

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

A proposal to establish a Teenage and Young Adult Clinical Studies Development Group (TYACSDG) was submitted to the NCRI in September 2003 on behalf of the research community and supportive voluntary sector organisations. The establishment of the TYACSDG was approved at the October 2004 meeting of the NCRI, and the Chair, Dr Jeremy Whelan was appointed in April 2005. The first meeting was held on December 2005, following recruitment of group members.

The remit of the Group is similar to that of other CSG's in that the primary aim is to increase the participation of this cohort into relevant clinical trials, with the eventual aim of developing a portfolio of high-quality national studies. The full group is concerned with developing a strategy and identifying priorities for research. A key aspect of this strategy will be the development and promotion of studies examining psychosocial factors, biological factors relating to the aetiology and behaviour of cancer in the TYA age group and research into optimal provision of healthcare in accordance with the recently released NICE guidelines.

### **Membership**

The Group membership was established through an open recruitment process and has representatives from the following areas:

- Medical oncology
- Malignant haematology
- Paediatric oncology
- Supportive and palliative care
- Epidemiology
- Primary care
- Research statisticians
- Teenage Cancer Trust Charity

The membership of the Group has remained stable since its establishment. In keeping with the NCRN remit of consumer representation on CSG and CSGDG it had been proposed that the TYACSDG should have consumer representation. However, within this cohort this is more complex and there have to date, been no conclusions as to how this will be best achieved.

The Teenage Cancer Trust agreed to support a Research Development Coordinator post to support the work of the TYACSDG. Dr Lorna Fern was appointed in April 2006 and took up the post in June 2006.

### **Priorities for research**

To date, the TYACSDG has held two meetings. The group met for the first time in December 2005 to consider its remit and a working plan was proposed. Within this proposal it was decided that the work of the TYACSDG has essentially, five components:

1. Benchmarking trial availability and access
2. Evaluating relevance and activity in other CSGs and CSDGs
3. Identifying Health Service Research Priorities (HSRP)
4. Cancer registration for TYA
5. Follow-up, late effects and survivorship.

Within these components the role of the research and development co-ordinator would be to primarily carry out the benchmarking exercises and work with other CSGs. In a bid to realise the remaining objectives three working parties have been established; Cancer Registry, Survivorship, Late Effects and Follow-up and Health Service Research, each led by a member of the main group who has expertise in that specific area. The focus of each working party is explained briefly below and in more detail in the appendix.

### **Working Parties**

The aims of the Cancer Registry Working Party are based on the recently ruled NICE guidelines aimed at improving outcomes for young people with cancer, specifically addressing the recommendation surrounding the 'the potential value of a separate register for TYA. This will be addressed at a forth coming workshop.

The Survivorship and Late Effects Working Party aims to address, what the key issues of survivorship are and what are the appropriate models for long term follow-up, determine how late effects should be prevented and managed, and what studies should be undertaken in these areas.

The Health Service Research/ Working Party will address place of care along with age appropriate care for TYA, diagnostic delay, community support and fertility issues.

### **Activities**

A number of CSG's have been identified to be of particular interest to TYACSDG, these groups are those whose tumours peak within the age group covered by the TYA, such as germ cell tumours, soft tissue sarcomas, bone sarcomas, acute leukaemia and lymphomas. In order to engage these groups with the TYACSDG a questionnaire is in development to send out to each CSG. It is anticipated that this will result in a three tier response, those groups such as prostate which will have no relevance to TYACSDG, those in which some studies may be of relevance, such as breast and those which are highly applicable to this cohort.

One of the objectives of the Research Development Co-ordinator is to carry out benchmarking and trial availability. The primary task is to track accrual of TYA onto clinical trials at a network and national level. The NCRN database in Leeds does not track by age. A search has been carried out on trials related to the main tumour types. Eligibility criteria was then used to eliminate studies which were not relevant. This has then been sent back to Leeds who are currently identifying trial centres who are carrying out these studies. The intention is to contact the trial centres individually and ask them to release the year of birth of patients entered onto relevant trials. The NCRN database has recently been changed to include other parameters including age; this is now being rolled out across the networks but will not be mandatory for at least another year.

It is anticipated that a report on trial availability for TYA's will be ready by mid autumn which will detail accrual at a national and network level. It is hopeful that barriers to accrual can be identified; once this has been done it may be possible to then identify solutions with the ultimate aim of increasing accrual.

### **National Meetings**

No national meetings are planned by the Group this year, however the Group will host a parallel session at the NCRI conference in October 2006. In addition a number of members of the Group attended the TYA annual meeting and conference in June 2006.

### Strategic Direction 2006-9

The strategic direction of the Group is given in the table below.

Theme	Tasks	Output	Target
Trial Accrual benchmarking	#Identify relevant trials, status by Network, accrual of TYA #identify areas for improvement and measures #Reassessment	#Report for discussion by group and publication  #performance measures	#1 <sup>st</sup> draft Autumn 2006  #2007  #annually
Working with CSGs/CSDGs	Introduction questionnaire Meetings with chairs/groups Identify key groups.	#CSG specific TYA action plans #TYA appropriate trial development	#2006-7  #2007-8
HSR	#establish 3-4 priority areas  #outline study proposals #seek funding or investigators	#Report for discussion by group	#End 2006  #2007  #2007-8
Cancer Registration	Recommend policy for registration of TYA and use of data	#National Stakeholder meeting #Report for National Cancer Director	#2006  #1 <sup>st</sup> qtr 2007
Survivorship and Late Effects	#identify key issues specific to TYA #identify partnerships #recommend studies #outline study proposals #seek funding or investigators	#Report for discussion by group	#1 <sup>st</sup> qtr 2007  #1st qtr 2007  #1st qtr 2007  #3 <sup>rd</sup> qtr 2007  4 <sup>th</sup> qtr 2007

Dr Jeremy Whelan, Chair

## **Appendix 1: Working party progress reports**

### **Survivorship and Late Effects Working Party (SLEWP)**

The first meeting of the SELWP was held in Birmingham in June 2006. Prior to the meeting the Chair of the party had distributed a background paper for the group members to consider. The SLEWP currently consists of Dr Mike Hawkins (Chairman), Dr Robert Grant, Dr Meriel Jenney, Prof John Radford, Ms Vikky Riley, Dr Helen Spoudeas, and Dr Hamish Wallace.

The WP is fortunate in that party members have considerable expertise in the area of epidemiology and late effects, however it was recognised that it may have to expand in order to resolve the current objectives. Areas of expertise which may be sought in the future include Rob Coleman from Western Park Hospital in Sheffield who is the Chair of the NCRI Breast Cancer CSDG and has an interest in germ cell tumours, breast cancer and bone tumours. John Gribben or Ama Rohatiner working on transplantation, Ama having a particular interest in patients receiving high dose therapy developing myelodysplasia. It was proposed that it may be sensible to have a health educationalist or a psychologist but no specific names were proposed and it was also observed that such specialists could be co-opted for specific questions.

The broad aims of the working party as identified by the TYACSDG group are;

- What are the key issues of survivorship and appropriate models for long term follow-up?
- How should late effects be prevented and managed?
- What work is being undertaken and what partnerships exist?
- What studies should be undertaken in these areas.

At the first meeting there was a wide ranging and comprehensive discussion regarding the priorities of the group. The outcome of these discussions was an agreement of the priority areas that the SLEWP should focus on:

- Develop a research proposal to establish a national cohort study to investigate mortality and the incidence of second primary neoplasms in individuals diagnosed with cancer between the ages of 15 and 40.
- Develop a research proposal to undertake a postal questionnaire survey of clinicians to determine current practice with regard to clinical follow-up of individuals diagnosed with cancer between the ages of 15 and 40.
- Develop a research proposal for a clinical cohort for which detailed clinical information would be collected and tests undertaken together with information on follow-up and lifestyle behaviours of the survivors. Cardiovascular dysfunction after lymphoma is a likely area of investigation.
- Develop a research proposal to undertake a postal survey of survivors diagnosed between the ages of 15 and 40 years to obtain information on the survivors' experience of clinical follow up, their knowledge of their treatment and its consequences, what they think the purpose of follow up is and to explore what would be their preferred model of follow up.

Subsequently two initial research proposals have been circulated:

- 1) "Core Standards - Long-Term Follow-up of survivors of Teenage and Young Adult Cancer" - an initial draft of what ultimately is intended to be a set of minimal standards for the clinical follow-up of long-term survivors of cancer in teenage and young adulthood
- 2) Proposal for a study of cardiovascular disease in a cohort of survivors of Hodgkin's lymphoma.

The SLEWP will meet again in November 2006.

### **Cancer Registration Working Party (CRWP)**

The first meeting of the Cancer Registration Working Party (CRWP) was held in Leeds in March 2006. The CRWP is chaired by Ian Lewis, Consultant Paediatric and Adolescent Oncologist. Membership includes Charles Stiller, Jill Birch, Tricia McKinney, Steve Proctor, Richard McNally, Henrick Moller, Richard Feltbower, David Forman and Louise Parker, the members contribute expertise in the field of clinical oncology, haematology, epidemiology, and cancer registration.

The aims of the CRWP are based on the recently ruled NICE guidelines aimed at improving outcomes for young people with cancer, specifically addressing the recommendation surrounding the 'the potential value of a separate register for TYA.

The group agreed what would form the basic principles for a TYA register:

- 1) There is a clear need for data on TYA both for clinicians locally and epidemiologists/public health professionals nationally, and such data should be fully exploited.
- 2) In conjunction with the UKACR/CR and stakeholders, a core dataset needs to be formulated (possibly as an extension to that already provided by the ONS and held by Jill Birch.
- 3) Tumour (and age) specific datasets should be considered and developed.
- 4) Existing data from Specialist Tumour Registries (Northern/Yorkshire) should be utilized.
- 5) The TYA dataset should be linked to an existing regional cancer registry to collate data and offer an 'intelligence' function.

The group have planned a registry workshop to be held in early autumn 2006. The purpose of the forthcoming workshop is to outline thoughts about registry of TYA and to engage with a wider interested audience, to collect views about usefulness and outputs from registry function, and to identify other key stakeholders.

The workshop will be segmented into three sessions encompassing;

- 1 – What do we know so far?
- 2 – What are current resources?
- 3 – What do we want to know?
- 4 – How do we get there?

### **Health Services Research Working Party (HSRWP)**

The Health Services Research Working Party (HSRWP) is chaired by Margaret Rodgers, lecturer in Supportive and Palliative Care. Group members include Simon Davis, Tim Eden, Faith Gibson, Anne Grinyen, Gill Harley, Mike Hawkins, Toni Menezes, Sue Morgan, and Sam Smith. The first meeting was held in February 2006, with a second being held in May 2006.

To date the efforts of the HSRWP have gone some way in identifying health service areas in need of research. The following have identified as key areas for research:

- Recruitment into clinical trials
- Place of care along with age appropriate care
- Diagnostic delay
- Community support
- Fertility counselling and preservation

Whilst fertility counselling has been addressed within the HSRWP, fertility will also be considered by the Survivorship and Late Effects Working Party.

The HSRWP have selected two consumer representatives who attended the last HSRWP meeting, it has been agreed that the level of consumer involvement will depend on the nature of the research. In order to reach a wider audience the HSRWP intend to use the 'jimmyteentv' program and utilise their website to canvass the opinion of young people with cancer about the research priorities of the HSRWP.

The HSRWP are currently undertaking scoping exercises to determine which are the most important research questions in each of the key areas of identified. Specific research questions will be addressed by the party.