

30. Teenage Cancer Trust 311013



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**Response to Nuffield Council on Bioethics Call for Evidence on
Children and clinical research: ethical issues**

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This statement is a general response to the consultation, however some points may be most relevant to questions 11-13 of the call for evidence.

Introduction

Teenage Cancer Trust is the only UK charity dedicated to improving the quality of life and outcomes for the seven young people aged between 13 and 24 diagnosed with cancer every day. We fund and build specialist units in NHS hospitals and provide dedicated staff, bringing young people together so they can be treated by teenage cancer experts in the best place for them.

Cancer is the most common cause of non-accidental death in young people, and five-year survival rates remain lower in teenagers than in children¹. Through education of young people about the signs of cancer and working with health professionals to improve their knowledge, we work to significantly improve their diagnosis experience. And through our own research and working with our partners in the NHS, across the UK governments, and organisations both nationally and internationally, we strive to improve outcomes for young people.

Investment in research and medicines is important to young people with cancer, who know that access to clinical trials and developing best care and treatment can save lives². Teenagers and young adults get some of the rarest forms of cancer, and effective treatment for teenagers and young adults may differ from what works best for children or adults due to different cancer biology, different treatment protocols and different response to treatment. However, there is a significant lack of trials for the types of cancers that affect teenagers and young adults, and where ones do exist, often the age criteria excludes patients in this age group. These two issues of choice and age are key to explaining why less than 20% of cancer patients aged 15-24 are currently getting access to clinical trials in the UK, compared with around 50-70% of children³.

Choice

Although cancer in this age group is rare, the number of life years lost to cancer in young people is estimated to rank second highest, behind breast cancer⁴. The 2013/14 Outcomes Framework set out by NHS England includes an indicator on reducing the PYLL in children and young people from causes considered amenable to healthcare. This is clearly a priority for the NHS, however in practice young people are not being offered the standards of care they deserve and which could improve their outcomes.

¹ Cancer Research UK (2013), *Cancer Stats Report: Teenage and young adult cancer*

² Teenage Cancer Trust (2012), *Young Voices: Transforming the lives of young people with cancer*

³ Cancer Research UK (2013), *Cancer Stats Report: Teenage and young adult cancer*

⁴ CYP IOG Advisory Group Annex M (2010), *Children and young people with cancer 2015*

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Young people get some of the rarest forms of cancer. While government and charity funders spend over £500m annually on cancer research, only 33% goes toward cancers that affect young people, and without leukaemia this drops to 18%⁵. This may be because small populations of patients with rarer cancers mean specific trials for these cancer types are often viewed as less commercially viable by drug developers.

Even where trials do exist, young people continue to suffer from inequity of access. For example, bone sarcoma trials have a wide age eligibility criteria, yet between 2005-2007 the accrual rate of 15-24 year olds was approximately half that of 5-14 year olds⁶. Currently in the UK, the best way for young people with cancer to be considered for relevant clinical trials is via the teenage and young adult multi-disciplinary teams (TYAMDT) where Teenage Cancer Trust units are based, all located in Principal Treatment Centres for cancer. Only around half of young people with cancer are currently discussed at a TYAMDT and this is something Teenage Cancer Trust is working to change.

Age

Arbitrary age criteria of clinical trials is another barrier to access for teenagers and young adults with cancer, whether in paediatric trials with an upper age limit or adult trials with a lower age restriction. This problem has been identified by the National Cancer Research Institute, who are now working with the National Institute of Health Research to review their research portfolio and ensure no arbitrary age barriers are set at the start of trials.

EU regulations stipulate that a Paediatric Investigation Plan (PIP) must be submitted in all cases of drug development where there may be potential benefit to young people. Drug companies must either justify not submitting a PIP or they must include a trial for children and young people as part of their development. However, in cases where the specific cancer does not occur in children and young people, yet the mechanisms of action of the drug being tested may still have a positive impact on them, young people remain excluded⁷.

Age barriers to clinical trials: Chloe Drury's story

Chloe was diagnosed with Ewing Sarcoma. Her mother, Debbie Binner, tells their story on her blog <http://achildofmine.blogspot.co.uk/>

“Chloe was blocked from entering a clinical trial for a new investigational drug when she was 17 and nine months. The entry criteria for the trial was 18. There was no clinical reason why the entry criteria was 18 (at nine stone Chloe was an adult weight). At this point we had run out of all other options and we were told this drug ‘may’ work. We kicked, screamed and begged to be allowed on this trial. Doctors agreed we should have been allowed on it, Simon Davis, CEO of Teenage Cancer Trust, intervened personally and we had help from our local GP. The Royal Marsden wanted Chloe to go on the trial; so did University College London Hospital. But the door remained tightly closed and Chloe was not allowed on the trial.

Chloe died and so will other young people who have the same illness if we don't do something quickly about changing the current entrenched status quo.”

Summary

⁵ Cancer Research UK (2012), *Research Strategy Progress Report 2011/12*

⁶ Fern et al (2008), *Rates of inclusion of teenagers and young adults in England into National Cancer Research Network clinical trials*, British Journal of Cancer: 99 (12), 1967-1974

⁷ Vassal et al (2013), *Is the European Paediatric Medicine Regulation Working for Children and Adolescents with Cancer?*, Clinical Cancer Research: 19 (6), 1-11

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There are significant arbitrary, commercial and legislative barriers which mean that only 20% of teenagers and young adults with cancer in the UK have access to clinical trials. Although legislation does not restrict access for this age group, the practice of trial protocol setting is often leaving them out. There is also a lack of innovation and investment in drug development for many rare cancers which are prevalent in teenagers and young adults. The future of drug development, with a focus on personalised medicines and mechanisms of action, may benefit groups like young people with cancer and those with other rare diseases. However, these changes are likely to require industry, regulators and researchers to function differently in order for these benefits to take effect.