Cancer in Children, Teenagers and Young Adults (0-25 years)

Study Protocol 12/05/2016

Study Advisory Group Members

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Steering Group Members

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Introduction

Cancer is the leading cause of death amongst children, teenagers and young adults (TYA) aged between 0-25 in the UK. Each year there are on average 3700 cases of cancer diagnosed in this age group, with over 600 cases dying every year (*Cancer Research UK*). Childhood and TYA cancer accounts for 3-4 % of all cancers. The estimated crude rate of cancer varies from between 127 to 270 per year for every million 0-25 year olds in the UK. In potential years of life lost (PYLL) from causes considered amenable to healthcare, for children and young people, childhood cancer remains the biggest contributor. The annual NHS costs for cancer services are £5 billion, but the cost to society as a whole – including costs for loss of productivity – is £18.3 billion. Treatment related complications such as sepsis cost £20,000.00 per admission. (*Department of Health-DOH*). Although cancer outcomes in children and young people have improved dramatically over the last few decades, of those who die, approximately half will do so of treatment related complications many of which are avoidable. For all those who die there is variation in the quality of end of life care. There is also growing anecdotal evidence that chemotherapy regimens may be being prescribed for patients with minimal chance of a positive outcome, a finding highlighted in the 2005 NCEPOD study on SACT in adults. Thus improving survival is now less about new therapies and more about better quality healthcare

Most treatment related deaths are from bacterial sepsis and should therefore be preventable. Arguably every death from infection could represent some form of systems failure and thus its investigation should be central to a quality driven commissioning process. Neutropenic sepsis is relatively common, resulting in hundreds of hospital admissions every month and causing the deaths of an estimated 1 in 500 people diagnosed with cancer. Emergency care of cancer patients with infection/sepsis has significant failings as highlighted in the recent Parliamentary and Health Service Ombudsman – Time to Act: Severe Sepsis Rapid Diagnosis and Treatment Saves Lives (2013). These failings include lack of appropriate clinical assessment, inadequate and/or delays to timely treatment, delays in transfer to critical care, delays in senior medical input and failure to recognize the early warning triggers of deteriorating patients. It has been estimated that the total number of deaths from neutropenic sepsis in England and Wales has more than doubled over the last 10 years from around 300 in 2001 to around 700 in 2011. Neutropenic sepsis is also the second most common reason for hospital admission among children and young people with cancer, with approximately 4000 episodes occurring annually in the UK.(*NICE: Neutropenic Sepsis, Prevention and Management in Cancer Patients 2012*)

This confidential enquiry into cancer treatment in patients aged 0-25 will highlight areas of the pathway where care can be improved and enhance the quality of care in this group of patients.

Aims and objectives

Overall aim:

The aims of this study are to study the process of care of children, Teens and Young Adults aged 25 years and younger who died/ or had an unplanned admission to critical care* within 60 days of receiving systemic anti-cancer therapy in order to:

1) Look at the decision making and consent process around the prescription of SACT in this group of patients
2) Explore remediable factors in the quality of care provided to patients during the final line of therapy.
3) Look at preventable causes of treatment-related mortality in young people's cancers.
4) Look at the configuration of the service and organizational structures in place for the safe delivery of SACT to children, teenagers and young adults

Objectives

1) The Prescription of the final course of SACT
    a. The right protocol*
    b. The service overseeing the treatment decision/ prescription of SACT
    c. The intent- palliation Vs cure
    d. Performance status of the patient at time of prescription of the first cycle of SACT
    e. Consideration of Toxicity/ side effects/ quality of life
    f. The consent process
    g. Communication of patient information between different services and communication of information to the patient
    h. Was the patient on a clinical trial?

2) Delivery of last cycle* of SACT
    a. Process of prescription of last cycle of SACT
    b. Performance/disease status at time of administration of SACT
    c. Process of administration of SACT
    d. Safety netting
3) Preventable death/ICU admission
    a. Recognition of the sick patient throughout the pathway
    b. Sepsis pathway: Antimicrobial delivery and fluid resuscitation
    c. Appropriateness of ICU admission/access to ICU/ process of ICU admission

4) Organisational issues
    a. Types of service: PTC/ TYA-designated hospital/ POSCU
    b. Acute paediatric services, acute oncology- availability (24/7)
    c. Where patients are admitted to acutely
    d. PICU/ ICU onsite
    e. TYA-CNCG – coordinating group- network functioning
    f. Pre-alerts from primary care? via GP, 111, POSCU , ambulance service

    g. Quality improvement
        i. MDT- discussion
        ii. Peer review -CQUINS
        iii. M&M meetings
        iv. Clinical governance/ RCA
        v. Shared care centres/ POSCUs
        vi. Levels of care
        vii. Variation in the pathway- nearest POSCU
    h. Transition child to adult
        i. Structure of care delivery
        ii. Cut-off ages
    i. Information/ staff training /education
        i. Nursing staff / ambulance staff
        ii. Telephone advice
        iii. Programmes of education in the organisation for haematological emergency – febrile neutropaenia.
    j. Palliative care provision
    k. Staffing
        i. Number of WTE devoted to age appropriate haematology/ oncology
        ii. Ratios/on-call ratios - Nursing
        iii. Dedicated Paediatric trained resus team iv. Competencies of staff
    l. Communication:
        i. record sharing of chemotherapy administration between POSCU and PTC ii. Information for patients/ families
    m. Policies/ protocols
        i. Neutopaenic fever guideline- linked to PTC
        ii. Protocol to deal with acutely unwell paediatric/TYA oncology patient

n. MDT
   i. Is every treatment change for a given patients discussed at an MDT?
   ii. Which staff members attend

Methods

Population/Inclusions

1) Children, teenagers and young adults under the age of 25 years (age at time of death/unplanned critical care admission).
2) Who have been diagnosed with a solid tumour (including CNS) or haematological malignancy (using NICE definition)
3) And who received systemic chemotherapy (using SACT data)
4) And Died or underwent an unplanned admission to critical care within 60 days of receiving chemotherapy

Exclusions

- Planned admissions to ICU for procedures such as surgery
- Incidental death/ ICU admission e.g. trauma

Case identification

A spreadsheet consisting of 2 worksheets were sent out to our Local Reporters for completion to identify patients for the study.

Treatment worksheet Patients aged ≤ 25 years who were coded with ICD10 code (any position) for cancer (C00-D09; D37-D48) during the study period 01/03/2014 - 31/05/2016. For these patients we will collect some basic data including: NHS number, case note number, applicable ICD10 codes, date of prescription of last protocol of SACT, responsible prescribing clinician, date of delivery of final cycle of SACT.

ICU/death worksheet Patients aged ≤ 25 years who died or were admitted to critical care and were coded with ICD10 code (any position) for cancer (C00-D09; D37-D48) during the study period 01/06/2014 - 31/05/2016. For these patients we will collect some basic data including: NHS number, case note number, applicable ICD10 codes, ourcome, ICU admission date, date of admission/discharge/death, whether the patient was admitted to ICU, name of intensivist, name of admitting and discharging clinicians.
An ONS run of data will be carried out for the same timeframe to make sure there are not cases missed for patients who died outside of the hospital.

Sample size

During a 1 year period it is estimated that approximately 600 patients in this age group (0-25) with cancer will die in the UK (Cancer Research UK). In addition it is estimated there will be around 300 patients admitted to intensive care (PICANET UK & Ireland data (age 0-16) plus estimates extrapolated from numbers of patients aged 16-25 admitted to ICU with cancer diagnosis (ICNARC). Identifying patients over a 2 year period should give an initial sample of around 1800 cases of patients who died with a cancer diagnosis. A sub-set of these patients – those who died within 60 days of administration of final course of SACT will be selected for peer review, which should give a sample size of at least 500.

Sample period

To ensure there are enough cases are identified, cases of patients who died or were admitted to critical care will be identified over a two year period: 1st June 2014- 31st May 2016. Cases of patients, who had received SACT within 30*days of death/ ICU admission will then be identified from the date of administration of the last/ prior course of SACT.

Method of data collection

Having identified a sample of patients from the case ID spreadsheet data, further information will be collected from the following sources:

- A clinician questionnaire will be sent for completion to the consultant responsible:
- o For prescription of the last line of SACT
- o For discharge from final admission/ICU admission

- A short ICU form (if applicable)

- Copies of the case notes will be requested for 3 months prior to death death/ICU admission. This is with the aim to include the prescription of the first cycle of SACT (including when consent was given). If this is not included within 3 months of notes then we would need to request further notes

- Requested extracts will include: Clinical annotations, inpatient / outpatient appointments, emergency department notes, nursing notes, microbiology, biochemistry, radiology reports, DNA-CPR forms, surgical/anaesthetic charts, acute/sepsis care pathways, rehabilitation notes, ICU charts and a copy of the death certificate and autopsy report (if applicable/available)

- Copies of the Ambulance Service Patient Report Form

- Reviewer Assessment form : A multidisciplinary group of Reviewers will assess case-notes and clinician questionnaires and give their opinion on quality of care via completion of the RAF in the NCEPOD office

- An organisational questionnaire will be disseminated to all participating sites and collect data on organisational aspects of care of children, teens and young adults with cancer.

Participating sites

Hospital providers that deal with children, teens and young adults, either where SACT is delivered or where patients are admitted acutely (sites with a critical care unit) this would include: principal treatment centres (PTC), paediatric oncology shared care united (POSCUs), acute hospitals, cancer specialist hospitals.

Community hospitals, mental health hospitals, independent hospitals and stand-alone tertiary specialist hospitals (non-cancer) will not be required to take part in this study

Pilot Study

A pilot study will be performed to test the method of data collection (including case identification spreadsheet) and the data collection materials and ensure that they are robust.

Analysis and Review of Data

Reviewers (peer review)

A multidisciplinary group of Reviewers will review the data collected and provide opinion on the care received by this group of patients, from admission to discharge. The Reviewer group will be made up of oncologists, paediatric oncologists, intensivists, paediatric intensivists, paediatricians, critical care nurse specialists, general physicians, acute physicians, emergency department physicians, general surgeons and paediatric nurses

Data Entry

All clinician questionnaire data will be electronically scanned and combined with data from the assessment form completed by the Reviewers. Quantitative data analysis will be undertaken using Excel and qualitative analysis will be undertaken by reviewing the themes arising from the Reviewer meetings.

Confidentiality and data protection

Once the data have been extracted by the NCEPOD researchers, the questionnaires and case notes will be anonymised to remove patient identifiers prior to review by the Reviewers.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 approval will have been obtained to perform this study without the use of patient consent.

Public Benefit and Privacy Panel for Health and Social Care (NHS Scotland) has reviewed our work programme and approval for our applications can be viewed via our website.

Dissemination

On completion of the study a report will be published and widely disseminated.

Definitions

Critical care : Critical care helps people with life-threatening injuries and illnesses. It involves close, constant attention by a team of specially-trained health care providers. Critical care usually takes place in an intensive care unit (ICU) or trauma center.

Cycle: Chemotherapy is typically given in cycles, which is a treatment followed by a period of rest. A cycle can last one or more days, but is usually one, two, three, or four weeks long.

Protocol: (also known as a course): A protocol of chemotherapy is the number of cycles of chemotherapy that consistute a complete chemotherapy treatment. Typically 4-6 cycles of chemotherapy constitute a protocol (or course) of chemotherapy.

TYA-CNCG: Teens and Young Adults - Cancer Network Coordinating Group