



Considerations for the inclusion of adolescent patients in adult oncology clinical trials guidance for industry

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Introduction

Cancer Council Victoria

Cancer Council Victoria is a non-profit organisation that has been leading the fight against all cancers for more than 80 years in the areas of research, patient support, cancer prevention and advocacy. Our mission is to prevent cancer, empower patients and save lives.

Since 1988, Cancer Council Victoria has provided significant funding to support the research conducted in clinical trials and collects Victorian clinical trial activity and recruitment data. Using this data, our [Victorian Cancer Trials Link](#) enables patients and clinicians to search for current Victorian clinical trials.

In this submission, Cancer Council Victoria welcomes the opportunity to comment on the proposed adoption of the Food and Drug Administration's (FDA) '*Considerations for the inclusion of adolescent patients in adult oncology clinical trials guidance for industry*', as a regulatory lever to improve access to clinical trials for adolescents, aged 12-17 years, who have been diagnosed with cancer.

Established in 1976, the Cancer Council Victoria Clinical Network brings together multidisciplinary health professionals and researchers who work with people affected by cancer. Its mission is to harness the voice of clinicians to improve outcomes for all Victorians affected by cancer. This submission has been informed by consultation with experts within our Clinical Network Executive Committee.

Context

Cancer Council Victoria positively supports actions that will improve accessibility of clinical trials for young people affected by cancer. While Australia has some of the best survival outcomes anywhere in the world, the burden of cancer is not evenly spread. We know that cancer is the leading cause of disease-related mortality in adolescents and young adults in Australia, comprising 8.8% of all deaths in young people between 2011 and 2015.¹ These outcomes can be changed through research and clinical trials. Accordingly, availability and access to clinical trials is a health equity issue.

The national *Optimal Care Pathways* recommend that all patients should be offered the opportunity to participate in a clinical trial or clinical research, if appropriate.² Clinical trials play an important role in providing treatment options for people affected by cancer. Many people with cancer are now living longer, with a better quality of life due to the treatments developed in clinical trials.

Cancer Council Victoria has recently undertaken extensive consultations with more than 600 community members and health professionals about Victorian cancer issues. These consultations called for better access to clinical trials and equitable access to treatment and care.³

We know that less than 6% of Victorian adults with cancer participate in clinical trials; a figure that is even lower amongst some groups. Whilst national data about the number of adolescent patients (aged 12-17) recruited into oncology clinical trials is limited; Victorian data indicates that in 2018, 62 adolescents were diagnosed with cancer.⁴ We also know that approximately 20 adolescents were enrolled in a Victorian clinical trial.⁵ None of these patients were recruited onto an adult oncology clinical trial. In 2019, data from our Victorian Cancer Trials Link showed that less than 3% of adult oncology clinical trials in Victoria included an age eligibility below 18 years.

Historically, strict age eligibility criteria have prevented adolescents from participating in adult oncology clinical trials. In Australia, age eligibility for clinical trials traditionally aligns with the age at which paediatric patients transition into adult care (≥ 18 years) despite recognition that some cancers, diagnosed in adolescent patients, display similar histologic and biologic behaviours to those observed in adults.⁶ Consequently, adolescent patients may experience delayed access to potentially effective therapies and improved cancer outcomes, compared to those of their paediatric and adult counterparts.

FDA guidance for industry

There is international momentum to accelerate cancer research and to make more treatments available to a larger and more diverse population of patients.⁷ The FDA guidance '*Considerations for the inclusion of adolescent patients in adult oncology clinical trials guidance for industry*' provides non-binding recommendations for the inclusion of patients under the age of 18 years.

Cancer Council Victoria believes the recommendations contained within the FDA Guidance are applicable to the Australian setting. This includes information on appropriate dose selection, safety monitoring and ethical considerations related to the treatment of adolescents aged 12-17 years, with cancers that are histologically and biologically similar to those found in adults. The FDA Guidance provides broad recognition of the similarity between adult and adolescent pharmacokinetics and complements aspects of earlier guidelines adopted by the Therapeutic Goods Administration of Australia (TGA), pertaining to the use of medicinal products in paediatric populations.^{8,9}

We share Tash's story below, to highlight the patient experience and the importance young people place on inclusion in clinical trials that provide access to treatments that may otherwise be out of reach. Cancer Council Victoria believes age should not be a barrier to accessing appropriate treatment.

Cancer Council Victoria supports the proposed adoption of the FDA Guidance by the TGA to ensure adolescents, like Tash, diagnosed with cancer, face fewer barriers to accessing appropriate clinical trials in Australia. We acknowledge there may be complexities including the provision of informed consent and the capability of adult health services to extend clinical trials to adolescent patients. However, we believe the adoption of the FDA Guidance will enable ethics and governance committees to offer more streamlined access to clinical trials for adolescents with cancer.

Case Study: "I was very excited that I would be in the trial...": Tash

Tash was diagnosed with Lymphoma in 2012. In her first year of treatment, she had chemotherapy, but also needed a stem cell transplant. When this transplant failed, she was referred to another specialist to discuss enrolling on a clinical trial.

"...because I was 15 going into an adult trial, I had to go through an ethical committee to get approval to actually go on the trial..."

"...it was daunting because your fate is sort of in the hands of a group of people deciding whether or not your cancer is valid, I suppose..."

"...I was very excited when I got the news that I would be in the trial, but I was also very nervous."

"If I hadn't had the clinical trial, I wouldn't have been able to go on the transplant and ultimately, I think I wouldn't have gone into remission."

Recommendation

Recognising the dearth in guidelines specifically addressing adolescent inclusion in adult oncology clinical trials in Australia, Cancer Council Victoria supports the TGA’s proposal to adopt the FDA’s *‘Considerations for the inclusion of adolescent patients in adult oncology clinical trials guidance for industry’*. Adoption of the FDA Guidance, as applicable to the Australian therapeutic sector, will provide an important foundation for adolescent patients to access therapies and outcomes available in adult oncology clinical trials.

Summary

Cancer is the leading cause of disease-related death for adolescents and young adults in Australia, with adolescents (aged 12-17 years) historically excluded from participating in adult oncology clinical trials due to their age eligibility.

Excluding potential clinical trial participants on age alone represents an inequity in clinical trial access and as a result, these patients may experience barriers and delays in accessing potentially effective therapies available in oncology clinical trials.

With so many Australians affected by cancer, ensuring access to optimal cancer care is essential to improve their survival and quality of life outcomes.

For more information, contact Danielle Spence, Head of Strategy and Support, at Danielle.Spence@cancervic.org.au or on (03) 9514 6343.

Thank you for your consideration of this submission.

Todd Harper A/Prof Andrew Wei
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Cancer Council Victoria

Notes

¹Australian Institute of Health and Welfare, *Cancer in adolescents and young adults*.

Accessed from <https://www.aihw.gov.au/getmedia/ed22109b-ab23-4273-8d23-7949a8922ea2/aihw-can-110.pdf.aspx?inline=true>

² Australian Department of Health, *Optimal care pathways*. Accessed from <<https://www1.health.gov.au/internet/main/publishing.nsf/Content/occp>>

³Cancer Council Victoria, *Informing the next Victorian Cancer Plan* (Melbourne: Cancer Council Victoria, 2019).

⁴Victorian Cancer Registry (Melbourne: Cancer Council Victoria, 2019).

⁵Cancer Trials Management Scheme (Melbourne: Cancer Council Victoria, 2019).

⁶Ellis J, Robertson A, Watt A & O'Callaghan S. *Establishing a Cancer Clinical Trial with Age Eligibility Encompassing Adolescents and Young Adults (AYA)* (Melbourne: Victorian Comprehensive Cancer Centre, 2019)

⁷State of Victoria, Department of Health and Human Services, *Victorian cancer plan 2016-2020, Improving cancer outcomes for all Victorians*. (Melbourne: Department of Health and Human Services, July 2016).

⁸European Medicines Agency, *ICH Topic E 11. Clinical Investigation of Medicinal Products in the Paediatric Population* (2001) .

⁹European Medicines Agency, *Guideline on the Role of Pharmacokinetics in the Development of Medicinal Products in the Paediatric Population* (2006).