Cancer Intelligence Service.

The HSR Working Party has split into two smaller working Groups; 'Delay in Diagnosis' which is headed by Professor Tim Eden. The second was previously led by Dr Margaret Rogers but is now headed by new member Professor Faith Gibson, she will lead on the Essence of TYA cancer previously called 'Place-of-Care' project.

### **Portfolio and accrual**

Although the main object of the Group is not establishing a portfolio of trials, there are two studies into our portfolio. In 2009 we adopted the pilot study 'UK study of Childhood, Teenage and Young Adult Brain Tumours (UK CYAB)' funded by Samantha Dickson Research Trust. The study is part of an international program looking a possible cause of brain tumours including mobile phone use, diet and environment. The study is recruiting at two sites in the UK, Leeds and Manchester where it is led by Professor Jill

Birch.

'DELAYS'- cancer in young people' a narrative study exploring young people's experiences during the diagnostic period closed in December 2008 with 24 patients having been recruited. The study was led by Professor Faith Gibson and is in the process of being written up.

**Table 1: Teenage and Young Adult Clinical Studies Development Group Portfolio**

Acronym	Title	PI(s)	Status
UKCYAB	UK study of Childhood, teenage and Young Adult Brain tumours (UK CYAB): A pilot study	Professor Patricia McKinney Professor Jillian Birch	Open
DELAYS-cancer in young people	Cancer in young people: a narrative study to explore their experiences during the diagnostic phase	Dr Faith Gibson	Closed

16 patients were recruited to TYA studies in 2008/09.

### Studies in development

The Group has had 3 main projects in development:

**Diagnostic delay in TYA with Cancer-** A recent submission to Cancer Research UK's Population and Behavioural Sciences Committee was unsuccessful. However, Dr Lorna Fern and Dr Jeremy Whelan will pursue additional funding for the project '*Understanding the diagnostic pathways of teenagers and young adults with cancer*'. The project aims to identify, through examination of a large database of GP encounters (CPRD), common presenting patterns for TYA with cancer and present these in the general context of consulting patterns in order to develop 'red flag' symptom complexes for consultations with young people. The project is a joint initiative addressing delayed cancer diagnosis in primary care for teenagers and young adults and involves Professor Tim Eden (Project Lead), Dr Lorna Fern, Dr Bob Grant, Professor Ian Lewis and Dr Jeremy Whelan from the TYA CSG and Dr Christine Campbell, Dr Una Mcleod and Professor David Weller from the Primary Care CSDG.

Professor Eden and Dr Fern are preparing a review of the literature which is nearing completion.

**Essence of TYA Cancer Care-**This project is led by Dr Faith Gibson, Dr Jeremy Whelan and Ms Susie Pearce and aims to determine whether specialist TYA cancer care in England and Wales is associated with improved outcomes during and after treatment for cancer. It is a 2-phase large scale health care evaluation incorporating a longitudinal cohort study of TYA's newly diagnosed with cancer in England and Wales. Funding has been secured for phase 1 of the study which is a scoping and exploratory study of the current situation of TYA cancer care together with establishing the methodological feasibility and acceptability of data collection for phase 2. The second phase comprises a five year national collaborative longitudinal cohort study of all TYA diagnosed with cancer within one year together with cross sectional nested case studies, using multiple sources of data collection across multiple sites.

**The Late Effects and Survivorship Working Party**-This project is led by Professor Mike Hawkins. A postal questionnaire similar to the one which Professor Hawkins developed for the British Childhood Cancer Survivor Study (BCCSS) will be developed. In light of the recent changes to the Cancer Research UK Strategy we are currently proposing a flagging study to investigate mortality and second primary neoplasms for TYA. The proposal was submitted to CRUK IN July 2009 .

***Projects being developed out with the Group but supported by the TYA CSG***

The Group has been ask to comment on one grant proposal during the reporting period, being developed with the Group.

- Testosterone replacement in hypogonadal male cancer survivors, developed by Dr Jennifer Walsh, University of Sheffield, which was submitted as an outline proposal to CTAAC in December 2008 and was supported by the TYA CSG.

***Projects reviewed by the TYA CSG for CTAAC/FSC/PBSC funding***

We now review all relevant grant applications to CTAAC/FSC/PBSC. The Group considers;

- Whether issues relevant to TYA have been considered?
- Does the age eligibility criteria reflect the age incidence pattern of the tumour?

Over the last 12 months we have commented on eleven CTAAC applications, three FSC and four PBSC applications.

**Meetings**

In November 2008, we held a workshop to discuss the development of the survivorship study outlined above. The meeting was attended by approximately 20 people; the day involved a series of presentations and then round table discussion.

**Collaborations**

The Group is collaborating with the Primary Care CSDG for the joint delay study.

The Group also works closely with the TYAC Research and Registration (RR) Subgroup, Dr Angela Edgar has recently been appointed Chair of the RR Group, following on from Professor Tim Eden. Dr Jeremy Whelan, Dr Lorna Fern, Dr Faith Gibson, Professor Jill Birch, Dr Richard Feltbower are also members. The TYAC RR Subgroup was formed to foster collaboration and reduce duplication of research. Dr Lorna Fern is in the process of establishing an interactive database of the TYA research being carried out in the UK, and updates TYAC on the work of the Group through the quarterly TYAC newsletter.

During the reporting period the Subgroup has been highlighting the drop off in trial accrual beyond the age of 14 to relevant tumour specific CSG's, this led to an initial joint meeting between the CCLG and NCRI Brain CSG in December 2007 and a further meeting was held in December 2008. This has resulted in the adult and paediatric brain groups agreeing to collaborate during study planning and joined up biological research projects.

The addition of new members will allow the Group to further engage with relevant CSG/CSDG's. In particular the lymphoma CSG has been keen to work with the Group on TYA issues. Members Dr Robert Carr, Dr Clare Rowntree, Prof Eden, and Dr Angela Edgar are involved in these discussions.

Dr Dan Stark is a member of the Testis CSG/ QoL Survivorship subgroup. Dr Jeremy Whelan is a member of the Sarcoma CSG. Dr Lorna Fern attends the Testis and Haematological Oncology CSG's where possible.

Professor Eden chaired a Teenage Cancer Trust (TCT) sponsored consensus meeting between international adult and paediatric germ cell oncologists in June 2008

### **Other activities**

#### ***Benchmarking trial availability and access***

One of the key activities of the TYA CSDG is to track accrual of TYA to relevant clinical trials within the NCRI and Children's Cancer and Leukaemia Group (CCLG) portfolios. This is mainly carried out by the Group's Research and Development Co-ordinator Dr Lorna Fern. Recruitment for the period 2008/09 has not yet been reported.

The 2005-2007 data was published in the British Journal of Cancer in December 2008, and was also reported by BBC news. To date, we have reported accrual to the most frequently presenting tumour types which account for approximately 73% of newly diagnosed cases. We intend to analyse recruitment rates of the remaining 27% of patients who present with rarer cancers including early onset carcinomas. The trials analysed so far are those which are recruiting newly diagnosed patients to intervention trials we aim to expand this to record recruitment to relapsed and resistant trials, and epidemiological studies for relevant tumour types.

#### ***Consumer involvement***

We have now established an effective 'Core Consumer Group' (CCG) which have a remit to deliver our research to the wider TYA community.

In October 2008, we held a consultation exercise with approximately 350 TYA cancer patients. Approximately, 60% of TYA prioritised reducing the time to diagnosis as the most important area of research, followed by survivorship and late effects of treatment (22%). Place of treatment for TYA was prioritised by 6.6% of patients, and research surrounding clinical trials and information collecting were prioritised equally by 6.2% of TYA.

In the coming year we hope to train our CCG in the tools required to be actively engaged in our research process. The CCG also needs to be expanded to include more tumour types, ethnic diversity and geographical coverage.

An important change in the last reporting year has been the restructuring of the Children's Cancer and Leukemia Group (CCLG). The changes currently underway in the structure of the CCLG represent an important opportunity for adult and paediatric and TYA research communities to move closer together to the advantage of TYA. The Group hopes to be actively involved in discussions between the NCRN and CCLG on restructuring the latter.

Dr Fern and Ms Susie Pearce are working with the TCT assisting in using research to develop education programs, particularly around delay in diagnosis.

### **3-year strategy**

The work programme of the Group will continue around the following areas:

- *Trial access for TYA:* We will continue to track accrual, expanding coverage of trials and with further focus on specific tumours. We are also keen to provide some information on regional differences to allow local initiatives to be generated from the benchmarking. A further piece of planned work is to address the issues which determine the setting of age eligibility criteria and to look at the influence of consent on participation.
- *Health Services Research:* Work will continue on the three major projects outlined (Symptom interval; specialist care; survivorship) above as well as identifying other research areas particularly related to clinically relevant outcomes.
- *Tumour and host biology:* The CSDG will generate a strategy to evaluate age-related differences in host tolerance, tumour biology, treatment outcomes and late effects.

### **Priorities for next year**

The Group's priorities for 2009/10 are:

#### **2009:**

- Submission of grant proposals for specialist care and survivorship studies
- Resubmission of symptom interval study
- Agreement of 'TYA charters' with key CCLG/NCRI tumour groups
- Workshop for tumour and host biology strategy setting
- Expand membership to include members with biological expertise
- Expand consumer Group
- Seek funding to assist RDC

#### **2010:**

- Continued engagement with CSGs, development of trials inclusive of TYA needs
- Initiation of specialist care, survivorship and symptom interval studies
- Improvement in trial accrual of 15-24 year olds to the same level for 5-14 year olds
- Evaluation of the need for and effect of cancer related health education for TYA

Dr Jeremy Whelan, Chair

## **Appendix 1**

### **Key strengths and issues from the Progress Review, February 2009**

The key strengths of the Group identified at the February 2009 review were:

- Achievements to date since being set up 3 years ago and whilst working in a challenging and complex arena
- One study in the portfolio, another one with a funding body and several others in conception and planning
- Good collaboration with a number of CS(D)Gs and these have led to joint initiatives
- Good links with TCT and TYAC
- Trial accrual, bench marking, registry and symptom and early diagnosis work
- Number of publications
- Novel ways of engaging consumers in the Group's activities
- Productivity and output of the research development coordinator

The Panel identified the following issues which the Translational CSG needs to consider:

- Clarifying where the trial accrual/bench marking is going
- The balance of observational/epidemiological studies and trials in the portfolio
- Possibly concentrating on studies rather than trials first
- Focusing on low hanging fruit if the Group wish to develop biological studies
- Clarifying the role of the CCLG TYAC and TYA registry
- Continuing collaborations with other CS(D)Gs and advocacy work

The Panel agreed that the NCRN needed to:

- Include the TYA CSDG in discussions on the future of the CCLG

## **Appendix 2**

### **NCRI- Teenage and Young Adult CSDG 2007/08 Publications and Abstracts Report**

**Fern L, Campbell C, T Eden, Grant R, Lewis I, MacLeod U, Weller D, Whelan J.** Addressing delayed cancer diagnosis in primary care: Patterns of attendance and symptoms of teenagers and young adults seen in 3 general practices during 1 year. *National Cancer Research Institute Conference, Birmingham, U.K. Abstract No A108*

**Fern L, Davies S, Eden T, Feltbower R, Grant R, Hawkins M, Lewis I, Loucaides E, Rowntree C, Stenning S, Whelan J;** Rates of inclusion of teenagers and young adults in England into National Cancer Research Network clinical trials: report from the National Cancer Research Institute (NCRI) Teenage and Young Adult Clinical Studies Development Group. *British Journal of Cancer (12) 1967-74 2008*

**Fern L, Whelan J** Recruitment of adolescents and young adults to cancer clinical trials – international comparisons, barriers and implications. *Seminars in Oncology, October 2009 [In press]*

**Murray M, Eden T., Fern L, Nicholson,** Breaking Down Barriers: Improving Outcomes for Teenagers and Young Adults (TYA) with Germ Cell Tumors  
*Submitted to Clinical Oncology*

**Fern L, Irving C, Ashton J., Brooman K., Kay R., Millington H., Wright D, J Whelan** Involving young people with cancer in research – The National Cancer Research Institute's Teenage and Young Adult (TYA) Core Consumer Consultation Group- a new and evolving model.  
*Submitted to NCRI Conference 2009*

#### **External presentations by the R&D Co-ordinator**

**Fern L** Consulting with children and young people about research – the NCRI TYA CSDG model. *Royal College of Nurses Research Conference, Cardiff. March 2009 (accepted as part of symposium)*

**Fern L** The NCRI Teenage and Young Adult Clinical Studies Development Group – setting the research agenda with young people. *TYAC's Winter Education Day-Education Centre, YOU Christie's Hospital, Manchester. December 2008*

**Fern L** Variations in European Survival – How can we do better? Clinical trials (debate). 11<sup>th</sup> International Paediatric Haematology and Oncology Update, *Royal College of Physicians of Edinburgh, October 2008*

**Fern L, Campbell C, T Eden, Grant R, Lewis I, MacLeod U, Weller D, Whelan J.** Addressing delayed cancer diagnosis in primary care: Patterns of attendance and symptoms of teenagers and young adults seen in 3 general practices during 1 year. National Cancer Research Institute Conference, Birmingham, U.K. 'Proffered paper Cancer in the elderly' *Wednesday 8<sup>th</sup> October 2008*

**Fern L** 'Clinical trial entry- international comparison' *Fifth international conference on Teenage and Young Adult Cancer Medicine, Church House, Dean's Yard, Westminster, London SW10 3NZ. June 2008*

**Fern L** Clinical Trial Data (NCRI data), Germ Cell Tumours in Teenagers and Young Adults, *Consensus meeting, Church House, Dean's Yard, Westminster, London SW10 3NZ. June 2008*

### **Media coverage**

<http://news.bbc.co.uk/1/hi/health/7753283.stm>

### **External presentations given by the Chair**

**Whelan J** 'Osteosarcoma' (included NCRI TYA trial data) *Fifth international conference on Teenage and Young Adult Cancer Medicine, Church House, Dean's Yard, Westminster, London SW10 3NZ. June 2008*

### **External presentations given by the CCG**

**Whelan J., Ashton J., Brooman K., Kay R., Millington H., Starkey C.**, 'Research4U' *Find Your Sense of Tumour Conference, Center Parks, October 2008*

**Fern L., Ashton J., Brooman K., Irving C, Kay R., Millington H., Starkey C., Wright D.**, 'Research 4U', *NCRI Consumer Liaison Group meeting, January 2009*

**Irving C, Ashton J., Brooman K., Kay R., Millington H., Starkey C., Wright D.**, 'Research 4U', *North Trent Consumer Research Panel Conference, Living Beyond Cancer, March 2009.*