

On the Right Course?

A review of the quality of care provided to patients aged 24 years and under who were receiving systemic anti-cancer therapy and subsequently died or were admitted to critical care.



summary

On the Right Course?

A review of the quality of care provided to patients aged 24 years and under who were receiving systemic anti-cancer therapy and subsequently died or were admitted to critical care.

A report published by the National Confidential Enquiry into Patient Outcome and Death (2018)

The report has been compiled by:

AJ Michalski MRCP PhD FRCPCH – Clinical Co-ordinator
(Paediatric Oncology)

Great Ormond Street Hospital for Children NHS Trust
APL Goodwin FRCA FFICM – Clinical Co-ordinator
(Anaesthesia)

Royal United Hospitals Bath NHS Foundation Trust

A Butt BSc Psychology (Hons) – Researcher

D Ellis – Administrative Officer

H Shotton PhD – Clinical Researcher

M Mason PhD – Chief Executive

The study was proposed by: Dr Sujith Samarasinghe,
Consultant in Paediatric Haematology

The authors and Trustees of NCEPOD would particularly like to thank the NCEPOD staff for their work in collecting and analysing the data for this study: Heather Freeth, Dolores Jarman, Kathryn Kelly, Dee Koomson, Kirsty MacLean Steel, Nicholas Mahoney, Eva Nwosu, Karen Protopapa, Neil Smith and Anisa Warsame.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) is an independent body to which a corporate commitment has been made by the Medical and Surgical Royal Colleges, Associations and Faculties related to its area of activity.

The Medical and Surgical Clinical Outcome Review Programme is commissioned by the Healthcare Quality Improvement Partnership (HQIP) which is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. HQIP's aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies. www.hqip.org.uk/national-programmes Copyright© Healthcare Quality Improvement Partnership 2018.

This report should be cited as: The National Confidential Enquiry into Patient Outcome and Death. *On the Right Course?*. 2018. London

Designed and published by Dave Terrey
dave.terrey@greysquirrel.co.uk

Contents

Principal recommendations	3
Introduction	4
Method and data returns	5
Key findings	9
Recommendations	12
Executive summary	16
References	17

Principal recommendations

These recommendations have been selected using a consensus exercise, by all involved with the study, to be the primary action points. They have been taken from the full list of recommendations on pages 12-15.

Ensure that any new protocol of systemic anti-cancer therapy (SACT), to a given patient, is discussed at a multidisciplinary team meeting, in advance of commencing treatment.

(Medical Director, Director of Nursing, Consultants, Pharmacists, Specialist Nurses)

Ensure that discussions about systemic anti-cancer therapy (SACT) with patients and/or their parents are documented and include:

- a. The intent of therapy (curative versus palliative)
- b. The chances of cure or the benefits of palliative therapy
- c. The risk of toxicity including that SACT can be life threatening
- d. Ceilings of treatment in patients with a poor prognosis

(Consultants)

A nationally agreed consent form specific for systemic anti-cancer therapy (SACT) should be developed and implemented. It should include:

- a. The intent of therapy
- b. An assessment of the chance of cure
- c. The risk of toxicity and
- d. The potential risk of death

(NHS England, Welsh Government, Scottish Government and the Department of Health in Northern Ireland)

Ensure consultant review within 14 hours of an acute admission in line with the Royal College of Paediatrics and Child Health in '*Facing the Future*' and the Royal College of Physicians of London in the '*Acute Care Toolkit 4*'.

(Medical Director, Director of Nursing, Consultants)

Introduction

Cancer outcomes in children and young people have improved dramatically over the last few decades with over 80% of those diagnosed now being cured of their disease.² Of those who die, approximately half will do so from treatment related complications many of which are avoidable, this has been shown in acute lymphoblastic leukaemia, for example.^{3,4} Most treatment related deaths are from bacterial sepsis and should therefore be preventable. Emergency care of cancer patients with infection/sepsis has significant areas for improvement as highlighted in the recent Parliamentary and Health Service Ombudsman report – *'Time to Act'*.⁴ These failings included 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 recognise the early warning triggers of deteriorating patients.

In children and young people whose cancer is not likely to be curable, difficult decisions need to be made as to the role of further systemic anti-cancer chemotherapy (SACT). There is an evolving understanding that patients and their families want to pursue therapy directed against the tumour in addition to symptom directed care right up to the end of a patient's life.⁵ Patients and their families will seek out

opportunities for cancer directed therapy with or without the input from their treating oncologist and this means that discussions regarding therapy will continue throughout a patient's care even when a patient is deteriorating from progressive disease. Whether further SACT is appropriate and also balancing its potential benefits with its toxicity are contentious and topical issues.

Thus, a confidential enquiry into cancer deaths and morbidity is timely and has the capacity to significantly enhance cancer outcomes. This report deliberately focuses on a sample of patients who were a high-risk group who died or who had an unexpected admission to intensive care. The rationale being that this is where care-planning, service provision and communication should excel. Any remediable factors in care for this group would benefit all children, teenagers and young adults receiving SACT.

This study is not an epidemiological study reviewing the care of all patients undergoing SACT but a confidential enquiry, reviewing the quality of care of a sample of patients to test the healthcare system. Numbers in this report should not be extrapolated.

Method and Data Returns

Study advisory group

A multidisciplinary group of clinicians comprising consultants from paediatric, adult and teenager and young adult (TYA) haematology and oncology, paediatric surgery, paediatric neurosurgery and anaesthesia, paediatric critical care, children's and TYA cancer nursing and paediatric palliative care, and a family representative contributed to the design of the study and reviewed the findings.

Aim

The aims of this study were to examine the process of care of children, teenagers and young adults aged 24 years and under who died and/or had an unplanned admission to critical care within 60 days of receiving systemic anti-cancer therapy (SACT) in order to:

- Review the decision making and consent process around the prescription of SACT in this group of patients
- Explore remediable factors in the quality of care provided to patients during the final protocol of SACT
- Explore preventable causes of treatment-related mortality in young peoples' cancers
- Examine the configuration of the service and organisational structures in place for the safe delivery of SACT to children, teenagers and young adults.

Objectives

Based on the issues raised by the Study Advisory Group, the objectives of the study were to collect information on the following aspects of care:

- The prescription of the final protocol of SACT
- Delivery of last cycle of SACT
- Final admission to hospital leading to death and/or critical care admission
- Organisational issues

Study population and case ascertainment

Patients aged under the age of 25 years (age at time of death/unplanned critical care admission) who had been diagnosed with a solid tumour (including central nervous system) or haematological malignancy (using the NICE definition) and who received SACT between 1st March 2014 and 31st May 2016 and who died or underwent an unplanned admission to critical care within 60 days of receiving SACT.

Exclusions

Patients for whom the admission to critical care was planned or whose death/critical care admission was completely incidental, for example patients admitted to critical care following a surgical procedure or whose death/critical care admission was related to trauma were excluded from this cohort.

Hospital participation

Hospitals within Acute Trusts/Health Boards in England, Wales, Northern Ireland and Scotland where SACT is prescribed to patients or where patients who have complications of SACT may be admitted as an emergency were expected to participate, as well as public hospitals in the Isle of Man, Guernsey and Jersey. Within each hospital, a named contact, referred to as the NCEPOD Local Reporter, acted as a link between NCEPOD and the hospital staff, facilitating case identification, dissemination of questionnaires and data collation.

Case identification

NCEPOD Local Reporters were asked to retrospectively identify patients aged 24 years and under who were coded with a cancer diagnosis using ICD10 codes C00-D09; D37-D48. Once identified Local Reporters were asked to complete two data collection spreadsheets identifying:

- 1) Patients who had SACT during the study period 1st March 2014 and 31st May 2016
- 2) Patients who were admitted to hospital and either died (in hospital or following discharge) or who were admitted as an unplanned admission to critical care during the study period 1st June 2014 – 31st May 2016.

These spreadsheets were imported into our database and then underwent a matching process to identify patients who appeared on both spreadsheets. This list of patients was then filtered to include only those who had been admitted to critical care or who had died within 60 days of a SACT cycle. In the instance of patients undergoing multiple cycles, the last one listed during the study period was taken as the index cycle.

Questionnaires

Three questionnaires were disseminated to collect clinical and organisational data:

Clinician questionnaire: protocol of SACT

This questionnaire was sent to the responsible onco-haematology consultant in the hospital where the patient had their protocol of SACT prescribed. Information was collected relating to the care of the patient from the initiation of the protocol including the taking of consent, the MDT and decision making process, through to the final cycle of SACT.

Clinician questionnaire: final admission to hospital

This questionnaire was sent to the named critical care consultant or onco-haematology consultant (as applicable) in the hospital where the patient was admitted to when they died or were admitted to critical care (final admission questionnaire).

The two clinician questionnaires also gathered the secondary care clinician's opinion on the adequacy of care in the primary care setting prior to admission.

Organisational questionnaire

An organisational questionnaire was sent to hospitals in which SACT was prescribed, or where patients who have complications of SACT may be admitted to as an emergency.

This included principal treatment centres (PTCs), paediatric oncology shared care units (POSCUs), acute secondary care hospitals and cancer specialist hospitals. Community hospitals, mental health hospitals, independent hospitals and stand-alone tertiary specialist hospitals (non-cancer) were not required to take part in this study. The data requested in the organisational questionnaire included information on the facilities and resources available for the management of patients with cancer, as well as the management of patients in emergency and specialist SACT (where applicable). For the purposes of this study, 'organisation' was defined as a hospital rather than a Trust/Health Board as a whole.

Case notes

Photocopied case note extracts for each case for peer review were requested covering the whole admission. The following documents were requested for up to three-months prior to the date of death/ critical care admission with the aim of covering the start date of the final SACT protocol within this timeframe:

- All inpatient and outpatient annotations
- Emergency department clerking proformas
- Consent forms
- SACT prescriptions
- Nursing notes
- Acute sepsis care pathways (if applicable)
- Observation charts
- Operation notes/anaesthetic charts (if applicable)
- Radiology results
- Fluid balance charts
- Drug charts
- Haematology (full blood count), and biochemistry (liver function tests & urea and electrolytes) results
- Resuscitation documentation -DNA CPR forms (if applicable)
- Discharge summary
- Death certificate, autopsy report (if applicable)

Peer review of the case notes and data

A multidisciplinary group of case reviewers was recruited for the peer review process. This group comprised clinicians from the following specialties: paediatric oncology,

surgery, intensive care, nursing, TYA oncology, nursing, haematology, postgraduate pediatricians, adult oncology, haematology, nursing, intensive care, anaesthesia, acute medicine and pharmacy. All questionnaires and case notes were anonymised by the non-clinical staff at NCEPOD. All patient identifiers were removed so neither Clinical Co-ordinators at NCEPOD, nor the reviewers, had access to patient identifiable information.

Once each case was anonymised it was reviewed by one reviewer as part of a multidisciplinary group. At regular intervals throughout the meeting, the Clinical Co-ordinator chairing the meeting allowed a period of discussion for each reviewer to summarise their case and ask for opinion from other specialties or raise aspects of the case for discussion. Using a semi-structured assessment form, case reviewers provided both quantitative and qualitative responses on the case that had been provided.

Throughout the reviewer assessment form, where the reviewers felt that there was insufficient information available in the case note extracts present to make a judgment decision, there was the option to select 'insufficient data'.

The grading system was used by the reviewers to evaluate the overall care that each patient received:

- Good practice** – a standard that you would accept for yourself, your trainees and your institution
- Room for improvement** – aspects of **clinical** care that could have been better
- Room for improvement** – aspects of **organisational** care that could have been better
- Room for improvement** – aspects of both **clinical and organisational** care that could have been better
- Less than satisfactory** – several aspects of **clinical and/or organisational** care that were well below satisfactory
- Insufficient information** submitted to assess the quality of care

Information governance

All data received and handled by NCEPOD complies with all relevant national requirements, including the Data Protection Act (DPA) 1998 at the time of collection, and now the General Data Protection Regulation 2016 (Z5442652), the NHS Act 2006 (PIAG 4-08(b)/2003, App No 077) and the NHS Code of Practice.

Quality and confidentiality

Each case was given a unique NCEPOD number so that cases could not easily be linked to a hospital.

The data from all questionnaires were electronically scanned into a preset database. Prior to any analysis, the data were cleaned to ensure that there were no duplicate records and that erroneous data had not been entered during scanning. Any fields in an individual record that contained spurious data that could not be validated were removed.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced. The qualitative data collected from the Reviewers' opinions and free text answers in the clinician questionnaires were coded, where applicable, according to content to allow quantitative analysis. The data were reviewed by NCEPOD Clinical Co-ordinators, a Clinical Researcher and a Researcher to identify the nature and frequency of recurring themes.

Case studies have been used to illustrate particular themes and are developed from multiple similar cases.

All data were analysed using Microsoft Access and Excel by the research staff at NCEPOD.

The findings of the report were reviewed by the Study Advisory Group, Reviewers, NCEPOD Steering Group including Clinical Co-ordinators, Trustees and Lay representatives prior to publication.

Data returns

In total 19,920 cycles of SACT and 2,171 admissions to hospital were identified during the study time period (Figure 1.1). When the sampling criteria, matching patients who died or went to critical care within 60 days of receiving SACT was applied 733 patients were identified. In the event of a patient receiving multiple cycles of SACT and/or were admitted to critical care on several occasions within a 60 day timeframe, only the final cycle and/or final critical care admission were taken as the index admission.

Within this study the denominator will change for each chapter and occasionally within each chapter. This is because data have been taken from different sources depending on the analysis required. For example, in some cases the data presented will be a total from a question taken from the clinician questionnaire only, whereas some analysis may have required the clinician questionnaire and the case reviewer’s view taken from the case notes. The term ‘clinician’ is used to refer to data obtained from the clinician responsible for that patient’s discharge and care and the term ‘reviewer’ used to refer to data obtained from the multidisciplinary group who undertook the peer review of case notes.

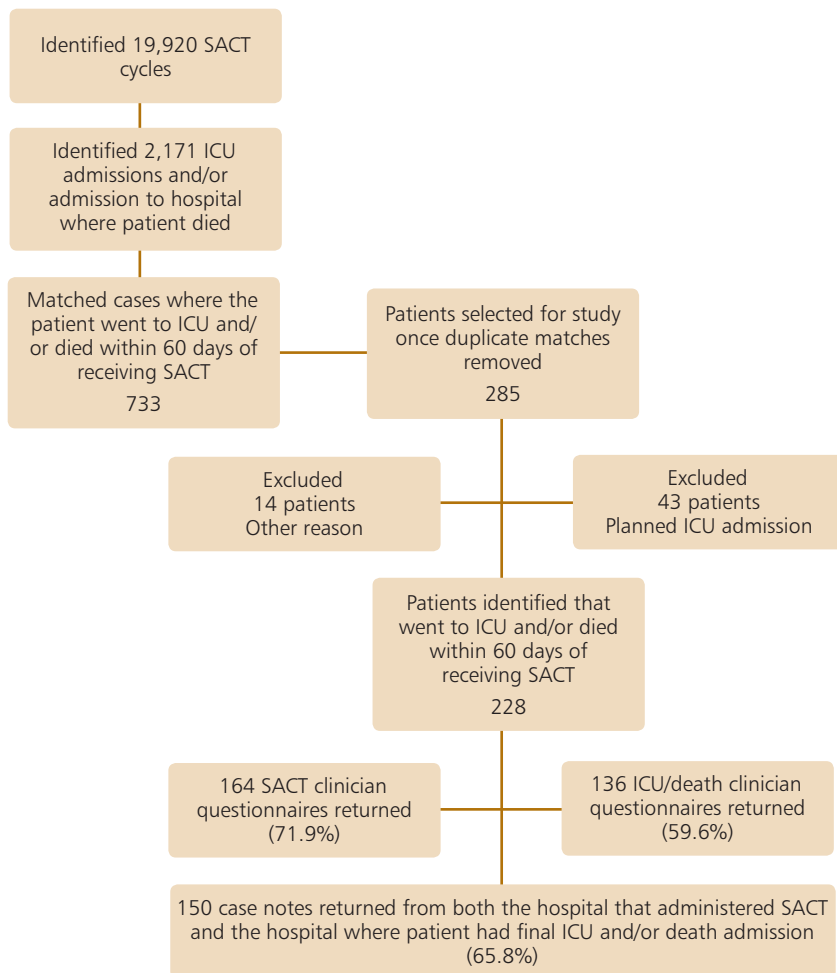


Figure 1.1 Data returns

Key Findings

Organisation of services

- 1 7/149 (4.7%) hospitals from which an organisational questionnaire was received, were not part of a specific cancer network
- 2 25/30 of hospitals in England were yet to adopt electronic prescription of SACT at the time of data collection
- 3 60/112 (53.6%) hospitals had no formal policy that SACT prescribed by a pharmacist should be checked by a second pharmacist
- 4 There were no formal training programmes for pharmacists to prescribe SACT in 43/91 hospitals or in the use of electronic prescribing systems in 19/97
- 5 The routine assessment of performance status of patients before administering SACT was not documented in 76/131 (58.0%) hospitals
- 6 Audio-visual sources were used to transmit information to patients in only 34/130 (26.2%) of hospitals
- 7 Non-medical staff could prescribe SACT in 49/115 (42.6%) hospitals
- 8 Should a patient be admitted with a complication of SACT to the prescribing hospital, 93/112 (83%) had a mechanism for informing a named haemato-oncologist. Should the patient be admitted to a different organisation this fell to 51/85 (60%)
- 9 Patients had a maximum journey time of more than one hour in 27/116 (23.3%) hospitals where they were treated
- 10 Patients were discussed at age appropriate multidisciplinary team meetings in 105/109 (96.3%) of hospitals
- 11 In only 33/77 of hospitals was there a policy for the transition of care from the paediatric service to adult services
- 12 SACT toxicity was not audited in 56/105 (53.3%) of hospitals and nausea and vomiting was not undertaken in 82/109 (75.2%). In 60/106 (56.6%), death within 60 days of SACT was not audited and in 41/106 (38.7%) central line complications were not audited
- 13 Most hospitals 99/103 (96.1%) participated in peer review or self-assessment exercises relating to UK cancer standards
- 14 In 113/117 (96.6%) hospitals a helpline number was provided for patients to contact
- 15 In 25/113 (22.1%) hospitals, advice over the telephone was provided by general rather than specialist staff
- 16 2/17 children's principal treatment centres from which a response was received did not have on-site paediatric critical care support
- 17 Only 27/43 hospitals to which teenage and young adult patients were admitted, had separate facilities or protocols for this group
- 18 In only 9/105 (8.6%) of hospitals did intensivists attend oncology morbidity and mortality meetings.

KEY FINDINGS

Study population

- 19 The patient population in this study was high-risk with diagnoses that needed planned aggressive therapy and therefore had less good survival rates when compared with the population of childhood cancer as a whole
- 20 53% (69/130) of the patients had relapsed disease
- 21 65.6% (105/160) of patients had been treated with more than one protocol of therapy with some patients having more than six previous protocols of treatment

Management of systemic anti-cancer therapy

- 25 There was no multidisciplinary team discussion about starting a protocol of SACT in 33.8% (50/148) of patients
- 26 In 12.3% (19/155) of cases clinicians felt under pressure from the patient's family to prescribe SACT
- 27 39/91 of General Practitioners and 40/71 of POSCUs had inadequate information about SACT and the expected toxicities
- 28 83.7% (128/153) of consent forms were completed by a consultant
- 29 Only 62.2% (92/148) of notes had a copy of the consent form included
- 30 In 16/145 (11%) sets of case notes the reviewers did not find evidence that the intent of treatment was clear
- 31 According to the clinicians at the hospitals, treatment intent was not recorded in 14.1% (128/149) of cases
- 32 17.6% (23/131) of consent forms did not state the risk/benefit of SACT or the chances of cure in 27/133 (20.3%)
- 33 Only 37/85 consent forms mentioned that SACT could be life threatening
- 34 In 12-16 year old patients, assent was only recorded in 7/11 cases
- 35 There was good practice in grade and specialty of doctors who prescribed SACT

- 22 The population had a significant number of comorbidities
- 23 The unplanned admission to critical care or death occurred during the first cycle of therapy in around half the patients – so the choice of protocol had not given the relapsed patients significant prolongation of survival before the event took place
- 24 33.9% (38/112) of the patients in the study died in critical care suggesting that either the death was not expected or that ceilings of treatment had not been put in place.
- 36 Prescriptions were not electronic in 27/58 of cases reviewed and not checked by a pharmacist in 13/87
- 37 30.5% (43/141) of cases reviewed did not have any electronic record of SACT received by a patient – most were hardcopy records only
- 38 Good practice was seen in checking essential investigations. However, a formal assessment of performance status before considering a protocol was not carried out in 89/162 (54.9%) of patients
- 39 A formal assessment of toxicity of the last SACT cycle was only performed in 56% (79/141) of patients
- 40 Assessment of disease response was found in 67.2% (84/125) of cases reviewed – of these 48/80 patients were not responding to treatment and in the opinion of the reviewers only 20/41 of these should have received further SACT
- 41 There was only evidence in only 61/92 of cases that patients and their families had received adequate training in the management of febrile neutropaenia.
- 42 There was no evidence of 16/125 (12.8%) parents and 48/122 (39.3%) patients receiving written information about toxicity or chances for care
- 43 In only 17/42 palliative care patients were ceilings of treatment discussions documented and only 18/146 (12.3%) had end of life care discussions
- 44 82% (132/161) of patients were not on a clinical trial.

Final admission to hospital

- 45 Following admission 83/90 patients were reviewed by a doctor in a timely manner
- 46 Initial management of patients was undertaken by the appropriate specialty in 99.2% (130/131) of cases
- 47 12/39 patients were not reviewed by a consultant within 14 hours of admission, 8 of whom were acutely unwell with significant complications due to disease progression or SACT toxicity
- 48 Patients' vital signs were appropriately recorded in 91.3% (95/104) of patients and reviewers considered this to be good practice
- 49 34/133 (25.6%) patients had signs of sepsis on admission, 39.2% (31/79) of patients showed signs of sepsis whilst in hospital
- 50 12/19 patients received antibiotics more than one hour following admission
- 51 The reviewers considered that 31.3% (41/131) of patients had other problems relating to toxicity of the SACT on admission
- 52 The reviewers were of the opinion that in those patients admitted to critical care the admission was appropriate and that all appropriate treatments were given to the patient whilst in critical care
- 53 In only 37/68 was there any evidence of a discussion between referrer to intensive care and the intensivist, regarding the appropriateness of critical care
- 54 On admission to critical care, ceilings of treatment were only in place in 11/60 patients
- 55 Critical care was often not represented at MDT meetings
- 56 In those patients who showed deterioration relating to tumour progression, the reviewers found evidence that treatment options relating to the deterioration had been discussed with the family 69/72 of the time
- 57 In 21.7% (23/106) of patients the reviewers were of the opinion that the SACT had played a major part in hastening death or the patient died as a direct result of a complication caused by SACT. A further 24.5% (26/106) of patients had some toxicity
- 58 The patient's death was discussed at an audit or morbidity and mortality meeting in 64/80 cases, and in only 15 cases was the discussion recorded in the case notes.

Recommendations

	Recommendation	Study key findings
1	<p>Ensure that any new protocol of systemic anti-cancer therapy (SACT), to a given patient, is discussed at a multidisciplinary team meeting in advance of commencing treatment.</p> <p>(Medical Director, Director of Nursing, Consultants, Pharmacists, Specialist Nurses)</p>	<ul style="list-style-type: none"> • There were no MDT discussions about starting a protocol of SACT in 33.8% (50/148) of patients • Patients were discussed at age appropriate multidisciplinary team meetings in 105/109 (96.3%) hospitals
2	<p>Hospitals in which systemic anti-cancer therapy (SACT) is administered should have a policy for use prior to treatment with SACT, which includes an assessment of 'fitness for SACT' and a formal performance status score. This policy should be reviewed as part of the organisation's annual review.</p> <p>(Medical Director, Director of Nursing, Oncology Consultants, Specialist Nurses)</p> <p>NB: This is already linked to a CQUIN in England</p>	<ul style="list-style-type: none"> • The routine assessment of performance status of patients before administering SACT was not undertaken in 76/131 (58%) hospitals • Good practice was seen in checking essential investigations, but performance status was only checked in 46.6% (61/123) of patients • A formal assessment of performance status before considering the protocol was not carried out in 89/162 (54.9%) of patients
3	<p>Ensure that discussions about systemic anti-cancer therapy (SACT) with patients and/or their parents are documented and include:</p> <ol style="list-style-type: none"> a. The intent of therapy (curative versus palliative) b. The chances of cure or the benefits of palliative therapy c. The risk of toxicity including that SACT can be life threatening d. Ceilings of treatment in patients with a poor prognosis <p>(Consultants)</p>	<ul style="list-style-type: none"> • Only 37/85 consent forms mentioned that SACT could be life threatening • 20.3% (27/133) of consent forms did not state the benefits of SACT or the chances of cure • In 16/145 (11%) sets of case notes the reviewers did not find evidence that the intent of treating the patient was clear • According to the clinician questionnaire, intent of treatment was not recorded in the notes in 14.1% of cases • 23/131 (17.6%) cases reviewed did not have the benefits appropriately documented nor the chance of cure in 27/133 (20.3%) • 16/125 (12.8%) parents, and 48/122 (39.3%) patients did not receive written information about toxicity or chances of cure • Only 17/42 palliative patients had ceilings of treatment discussions, and only 18/46 had end of life care discussions

RECOMMENDATIONS

	Recommendation	Study key findings
4	<p>A nationally agreed consent form specific for systemic anti-cancer therapy (SACT) should be developed and implemented. It should include:</p> <ol style="list-style-type: none"> The intent of therapy An assessment of the chance of cure The risk of toxicity and The potential risk of death. <p>(NHS England, Welsh Government, Scottish Government and the Department of Health in Northern Ireland)</p>	<ul style="list-style-type: none"> 20.3% (27/133) of consent forms did not state the benefits of SACT or the chances of cure 37/85 consent forms mentioned that SACT could be life threatening
5	<p>Assent for systemic anti-cancer therapy (SACT) treatment should be sought from any young person with capacity up to the age of 15 years, with consent being sought from patients aged 16 years or older.</p> <p>(Consultants)</p>	<ul style="list-style-type: none"> In 12-16 year old patients, assent was only recorded in 7/11 cases
6	<p>Provide written information to patients and their families about the potential side effects of systemic anti-cancer therapy (SACT), in particular the recognition and management of febrile neutropaenia.</p> <p>(Consultants, Lead Cancer Nurse and Specialist Nurses)</p>	<ul style="list-style-type: none"> There was only evidence in 61/92 of cases that patients and their families had received adequate training in the management of febrile neutropaenia
7	<p>The treating team should send appropriate information to General Practitioners and Paediatric Oncology Shared Care Units (POSCU) about the systemic anti-cancer therapy (SACT) patients under their care receive and the potential toxicities the patient may experience at the time of SACT administration</p> <p>(Medical Director, Director of Nursing, Consultants, Lead Cancer Nurse and Specialist Nurses, Oncology Pharmacists)</p>	<ul style="list-style-type: none"> 39/91 of General Practitioners and 40/71 of POSCUs had inadequate information about SACT and the expected toxicities in the view of the reviewers
8	<p>Assess at the point of prescribing, and again at the time of any subsequent cycles of systemic anti-cancer therapy (SACT), the following:</p> <ol style="list-style-type: none"> Toxicity of any previous SACT cycles Disease response to treatment The patient's performance status <p>(Medical Director, Director of Nursing, Consultants)</p>	<ul style="list-style-type: none"> The routine assessment of performance status of patients before administering SACT was not documented in 76/131 (58%) hospitals Good practice was seen in checking essential investigations, but performance status was only checked in 49.6% (61/123) of patients A formal assessment of toxicity of the last SACT cycle was only performed in 56% (79/141) of patients Assessment of disease response was found in 67.2% (84/125) of cases reviewed – of these 48/80 patients were not responding to treatment and in the opinion of the reviewers only 20/41 of these should have received SACT

RECOMMENDATIONS

	Recommendation	Study key findings
9	Systemic anti-cancer therapy (SACT) prescriptions should be checked and validated by a suitably trained doctor, nurse or pharmacist in SACT, other than the prescriber. (Medical Director, Director of Nursing, Consultants, Pharmacists, Specialist Nurses)	<ul style="list-style-type: none"> • There was no formal policy that SACT prescribed by a pharmacist should be checked by a second pharmacist or clinician in 60/112 (53.6%) hospitals • There were no formal training programmes for pharmacists to prescribe SACT in 43/91 hospitals
10	All systemic anti-cancer therapy (SACT) prescriptions should be available on hospital IT systems and all clinicians should have easy 'read only' access to them. (Medical Director, Director of Nursing, Consultants, Lead Cancer Nurse and Specialist Nurses, Oncology Pharmacists)	<ul style="list-style-type: none"> • 25/30 of hospitals in England were yet to adopt electronic prescription of SACT at the time of data collection • There were no formal training programmes in the use of electronic prescribing systems in 19/97 • 30.5% (43/141) of cases reviewed did not have any electronic record of SACT received by patients – most were hardcopy only • Prescriptions were not electronic in 27/58 of cases reviewed
11	Patients in hospital should receive appropriate antibiotics within one hour of recognition of sepsis or suspected sepsis, as outlined in NICE QS161 (Medical Director, Director of Nursing, Consultants)	<ul style="list-style-type: none"> • 12/19 patients received antibiotics more than one hour following admission
12	Ensure consultant review within 14 hours of an acute admission in line with the Royal College of Paediatrics and Child Health in ' <i>Facing the Future</i> ' and the Royal College of Physicians of London in the ' <i>Acute Care Toolkit 4</i> '. (Medical Director, Director of Nursing, Consultants)	<ul style="list-style-type: none"> • 12/39 patients were not reviewed by a consultant within 14 hours of admission. Eight of whom were unwell with significant complications relating to disease progression or SACT toxicity
13	Ensure that prior to admission to critical care, or at the earliest opportunity after admission, ceilings of treatment are discussed with the patient and/or relatives and agreed between the referring clinician and admitting critical care consultant. If critical care is not available on-site, robust clinical protocols and pathways must be in place to ensure there is no delay in care of the critically ill patient. The discussion and plan should be documented clearly in the patient's case notes and reviewed during the admission. It is essential that all organisations recognise the advantage of access to on-site age-appropriate care. (Medical Director, Director of Nursing, Consultants)	<ul style="list-style-type: none"> • 2/17 children's principal treatment centres, from which a response was received, did not have on-site paediatric critical care support • 33.9% (38/112) of the patients in the study died in critical care suggesting that either the death was not expected or that ceilings of treatment had not been put in place • In only 37/68 cases was there any evidence of a discussion between referrer to intensive care and the intensivist, regarding the appropriateness of critical care • On admission to critical care, ceilings of treatment were only present in 11/60 of patients

RECOMMENDATIONS

	Recommendation	Study key findings
14	<p>Local audit of the side effects and outcomes of systemic anti-cancer therapy (SACT) should be undertaken in hospitals in which SACT is administered. Action plans and quality improvement goals should be made and discussed, with findings reported at Board level.</p> <p>(Medical Director, Director of Nursing, Consultants, Specialist Nurses)</p>	<ul style="list-style-type: none"> • SACT toxicity was not audited in 56/105 (53.3%) of hospitals • Nausea and vomiting was not audited in 82/109 (75.2%) hospitals • Death within 60 days of SACT was not audited in 60/106 (56.6%) hospitals • Central line complications were not audited in 41/106 (38.7%) hospitals
15	<p>Hospitals in which systemic anti-cancer therapy (SACT) is administered should have a policy requiring all clinicians involved in the care of oncology patients to undertake morbidity and mortality reviews and attend morbidity and mortality meetings. This should also include the completion of an attendance log.</p> <p>(Medical Director, Director of Nursing, Consultants, Specialist Nurses)</p>	<ul style="list-style-type: none"> • In only 9/105 (8.6%) of hospitals did intensivists attend oncology morbidity and mortality meetings • The patient's death was discussed at audit or mortality and morbidity meetings in 64/80 cases. In only 15/59 was there any evidence in the patient's notes of these discussions
16	<p>Hospitals in which systemic anti-cancer therapy (SACT) is administered should have a person-focused policy for the transition of oncology care between paediatric, teenage and young adult and adult teams. This should be reviewed as part of the organisation's annual review.</p> <p>(Medical Director, Director of Nursing, Oncology Consultants, Specialist Nurses)</p>	<ul style="list-style-type: none"> • In only 33/77 of hospitals was there a policy for the transition of care from the paediatric service to adult services

Executive summary

This analysis of care delivered to children and young adults who either died or had an unexpected admission to critical care within 60 days of receiving systemic anti-cancer therapy SACT has shown a mixed picture.

Overall 58% of patients were thought to have good care and there were many areas of excellent practice. However, in 22% of this high risk group the SACT was directly responsible for death or admission to critical care or had a major role in the outcome. In a further 25% substantial toxicity was observed.

The decision to start SACT is a really important one but in a third of patients (50/148; 33.8%) there was no discussion in a properly constituted multidisciplinary team meeting. Patients and families need frank discussions about the potential risks and benefits, but a fifth (23/131; 17.6%) of consent forms did not state the chances of the treatment being of benefit and in under half (37/85) was there any mention that SACT could be life threatening. There was evidence that doctors felt under pressure from families to prescribe SACT, therefore discussing benefits and risks is of paramount importance and should be addressed by development of a nationally agreed bespoke consent form for SACT in this age group.

Assessing patients before the administration of SACT was variable - essential investigations were done in almost all patients but assessing disease response, previous toxicity and holistically assessing the patient for their fitness to receive SACT (performance status) was only performed in half (61/123; 51.4%) the patients. These assessments were performed more frequently in patients who were on clinical trials, but only 18% of this study population were on a clinical study for this prescription of SACT due to the fact that they had been selected from a high-risk group of patients often with relapsed or recurrent disease. Almost 70% of the study population had been treated previously

with at least one protocol of therapy, therefore a much higher percentage of patients may have been on clinical trials for their front-line therapy. This study highlighted the absence of clinical trials for patients with resistant or recurrent disease and the reviewers, in their discussions, strongly advocated the use of trials in this group as a mechanism of improving patient care. Whilst the data showed that patients in this study were found to have better care when they were on a trial, the study did not have sufficient data to justify a formal recommendation to expand clinical trial availability.

Sepsis is a major risk in patients receiving SACT but opportunities to adequately train patients and families in its recognition were not taken in a third of patients.

Open discussions about the appropriateness of intensive care and of ceilings of treatment are always difficult but even in patients who were being treated with palliative intent only, these occurred in a minority. The reviewers were of the opinion that these discussions were better facilitated when the oncology unit and intensive care unit were co-located.

Audit and quality improvement methods, with action plans, are essential for on-going improvement but require access to data. Electronic prescribing was not universal at the time of data collection and many hospitals had no ready access to information on which patients had received SACT and their outcomes. Routine auditing of toxicity of SACT happened in less than half (49/105; 46.7%) and of deaths within 60 days of treatment in only two thirds (46/106; 43.4%).

The recommendations from this report are largely based on factors that can be improved quickly and without large financial implications in terms of structure or equipment. As with many other NCEPOD reports, adequately trained staff, good team working and clear local leadership are key to improving care for this vulnerable population.

References

- 1 National Confidential Enquiry into Patient Outcome and Death (NCEPOD). For Better, For Worse. 2008
http://www.ncepod.org.uk/2008report3/Downloads/SACT_report.pdf
- 2 National Cancer Registration and Analysis Service (NCRAS). Childhood Cancer Statistics, England Annual Report. 2018
www.ncin.org.uk/view?rid=3715
- 3 O'Connor D, Bate J and Wade R et al. Infection-related mortality in children with acute lymphoblastic leukemia: an analysis of infectious deaths on UKALL2003. *Blood*. 2014 Aug 14;124(7):1056-61
- 4 Vora A, Goulden, N and Wade R et al. Treatment reduction for children and young adults with low-risk acute lymphoblastic leukaemia defined by minimal residual disease (UKALL 2003): a randomised controlled trial. *The Lancet Oncology*, Volume 14, Issue 3, 199 – 209
- 5 Parliamentary and Health Service Ombudsman Report. Time to act - Severe sepsis: rapid diagnosis and treatment saves lives. 2013
- 6 Bluebond-Langer M, Hargrave D, Henderson EM et al. 'I have to live with the decisions I make': laying a foundation for decision making for children with life-limiting conditions and life-threatening illnesses. *Archives of Disease in Childhood* 2017; 102(5): 468-471

Published December 2018
by the National Confidential Enquiry
into Patient Outcome and Death

Ground Floor
Abbey House
74-76 St John Street
London EC1M 4DZ

T 0207 251 9060
F 0207 250 0020
E info@ncepod.org.uk
w www.ncepod.org.uk

ISBN: 978-1-9995925-1-6

A company limited by guarantee Company no. 3019382
Registered charity no. 1075588