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To whom it may concern

**Endorsing the Food and Drug Administration (FDA) guidance recommending lowering of the age of eligibility of cancer clinical trials**

The Clinical Oncology Society of Australia (COSA) is the peak national body for multidisciplinary health professionals working in cancer care and control. The COSA Adolescent and Young Adult (AYA) Executive Committee has representation from each state and includes representatives from the disciplines responsible for AYA cancer care including paediatric oncology, medical oncology, radiation oncology, adult haematology, nursing and AYA healthcare management.

AYA cancer compromises approximately 2% of the total cancer diagnoses in Australia each year. Whilst overall improvements in survival amongst this group have been achieved over the past 30 years, cancer continues to be the leading cause of disease related death with many subtypes of AYA cancer continuing to have very poor clinical outcomes. The low level of cancer clinical trial participation amongst AYA patients with cancer is considered a strong contributor to the lack of improvement in survival in this age group. This was articulated in the COSA AYA Group Executive Committee “Research Strategy Workshop Report” to the COSA Council published in March 2014 (Appendix 1). This workshop included participation by several clinical trial groups in Australia including ANZCHOG, COGNO, ASSG (now ANZSA), ALLG, ANZMTG (now MASC), and ANZUP. There are many factors contributing to low level of clinical trial participation including lack of dedicated trial funding specifically for this age group; no single cooperative group focusing on the diseases of AYA; institutional barriers to adult centers opening paediatric trials and industry studies stipulating a lower age limit of 18 years in the inclusion criteria, thereby precluding many younger adolescent patients from trial participation.

With a significant proportion of AYA cancer patients receiving their care in the adult oncology sector, lowering the cancer clinical trial age of eligibility is essential to standardise, facilitate and promote research in the younger AYA patients. There is no valid biological, social, medical or legal justification for this not to occur. The AYA Executive Committee endorses the planned adoption of the “FDA’s, Considerations for the Inclusion of Adolescent

Patient in Adult Oncology Clinical trials, Guidance for Industry” by the Therapeutic Goods Administration (TGA) of Australia. This recommends lowering the age of eligibility for the inclusion of 12-17yr old patients in disease - and target - appropriate adult oncology clinical trials to enable earlier access to investigational and approved drugs to these patients. The FDA acknowledges that the Guidance is a recommendation and not legally enforceable. We recognise that a TGA endorsed guidance is a positive step in furthering the goal of enrolling more young patients with cancer on clinical trials; however, consideration should also be given to requesting a legislative framework to ensure compliance with this recommendation by the pharmaceutical industry.

As stated in the guidance the COSA AYA Executive Committee supports the recommendation that adolescents should be eligible for enrolment in adult clinical trials at all stages of drug development when the history and biologic behaviour of the cancer under investigation is the same in, or the molecular target of the drug relevant to, cancers in both adult and adolescent patients. The practical considerations of how and where to implement these recommendations with respect to enrolling and treating patients on adult oncology clinical trials in the Australia healthcare setting can be managed through the Youth Cancer Service (YCS). The YCS is a national clinical network for the management of AYAs with cancer. The National Service Delivery Framework for Adolescents and Young Adults with Cancer specifies the appropriate care providers for AYAs with cancer. This includes appropriate medical and psychosocial support.

A perceived barrier to making adult oncology clinical trials available to younger AYA patients has been the legal and ethical considerations when enrolling patients on clinical trials. There is a well-established legal and ethical framework for enrolling younger patients on clinical trials in Australia. This includes obtaining informed assent from young patients and legal consent from parents or guardians as are currently obtained when enrolling children on clinical trials. With appropriate support, this approach could easily be implemented for younger adolescents being enrolled on adult oncology clinical trials. In contradistinction to the Pharmaceutical Industry, cooperative clinical trial group sponsored studies have embraced the more complex consent issues in younger patients and have facilitated their enrolment onto trials.

We strongly advocate that the TGA endorse the “FDA’s, Considerations for the Inclusion of Adolescent Patient in Adult Oncology Clinical trials, Guidance for Industry”.

If you would like to discuss any matter regarding our submission, please contact Dr Wayne Nicholls directly on [Wayne.Nicholls@health.qld.gov.au](mailto:Wayne.Nicholls@health.qld.gov.au) or 0432 503 433, or the COSA CEO Ms Marie Malica [marie.malica@cancer.org.au](mailto:marie.malica@cancer.org.au) or 0418 219 794.

Yours sincerely



**Nick Pavlakis**  
COSA President 2019-2020



**Wayne Nicholls**  
Chair, COSA AYA Group



**Clinical  
Oncology  
Society of  
Australia**

***COSA AYA Group Executive Committee  
Research Strategy Workshop Report***

**Monday 17 March 2014**

**COSA Offices, Sydney**

**Report prepared by Hayley Griffin, COSA Project Coordinator**

## 1. Background

The Clinical Oncology Society of Australia (COSA) is the peak national body for multidisciplinary health professionals working in cancer care and control. Over the past few years the COSA Adolescent and Young Adult (AYA) Group has been working to deliver projects funded by the Federal Government under the Youth Cancer Networks Program and administered by CanTeen as part of the Youth Cancer Fund.

These projects included the establishment of an AYA cancer network, development of three AYA clinical practice guidances which were published on Cancer Council Australia's Wiki platform, the development of AYA specific treatment protocols on eviQ in partnership with Cancer Institute NSW, and an AYA clinical research project which aimed to develop support for clinical research and increased clinical trial participation by AYAs.

While funding for these projects is now complete, promotion of the clinical practice guidances continues to health professionals and relevant organisations across Australia and the AYA PK Study and ALL6 trial (see section 4.2) established as part of the AYA clinical research project continue to recruit patients in several sites across Australia.

In 2013, the COSA AYA Group formalised its structure back within COSA by establishing membership and terms of reference for an AYA Executive Committee. The Executive Committee has representation from each state and a variety of disciplines within AYA cancer care including paediatric oncology, medical oncology, radiation oncology, adult haematology, nursing and AYA senior management. Dr Wayne Nicholls is the Chair of the Executive Committee and Dr Lisa Orme is the Deputy Chair.

The AYA Executive Committee held a strategic planning day in Melbourne on 6 September 2013 to discuss future priorities and develop an agenda for ongoing activities for the next 5 years. During this meeting the Executive Committee were able to identify several key areas of focus for the activities of the COSA AYA Group. One of these was to identify and formulate research priorities for AYAs with a workshop to begin work on this planned for the first quarter of 2014. The developed research strategy will subsequently form part of the COSA AYA Group's advocacy platform for research.

## 2. Purpose and Aims

The overall purpose of the workshop was to develop a national AYA research strategy.

In order to achieve this the workshop aims were to:

- Stock take current activities in AYA research
- Identify barriers and issues in AYA research
- Identify priorities for future AYA research

- Identify and promote collaboration opportunities
- Leverage health professional, clinical trial and non-government groups to advocate and achieve change.

### 3. Workshop Overview

The AYA research strategy workshop was held on 17 March 2014 at the COSA Offices in Sydney. Attendance was excellent with representation from the COSA AYA Executive Committee, Cancer Australia, CanTeen (including the Chair of the Youth Cancer Service Research Advisory Group), Australian Association of Adolescent Health, and eight of the Cancer Cooperative Trials Groups (CCTGs).

A list of attendees is shown in Appendix 1 and the workshop agenda in Appendix 2.

### 4. Workshop Sessions

#### 4.1 AYA Epidemiology

- An AYA person is defined as between ages 15 and 24, which accounts for 20% of the population. This population is widely dispersed in Australia which presents a challenge for treating AYA cancer patients.
- Some AYA cancers are similar to paediatric cancers, some similar to adult cancers and some are unique to the AYA population. Melanoma is the most common cancer in this age group, which is unique to Australia.
- Melanoma and cervical cancer incidence has decreased due to screening and public awareness programs such as the *Slip Slop Slap* campaign and pap testing.
- AYA survival from all cancers has improved however the rate of improvement is greater in older adults and children. The main cause of mortality is brain cancer especially high grade gliomas, which has had the same death rate for 30 years. There have also been no improvements in bone cancer cure rates; however acute lymphoblastic leukaemia (ALL) and acute myeloid leukaemia (AML) have seen impressive improvements.
- AYA patients with the lowest socio-economic status have significantly worse survival than those in the highest group.
- A major challenge are patients who reside in regional and rural areas as remoteness is associated with worse mortality in AYAs.

#### 4.2 Current Research in AYAs

A background paper was put together by the AYA Executive Committee and distributed to attendees prior to the workshop. This paper outlined current Australian studies in AYAs and

gaps and issues relevant to six priority areas and four priority diseases (established at the strategic planning day). See Appendix 3 for a summary.

Presentations were given on the AYA PK Study and the ALL6 trial (established as part of the AYA clinical research project) and some of the barriers and challenges they have faced as they continue to recruit patients in several sites in Australia.

#### **4.2.1 ALL6 Study**

The ALL6 study is a Phase II trial of an intensive paediatric protocol incorporating post-induction stratification based on minimal residual disease levels for the treatment of adolescents aged 15 years and above, and young adults aged up to 40 years, with newly diagnosed ALL.

Aims of the study are to: compare treatment deliverability in AYA ALL group to paediatric patients receiving the same protocol; compare risk groups, including MRD-defined, in AYA versus paediatric ALL on the same paediatric protocol; and examine feasibility of delivering intensified chemotherapy to patients at high risk of relapse.

One hundred ALL patients aged 15 to 40 years will be treated with the ANZCHOG Study 8 protocol and the primary endpoint will be time taken to reach day 78. The study will answer the question as to whether AYA patients can be given the same dose intensity as children.

Expressions of interest were sent to 49 ALLG sites. Eighteen expressed interest, with the projected annual accrual an ambitious 53 patients. There is a mixed picture nationally with the trial currently open in eight sites (Royal Adelaide, Sir Charles Gardiner, Westmead, Royal North Shore, Gosford, Wollongong, Canberra and Liverpool). The trial is awaiting TGA approval and site initiation at The Alfred (only site in Victoria) and Princess Alexandra. Negotiations are underway at Royal Prince Alfred, Prince of Wales and Townsville. The enrolment rate is currently slow (16 patients in just under 2 years) but there is hope that it will be close to the target in another two years.

Some of the barriers and challenges have included:

- Physician reluctance (only a minority of centres involved)
- Funding limitations (unsuccessful Cancer Australia grant application; funding from Youth Cancer Services Network and CanTeen)
- Bureaucracy (major delays in approval of trial)
- Slow accrual (limited number of centres at the beginning).

Physician reluctance may be due to several reasons e.g. believe these patients should be transplanted; competing trials for recruitment; only see a small number of patients so can't see value in joining the trial (tends to be the larger centres that get on board). Cross referral

can be a mechanism to get around some of these issues so that patients can transfer to a participating centre. In Victoria and New South Wales use of the clinical trials app can increase cross referrals. It was noted though that some patients may feel it is too hard or difficult to participate via another centre. Trials may be better received if they can incorporate access to local treatment in some aspects of the protocol.

#### **4.2.2 AYA PK Study**

The AYA PK study is a multi-institutional cross-discipline non therapeutic study supported by the ASSG investigating the pharmacokinetics and pharmacodynamics of doxorubicin in children and AYAs with newly diagnosed osteosarcoma (OS), Ewing sarcoma (EFT) and Hodgkin lymphoma (HL).

Aims of the study are to: evaluate the effect of gender and pubertal stage on the pharmacokinetics of doxorubicin in children and AYAs with EFT or OS; explore the relationship between doxorubicin pharmacokinetics and pharmacodynamics in children and AYAs with EFT, OS or HL, where PD is measured by neutropenia, thrombocytopenia, mucositis, fever neutropenia episode NCI CTCv3.0 (toxicity cycle 1) and HL IWGC, percent necrosis and RECIST (tumour response); explore the relationship between toxicity and tumour response; and explore the associations between doxorubicin pharmacodynamics and gender amongst AYA patients with EFT, OS or HL.

Inclusion criteria include patients with newly diagnosed with OS, EFT or HL, aged 1 to 50 years, planned treatment involving a standard doxorubicin-containing regimen and written informed consent from patient and/or their parent or legal guardian. Exclusion criteria include impaired hepatic function, significant uncontrolled systemic illness and females who are pregnant or breast feeding.

The trial opened in 2010 with the expected recruitment of 140-210 patients over three years. There are currently nine activated sites (Royal Children's Brisbane, Border Medical Oncology, Peter Mac, Royal Children's Melbourne, Children's Hospital Westmead, Princess Alexandra, Auckland City Hospital, Starship Children's Health and University College of London Hospital) with 64 patients recruited to date. A tenth and final site is due to be activated shortly (Prince of Wales). An interim analysis is planned for later in 2014.

As with the ALL6 study, the trial had a slow start and the timelines have been pushed out. Some of the barriers and challenges have included logistical issues around the administration of pharmacokinetics. The age limit has been subsequently increased from 40 to 50 and the instructions on pharmacokinetics have been reviewed.

It was noted that one barrier to AYA participation in clinical trials is remoteness and the COSA Rural and Regional Group are currently trying to facilitate cancer treatment being given in very

small centres so that patients serviced by telehealth could be recruited for clinical trials. It would still be important for these patients to receive supportive services though. Another rural and regional issue is Indigenous Australians and this is currently not addressed well in AYA research and should be taken into consideration.

### 4.3 AYA Research Support

Outcomes for AYAs can be enhanced via the following avenues:

- Improved networks and awareness
- Development of guidelines and protocols
- Education and training opportunities
- Clinical services
- Psychosocial supports
- **More research and improved access to clinical trials.**

Potential areas of research support from COSA and other organisations were noted. COSA is very supportive of activities that focus on advocacy and promotion; collaboration with other COSA groups (e.g. rural and regional) is also valued. Possible continuing activities by the COSA AYA Group have been identified as:

- Promote the establishment of a virtual national tumour bank. Biological differences exist across different age groups that are not fully understood so advocacy support would be valuable.
- Advocate for a reduction in the age of eligibility criteria for pharmaceutical sponsored trials. Age alone should not prevent a 15 year old AYA patient who is physiologically the same as an 18 year old from participating in a trial. Ethical and legal issues could be addressed to change this requirement.
- Foster cooperation between Australian clinical trials groups.
- Lobby Cancer Australia and Government to support AYA research activities.

COSA may also be able to assist by facilitating:

- Regular AYA workshops. COSA (with support from CanTeen) has previously convened six AYA cancer workshops. The purpose of these workshops has evolved over the years from enhancing AYA service delivery and building networks to more recently a targeted workshop for adult oncologists on 'expanding the continuum of care'. It is important for future workshops to be more relevant to the wider COSA membership and there may be scope to hold another workshop prior to the 2014 COSA ASM in Melbourne.
- Links with the COSA and CCTGs Executive Officer Network (EON). Delaine Smith, EON Chair, will feed the ideas from the current research strategy workshop back to EON members and an item may be included on future meeting agendas as required.
- Links with the Primary Care Collaborative Cancer Clinical Trials Group (PC4) to meet primary healthcare objectives for AYAs.



The purpose of developing an AYA research strategy was so it could be used for advocacy purposes by COSA and other groups. However, COSA and other organisations such as CanTeen are unable to fund everything. Funding opportunities must also be pursued from other groups such as NHMRC, Cancer Councils or Cancer Australia (especially for research studies). Cleola Anderiesz noted that there may be funding opportunities for people submitting projects to Cancer Australia, whose priorities are determined from the evidence base. The current priorities have been in place for one year and will remain for another two years.

It was noted that significant AYA research investment needs to come from the top (long term strategy) which will require data and evidence that something can be achieved for advocacy purposes (short term strategy).

#### 4.4 AYA Research Priorities

Workshop attendees made the following key points during the morning sessions:

- **Melanoma** has an excellent cure rate with surgery alone, however melanoma is one of the commonest causes of death in the AYA population due to the significant impact of stage 3 and 4 melanoma on survival. Ongoing pharmaceutical company and clinical trial group studies of melanoma should be encouraged to enrol patients down to the age of 13 to 15 years to attempt to improve outcomes for this age group.
- Patients with **soft tissue and bone sarcoma** still have relatively poor and unimproved outcomes including in the area of survivorship. A comprehensive investment into all aspects of sarcoma research is required to improve outcomes for this age group.
- **Common bio banking** is needed.
- **Health economic data** for both the system and individual is a promising area in the next five years for advocacy purposes, rather than focusing on priority diseases per se. It was noted though that care delivery is in state of flux so may not be the same in the future, but certainly health economics should be a part of any new study.
- **Youth participation** should be considered in all trial planning.
- There is overlap with **cancer survivorship**. Links with the COSA Survivorship Group and PeterMac (active survivorship program) could be established. In QLD it is hard for clinicians to have the time to see patients once they have finished treatment, therefore **primary healthcare** providers must have the relevant tools to see patients. One idea has been to provide each patient with a 'health passport' to take with them.
- Working with the **rural and regional** COSA Group could allow AYA patients serviced by telehealth to join clinical trials and address the issue of Indigenous Australians more effectively.
- AYA trial participation may be enhanced by:
  - Lowering the **age range** of adult trials
  - **Cross referring** patients to participating sites.

## **4.5 Collaborative Opportunities**

### **A. ALLG**

The ALLG clinical trial program has a national tissue bank which is a repository for all samples collected under research trial conditions. It has been very difficult to maintain a national tissue bank but the ALLG has received good support from the Leukaemia Foundation and is continuing to apply for further support from corporate organisations. Information on the tissue bank (e.g. types of samples, differentiating information on disease) is available on the ALLG website. ALLG also have a registry of all their clinical trials.

### **B. ASSG**

ASSG has the EE08 trial opening soon which has involved working closely with ANZCHOG to get things up and running. Monash are the lead ethics site. The trial will be open across eight adult and paediatric institutions nationally. This represents the first upfront treatment trial open in the adult sector for Ewing sarcoma. ASSG has used both national and international concepts for trials. ASSG continues to encourage research concepts of high importance to the AYA population. Currently underway include a retrospective study of bone sarcoma disease and late effects surveillance patterns in adult and paediatric sarcoma units in Victoria and a national survey of multidisciplinary health professionals regarding current disease and late effects surveillance practice. Further concepts under development include longitudinal studies of quality of life outcomes and physical function in the AYA sarcoma population.

### **C. COGNO**

COGNO are currently looking for new ideas for studies and are open to opportunities for collaboration, especially for AYAs. Last year COGNO did a patterns of care study in adults with medulloblastoma and results showed that there was few similarities between the management plans of different physicians treating medulloblastoma. There is an opportunity for research in this area but the disease is difficult to study prospectively because it is rare. One option may be to have a registry to collect data.

### **D. PoCoG**

In terms of AYAs the largest study PoCoG have currently open is the Recapture Life study, a national psychosocial trial for off treatment AYAs. There is interest in developing further concepts and there are some concept development workshops are planned.

## **E. ANZMTG**

ANZMTG does not have any AYA specific trials open at the moment. The discussion paper from the last CanTeen workshop was taken to the board, who agreed in principle that all ANZMTG led trials should have the additional paperwork to allow younger people (15-18 years) to participate. This will be rolled out for all new protocols (the patient information and consent form will be tailored for younger participants). ANZMTG are also looking to do investigator led trials with some of the new targeted therapy agents on the market, and AYA engagement would be considered here. Having an AYA focus group or concept development workshop for tumour specific areas is a very good idea. Dropping the age range in clinical trials is something that all CCTGs could work together to achieve.

## **F. ANZCHOG**

ANZCHOG encourages all opportunities for collaboration. May be able to help facilitate increasing the number of younger patients on trials for groups that are able to drop the age range. It would be ideal to have a paediatrician embedded into an adult hospital to facilitate younger patients participating in clinical trials. Having a large range of consent forms (up to ten per family in some hospitals) is a large barrier to youth participation in trials; finding ways to simplify the consent process is required.

## **G. ALTG**

Lung cancer (especially small cell) is being split into smaller groups and becoming more like rare diseases. Hence ALTG have issues in common such as tissue banking and molecular testing. ALTG have utilised concept development workshops.

## **H. CanTeen**

In November 2013, CanTeen established a Youth Cancer Service Research Advisory Group to conduct a project to establish future AYA cancer research priorities and determine how to best place the limited funds from the Phase 2 initiatives. CanTeen has worked up a protocol which has been submitted to the group for feedback and employed a project officer to develop a report (due in May). The report will include a literature review and survey to help identify areas for AYA cancer research. Outcomes from the COSA AYA research strategy workshop will be fed back to the CanTeen Research Advisory Group and it is hoped that both groups can work together to move the agenda forward.

CanTeen have also established a Youth Cancer Service Dataset Advisory Group, and it is anticipated that they will work closely with the research group.

## I. Cancer Australia

Cancer Australia has been working closely with CanTeen on AYA initiatives. In terms of research priorities and support, Cancer Australia funds the 13 national CCTGs to develop clinical trials protocols to the stage of submission for competitive funding (typically through NHMRC, Cancer Australia or Cancer Councils). Cancer Australia also assist the CCTGs by providing technical services such as health economics and quality of life so these can be built into trial protocols and costed prior to grant submission. Would encourage CCTGs to contribute to the collection of health economic data in driving and understanding better the issues for AYAs, even if it is a sub-study within a protocol.

The other new initiative is the GCCTI (Genomic Cancer Clinical Trials Initiative) to capitalise on the recent trend for many trials to focus on the genomic basis of tumours rather than the specific site of origin. This is a platform to help the CCTGs work together on protocol development rather than stay in tumour streams. However, it is not intended to replace the work of the individual tumour stream groups.

Cancer Australia also have the PDCCRS (Priority Driven Collaborative Cancer Research Scheme). The current research priorities are determined from the evidence base and include health economics and quality of life. While the scheme is not specific to AYAs it does not exclude them, so applications would certainly be considered.

## J. Australian Association of Adolescent Health

The Australian Association of Adolescent Health is a national organisation for anyone interested and involved in adolescent health. They are pushing to advocate for the health of AYAs and oncology will be an area of high priority. The association may be able to assist getting consumers on board for future work.

### 4.6 AYA Research Strategy

Participants agreed that the best strategy was to focus on the non-therapy issues affecting AYA research, rather than identifying specific studies (which can be done later).

The key afternoon session brainstormed such issues relating to the following areas:

- Clinical trials
- Tools
- Links with other groups
- Awareness/education/national curriculum
- Linking technologies
- Areas of need to add to the list of research priorities.

AREA	ISSUE	COMMENTS
Clinical trials	HRQoL and health economics (CREST)	<ul style="list-style-type: none"> <li>• CCTGs are receiving support from Cancer Australia to include these areas in trials</li> <li>• Cancer Australia can help facilitate this</li> </ul>
	Change in age of eligibility	<ul style="list-style-type: none"> <li>• Advocate for primary adult centres to lower the age range</li> <li>• Links with CCTGs and pharmaceutical companies may assist</li> </ul>
	Key international trials	<ul style="list-style-type: none"> <li>• Plenty of scope to tap into these</li> </ul>
	Survivorship	<ul style="list-style-type: none"> <li>• Overlap with AYAs</li> <li>• Links with the COSA Survivorship Group and PeterMac could be established</li> </ul>
Tools	Virtual tissue bank	<ul style="list-style-type: none"> <li>• Establish data linkages?</li> </ul>
	Clinical registry database	<ul style="list-style-type: none"> <li>• Clinical trial apps</li> </ul>
	AIHW vs research info	
Links with other groups	CCTGs (via EON)	<ul style="list-style-type: none"> <li>• Sub studies for AYAs may be easier way to incorporate</li> <li>• Cross representation between CCTGs and ANZCHOG/ACCT/COSA AYA committee to work towards collaborative opportunities for trial development, access</li> </ul>
	Non cancer research groups	
	Cancer Australia	
	Primary care	<ul style="list-style-type: none"> <li>• GP education</li> <li>• Consumers</li> <li>• Targeted information for survivorship</li> <li>• Invite to MDTs</li> </ul>
Awareness/education/national curriculum	Consumers	
	Primary care	
	Physician training	
	CCTGs	
	COSA	<ul style="list-style-type: none"> <li>• Annual workshop aimed at adult oncologists</li> </ul>
Link technologies	Clinical trials app	<ul style="list-style-type: none"> <li>• National coverage needed (currently just in NSW)</li> <li>• Could link to Cancer Council so don't have to update app</li> <li>• Best to broaden already existing registries like Australian Clinical Trials via Cancer Australia rather than start from scratch</li> </ul>
	Consumers	<ul style="list-style-type: none"> <li>• Personal access to registry</li> </ul>
Areas of need (to be added to list of research priorities)	Rural and regional	<ul style="list-style-type: none"> <li>• Work with COSA Rural and Regional Group and existing infrastructure</li> <li>• Possible CA grant application</li> </ul>
	Indigenous Australians	
	SES	

## 5. Acknowledgments

Overall the workshop was an excellent opportunity to identify issues and priorities for AYA research and promote collaboration between stakeholders.

COSA would like to thank the workshop speakers for preparing and delivering the presentations and attendees for their interest and participation.

## Appendix 1 List of Attendees

COSA AYA EXECUTIVE COMMITTEE			
Name	Representation	Present	Apology
Wayne Nicholls (Chair)	Royal Children's Hospital Brisbane	Y	
Antoinette Anazodo	Sydney Children's Hospital	Y	
Jennifer Chard	Western Sydney Youth Cancer Service	Y	
Lisa Orme (Deputy Chair)	Peter MacCallum Cancer Centre	Y	
Michael Osborn	Women & Children's Hospital Adelaide	Y	
Marianne Phillips	Princess Margaret Hospital for Children Perth	Y	
Kate Thompson	ONTrac at Peter Mac	Y	
Toby Trahair	Sydney Children's Hospital	Y	
Martin Tattersall	Sydney Cancer Centre Royal Prince Alfred		X
Kylie Mason	Royal Melbourne Hospital	Y	
OTHER ATTENDEES			
Marie Malica	COSA Executive Officer	Y	
Hayley Griffin	COSA Project Coordinator	Y	
David Currow	Cancer Institute of NSW	Y	
Kenneth Bradstock	University of Sydney/WMH	Y	
Cleola Anderiesz	Cancer Australia	Y	
Pandora Patterson	CanTeen	Y	
Donald Payne	Australian Association of Adolescent Health	Y	
Delaine Smith	ALLG	Y	
Paul Mitchell	ALTG	Y	
Peter Downie	ANZCHOG	Y	
Robyn Strong	ANZCHOG	Y	
Anna Hoadley	ANZMTG	Y	
Libby Paton	ANZMTG	Y	
Jeremy Lewin	ASSG	Y	
Denise Caruso	ASSG	Y	
Mustafa Khasraw	COGNO	Y	
Kate White	PC4		X
Ursula Sansom-Daly	PoCoG	Y	

## Appendix 2 Workshop Agenda

AGENDA ITEM	ATTACHMENT	SPOKESPERSON	TIME
1. Welcome and introductions		Wayne Nicholls	9.30am
2. Background to workshop	Att 2.1 Cancer in AYAs in Australia (AIHW 2011) Att 2.2 UK clinical trial participation (Fern 2008) Att 2.3 USA survival rates (Bleyer 2011) Att 2.4 UK research strategy (Fern 2013)	Wayne Nicholls	9.35am
3. Purpose and objectives of workshop		Wayne Nicholls	
4. Current research in AYAs <ul style="list-style-type: none"> <li>• What is happening in current research in AYAs?</li> <li>• What is working?</li> <li>• What are the barriers and issues in AYA research?</li> <li>• What are some of the solutions?</li> </ul>	Att 4.1 Background paper on current research, issues and gaps	All Attendees	9.50am
5. The ALL6 study		Ken Bradstock	10.30am
6. PK study		Lisa Orme	10.50am
7. AYA research priorities <ul style="list-style-type: none"> <li>• Priority areas <ul style="list-style-type: none"> <li>i) Biological/Pharmacology</li> <li>ii) Front line treatment</li> <li>iii) Psychosocial</li> <li>iv) Supportive Care/ Survivorship/Palliative Care</li> <li>v) Genetics Epidemiology</li> <li>vi) Health Economics</li> </ul> </li> <li>• Disease priorities <ul style="list-style-type: none"> <li>i) Poor Prognosis tumours</li> <li>ii) ALL</li> <li>iii) Sarcoma</li> <li>iv) Brain - Medulloblastoma</li> </ul> </li> <li>• Possible concepts</li> </ul>		All Attendees	11.10am
<b>LUNCH</b>			<b>12.30pm</b>
8. AYA research strategy <ul style="list-style-type: none"> <li>• One year</li> <li>• Five years</li> <li>• Funding opportunities</li> </ul>		All Attendees	1.00pm
9. Collaborative opportunities		All Attendees	4.00pm
10. Close and next meeting		Wayne Nicholls	4.30pm



### Appendix 3 Current Studies in AYAs

PRIORITY AREA	CURRENT STUDIES	GAPS/ISSUES/COMMENTS
Biological/ Pharmacology	<p><i>Victoria:</i></p> <ul style="list-style-type: none"> <li>• AYA PK 3 years into recruitment interim analysis due in next 6 months</li> <li>• Unfunded Proposal 2013 NHMRC melanoma in young people</li> <li>• Unfunded Proposal 2013 NHMRC cardiac toxicity</li> </ul>	<ul style="list-style-type: none"> <li>• Very little available in biology/pharmacology studies in the adult sector</li> <li>• Will be important to include in future studies for sub sites where there is a difference between AYAs and paediatrics or AYAs and adults e.g. sarcomas</li> </ul>
Front line treatment	<p><i>Victoria:</i></p> <ul style="list-style-type: none"> <li>• ALL6 open in a number of sites (part funded in Victoria by ONTrac)</li> <li>• Ewing 2008 opening 2014 at selected sites supported by ASSG</li> </ul>	<ul style="list-style-type: none"> <li>• At a national level, evaluating frontline AYA services and care would be valuable and important for justifying the existence of these services</li> <li>• The AYA patterns of care study will look at areas of frontline treatment however this is retrospective</li> </ul>
Psychosocial	<p><i>Victoria:</i></p> <ul style="list-style-type: none"> <li>• Youth Friendly Practice</li> <li>• Experiences of Care</li> <li>• Recapture Life</li> </ul> <p><i>New South Wales:</i></p> <ul style="list-style-type: none"> <li>• New in Sydney is a telehealth project between the two children's hospitals evaluating psychological assessment/intervention in AYAs</li> </ul>	<ul style="list-style-type: none"> <li>• Where the bulk of research has been so far, with many projects underway around the country</li> </ul>
Supportive Care/ Survivorship/ Palliative Care	<ul style="list-style-type: none"> <li>• Survivorship Connections: A Youth Friendly Model of Survivorship Care (work underway across multiple sites in Victoria by PeterMac)</li> <li>• Medical &amp; psychosocial symptom burden of AYA patients referred to a palliative care service</li> <li>• An Exploratory Study into the Relationship between AYA Cancer Patients and GPs and the Identification of Youth Friendly GPs throughout Victoria</li> </ul> <p><i>Under development:</i></p> <ul style="list-style-type: none"> <li>• An exploratory study of physical function &amp; quality of life among AYAs 15-40 years with bone sarcomas across the treatment trajectory</li> <li>• Cross sectional study of the health status of survivors of bone sarcoma</li> <li>• Disease surveillance &amp; long term follow up (LTFU) practices among multidisciplinary oncology teams caring for patients with bone</li> </ul>	<ul style="list-style-type: none"> <li>• Survivorship is a growing field with opportunities for research</li> <li>• Little happening in NSW in palliative care research, mostly due to resourcing. Keen staff available.</li> <li>• Biggest gap is the coordination of care between paediatric and adult centres - both with the consistency of treatment across both and also the transition of care from paed to adult centres (often in respect to long term follow-up)</li> <li>• Late effects is another gap</li> <li>• Education of primary care providers (GPs)</li> <li>• An emerging issue is the identification of AYA friendly specialists (outside of haematology) and allied health (psychology/psychiatry has been one area in particular here)</li> <li>• Lack of information about risk taking behaviours - smoking, drugs, alcohol that is targeted to the AYA cancer patient</li> </ul>

	<p>sarcomas in Australia</p> <p><i>Under discussion:</i></p> <ul style="list-style-type: none"> <li>• Fertility: COG study for HL/NHL</li> <li>• National FP database (Antoinette)</li> </ul>	
Genetics Epidemiology	<p><i>Victoria:</i></p> <ul style="list-style-type: none"> <li>• International Sarcoma Kindrid Study (ISKS)</li> <li>• Cancer 2015 (directed by David Thomas; pilot looking to expand; not AYA specific)</li> <li>• Patterns of Care</li> <li>• Phase 1 implementation and evaluation of education for healthcare professionals in a model of youth friendly genetic counselling (Victoria specific project for young people at risk of hereditary syndrome)</li> </ul>	<ul style="list-style-type: none"> <li>• Unaware of anything underway in the adult sector that's AYA focussed</li> </ul>
Health Economics	<ul style="list-style-type: none"> <li>• In association with a review of Westmead hospitals survivors of childhood medulloblastoma there has been an attempt made to assess the costs in long term follow up of these patients with the help of CREST (Cancer Research Economics Support Team) at UTS. It is proving a complicated exercise, even for a limited number of patients.</li> </ul>	<ul style="list-style-type: none"> <li>• Economic evaluation of AYA services will be important providing evidence for ongoing/future funding where there is increasing competition for already stretched public health resources</li> <li>• Health economic evaluation should be incorporated into new studies wherever possible</li> </ul>
<b>PRIORITY DISEASE</b>	<b>CURRENT STUDIES</b>	<b>GAPS/ISSUES/COMMENTS</b>
Poor Prognosis Tumours	<ul style="list-style-type: none"> <li>• Metastatic melanoma - several recent phase I and II drug studies in Australia (Rick Kefford and Georgina Long in Sydney)</li> </ul>	<ul style="list-style-type: none"> <li>• Need to keep encouraging researchers to keep eligibility open to under 16s</li> </ul>
ALL		<ul style="list-style-type: none"> <li>• Ongoing encouragement of adult and paediatric colleagues to collaborate is needed</li> </ul>
Sarcoma		<ul style="list-style-type: none"> <li>• Vivek Bhadri's ambitious study on AYA osteo/rhabdo/Ewing failed to get NHMRC funding in the last round. Uncertain as to whether this will be resubmitted with modification.</li> <li>• ASSG keen to collaborate</li> </ul>
Brain - Medulloblastoma		<ul style="list-style-type: none"> <li>• Although rare, an area where there is little to guide treatment in young adults and paediatric approach is dramatically different to the adult one (believe something is on the cards through COGNO, unsure who is running it)</li> </ul>